PART I

MEETING SUMMARY

Highlights of NABC 15, Biotechnology: Science and Society at a Crossroad

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NABC's fifteenth annual meeting, co-hosted by Washington State University and Oregon State University, June 1–3, 2003, was held at the Westin Seattle Hotel, a few blocks from the Pike Place Market and the Space Needle. As with NABC 13 in Chicago, there was some anticipation that protests would disrupt the proceedings; however, all remained quiet, at least outside of the meeting hall.

The meeting theme, emphasizing a crossroad of competing perspectives, and the modular structure of NABC 15 were chosen to enable participants to speak, listen, and to learn about a diversity of issues relating to agricultural biotechnology. That diversity was reflected in the 160-plus attendees: owners of organic farms and businesses, university students and professors, administrators, representatives of biotechnology industries, non-governmental organizations, members of the local and national press, *etc*.

A key innovation of NABC 15 was the organization of the meetings into five half-day "modules," comprising formal presentations followed by panels of expert questioners who engaged and queried speakers on specific points. The speakers then fielded questions and comments from the audience. The panel members then became discussion leaders at breakout sessions where attendees had further opportunities to air their views and ask questions on issues raised

in the modules; some found the transition challenging—from expert questioner with strong personal views to discussion leader.

Biotechnology: Science and Society at a Crossroad

Module I, moderated by Neal Van Alfen, consisted of keynote speakers, Lawrence Busch, Distinguished Professor of Sociology, Michigan State University, and James Cook, Professor of Plant Pathology, Washington State University. Their presentations appropriately set the "crossroad" theme of the meeting. In his address, "Lessons Unlearned: How Biotechnology is Changing Society," Dr. Busch pointed out possible errors of omission of the biotechnology industry in introducing their technologies without properly preparing all elements of the market: technology developers, government regulators, sellers, farmers, and consumers. He drew an analogy from the game of curling: in order to successfully introduce a revolutionary technology into society, many forces are needed as sweepers to get the technology over the goal line. In short, the biotechnology industry followed past practices in introducing new products, ignoring the unique features of genetic modification and the multifaceted concerns of a wide range of stakeholders (sweepers) it generated. As a result, Busch concluded that "agricultural biotechnology, despite a few successes here and there, has thus far been a failure."

Dr. Cook argued ("Biotechnology: Cause and Consequence of Change in Agriculture") that the driving forces for most farmers to adopt a new technology include the potential to increase profits, to save labor, to protect the environment, and to meet demands for safe and wholesome food. He argued that it is the "management used to grow a crop variety and not the variety itself that has impact on the environment." Cook presented examples of genetically modified plants that reduce the use of herbicides and pesticides or confer disease resistance. He advocated a vision for genetic modifications in minor crops for which the current regulatory processes involving EPA, USDA, and FDA would need to be less costly.

Sustainability, Environmental, and Production Issues

Module II, moderated by Terri Lomax (Fundamental Space Biology Division, NASA), brought out several contrasting viewpoints. Fred Kirschenmann of the Leopold Center, arguing that the current agricultural system is unsustainable, called for an ecosystems approach to achieve sustainability. He questioned whether transgenic technology's single-tactic approaches would ensure the food security for future generations that is now regarded as a basic human right. John Anderson of Monsanto argued that economics is possibly the most powerful force driving the acceptance of transgenic technologies on the rural landscape, with markets ultimately determining the fate of genetically modified crops. Kay Walker-Simmons, USDA-ARS, outlined the roles of the ARS in addressing the genetic modification of crops, noting that the "core responsibili-

ties of the ARS include conserving, safeguarding and characterizing genetic resources." Special new functions of the agency include biotechnology risk assessment, biosafety, and the effects of genetically engineered crops in agricultural production systems.

Consumer Issues and Trade

Module III was moderated by Thomas Wahl (Washington State University IMPACT Center). It included discussions on the remarkable complexities in the labeling of genetically modified foods (Nicholas Kalaitzandonakes, University of Missouri-Columbia), the traceability of ingredients in food products (Peter Phillips, University of Saskatchewan) and cross-national studies—in Japan, China, and Norway—on what consumers are willing to pay for genetically modified foods (Jill McCluskey, WSU IMPACT Center).

Biotechnology: Applications for Agriculture in Developing Countries

In Module IV, David Hoisington (CIMMYT, Mexico) and Christopher Ngichabe (KARI, Kenya) presented their work on the production and field-testing of insect-resistant maize for east Africa. They noted both the scientific and sociological obstacles of placing this product in the hands of growers.

Caution at the Crossroad: Evaluating Paths to Assure Sustainability in Agriculture

In Module V, Charles Benbrook (Benbrook Consulting Services) moderated a spirited tie-up discussion subsequent to presentations on the precautionary principle by Carolyn Raffensperger (Science and Environmental Health Network), on need for caution when "pharming" food crops by Thomas Lumpkin (AVRDC, Taiwan), and on philosophical perplexities and ethical enigmas inherent in the adoption of agricultural biotechnology by Paul Jepson (Oregon State University Integrated Plant Protection Center).

Ancillary Presentations

Speakers at the luncheons and dinner complemented the module discussions. Consultant Mike Thornton detailed the demise of a genetically engineered crop, the NewLeaf™ potato. Rapid initial acceptance by growers was followed by adverse publicity, raising consumer concerns, and processors found that the genetically modified potato did not add value to their business. With its rejection in 2000 by McDonalds and others, the NewLeaf™ potato provides an exemplary case of the fate of a biotechnology food product when consumer worries impact fast-food giants. As market signals from their primary buyers became less certain, growers decided they could not afford the risk of planting the genetically modified potato.

Dennis Gonsalves (USDA-ARS Pacific Basin Agricultural Research Center) showed that a single gene change in papaya could prevent papaya ringspot virus disease and save an entire industry and local economies—as happened in Hawaii. He also described and underscored the importance of early and continued engagement of growers and other stakeholders in the successful adoption of the genetically modified papaya. However, political issues are preventing acceptance of ringspot-free papaya elsewhere. This story illustrated how public-sector scientists can perform all phases, from research to regulatory approval, for a biotechnology product.

Gary Toenniessen of the Rockefeller Foundation advocated "giving a voice" to the millions of small-scale farmers in Africa and Asia. He decried the lack of freedom to operate that results from the many patents that block the public use of new technologies. He described the Public-sector Intellectual Property Resource for Agriculture (PIPRA), a coalition recently formed by several leading agricultural universities and research institutes along with the Rockefeller and McKnight Foundations, to support plant biotechnology research for developing countries while allowing universities to retain a portion of their patent rights on new technologies.

Joseph Jen, USDA Under Secretary for Research, Extension and Economics, provided a "USDA Perspective on Genomics" in which he reviewed research investments in genomics of agriculturally important species and in risk-assessment related to biotechnology.

The Road to Take?

The application of modern biotechnology to food and agriculture holds promise of a revolution as dramatic and far-reaching as the domestication of plants 10,000 years ago. Will the road to that revolution be smooth, rough, involve many detours, or lead to a dead end? This question, punctuating the previous fourteen NABC meetings, received a focus and refinement with NABC-15's theme of a "crossroad." At what crossroad does biotechnology currently find itself and which road will it take? What other crossroads can be expected in the future?

Keynote presentations, plenary sessions, and break-out workshops produced a wide range of crosscutting perspectives on biotechnology's current crossroad. Two themes emerged: communication difficulties and risk. Communication between the pro- and anti-agbiotech "camps" was problematic throughout the meeting. However, there was consensus that progress was made in the workshop break-out sessions, and future opportunities for dialogue of this type were requested. Various risks are the bases of concern among a wide variety of biotechnology stakeholders; particular risks vary by stakeholder. Some segments of the public worry about the health risks of genetically modified foods while others worry about the risk of concentrated economic power in society. Producers and farmers worry about the substantial financial risks

associated with shifts to bioengineered crops. Some scientists worry about the risk of unintended consequences (such as creating resistance to herbicides and insecticides) while others debate the very meaning of risk and the conditions under which it should be assessed and managed.

How in democratic societies can these various risk concerns be reconciled? Although there is no easy answer to this question, one thing is certain: the question itself and the responses it attracts from science, from industry, from government, and from publics will determine the road that biotechnology will take. They will also determine the nature of future crossroads.

PART II

WORKSHOP REPORT

NABC 15

Workshop Report

At NABC meetings, all attendees are active participants. Exchanges of information, ideas, and opinions occur at Q&A sessions following formal presentations, and during lively discussions at breaks, over meals, and at social functions. However, the workshops provide the most direct and most powerful means of participation with face-to-face discussions and debates. At the 2003 meeting, three-person panels convened at the conclusion of each formal session (prior to the audience Q&A sessions) to ask questions and initiate discussion on issues raised by the speakers. Subsequently, each panel member for Modules I, II, and III became a discussion leader at one of the break-out workshop sessions, which helped maintain and broaden discussion of the themes raised at the keynote and plenary sessions. The role of the discussion leaders was to facilitate verbal exchange. A few found it difficult to move from an asker of questions with a specific position to be a neutral facilitator. Note-makers recorded the salient points of the workshop discussions, which are summarized in the following pages.

The "Break-Out" Session Workshops

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The workshops were structured around three themes:

- Science and Society at a Crossroad
- Sustainability, Environmental and Production Issues
- Consumer Issues and Trade

Nine break-out sessions were held in total, three for each of the general themes. The discussion leaders and recorders are listed in the table at the end of this chapter. Notes received from the recorders were assembled and are summarized below.

Science and Society at a Crossroad

Issues associated with risk assessment were broadly debated. It was felt that many studies on risk are unsatisfactory to consumers—their concerns are not adequately addressed nor are the results of such studies communicated well. Pressing concerns included:

- the definition of risk,
- risk of genetically modified (GM) foods to human health,
- risk from corporate control of the food system, and
- risk of insect pests developing resistance to *Bt*.

Lack of availability of information from the federal agencies on risk assessments of GM foods was addressed; one response was that some information is available on the Internet at agency home sites.

The issue of food labeling was recognized to be complex. It was noted that many other countries require the labeling of GM foods. There was disagreement over whether labels should relate to the preparation process or to the product.

Doubt was raised as to whether it is possible to have symmetry in labeling across disparate products containing GM ingredients. Some felt that labeling is less a mechanism to provide choice to the consumer and more a ploy whereby market advantage may be gained. If traceability is to be a component of labeling—from seed through process to multi-ingredient product—some claimed that it may be impossible for labels to be exact and correct and still be informative for the layperson. Other participants noted that traceability might occur by means of barcodes, *etc.*, and not interfere with consumer comprehension. Further debate is needed on tolerance limits for GM ingredients in nominally non-GM foods. Some see that only a zero-GM option for organic foods would provide a meaningful alternative for those who wish to avoid GM foods. The United States can profit from the experience of other countries.

It was suggested that third-party laboratories should be charged with the task of determining the presence and levels of GM ingredients in nominally non-GM foods in order to maximize confidence in the results. But who: universities, agencies, private companies under contract, or non-profit entities? Resources would be needed to provide such a service on a meaningful scale; there was debate as to costs and value. In review, one of the facilitators recalled that it was suggested that if the biotech industry were to find such costs excessive, they could charge more for their "improved" products; conventional farmers should not have to pay for following age-old practices.

There is need for more funding for alternatives to GM commodities, such as research on organic farming practices.

Sustainability, Environmental and Production Issues

Again, risk was subject for discussion. Given that our understanding of genetics is incomplete, can we ever be sure that the federal regulatory system is adequate? On the other hand, it is important to bear in mind that risk is not unique to biotech, and applies also to conventional and organic agriculture. Doubt was raised as to the efficacy of buffer zones, knowing that some data indicate that pollen can be wind-transported beyond any such zones. Comprehensive research is needed to determine how far pollen can travel. On the other hand, buffer zones fulfill a need, as long as they are properly planted and maintained.

Risk is not unique to biotech, and applies also to conventional and organic agriculture.

Risk assessment is focused on GM crops. The dwarf wheat gene—a key component of the Green Revolution—did not provoke such assessment. Although, by comparison, conventional plant breeding seems fraught with risk,

few problems have arisen from it, raising the question of where the line should be drawn regarding assessment of risk from new crops. Canada regulates all novel traits, not just those produced through biotechnology; the risk assessment is based on the trait introduced.

A range of consumer opinions was voiced at the meeting, whereas no conventional farmers were in attendance, raising the question of whether consumer priorities are consistent with those of growers. Similarly, the direct advantages of GM crops to the farmer must be juxtaposed with the disadvantages of market losses, *e.g.* in Europe and Japan. On the other hand, over the past 6 years, GM technology has been aimed at farmers rather than consumers, compromising market choice and resulting in calls for labeling to allow choice of non-GM food by those who wish to eat it exclusively. This raises the question of whether it is possible, within the present system, to segregate non-GM soy from GM soy, non-GM corn from GM corn, *etc*. Will alternative elevators be needed and, if so, who will pay? As far as Roundup Ready® wheat is concerned, the Canadian Wheat Board has asked Monsanto not to request deregulation as it would pose significant segregation problems. Where is the line to be drawn between the interests of the biotech industry and the interests of society as a whole?

The on-going loss of wildlife habitat was raised as a threat to human survival. Are there ways in which biotechnology can help to, at least, slow this process as a component of improving or realigning the current agricultural system? It is always difficult to find a solution in hindsight—better to alter what we are doing to minimize the problem in the future.

It was suggested that we not make the mistake of regarding the current agricultural system as normative. Natural ecosystems should be regarded as normative—we should attempt to take a "natural system" viewpoint that marries sustainability with biotechnology. On the other hand, without knowing society's short- and long-term goals it would be unwise to choose an alternative system or alter the present system.

Increasing farm size has had adverse effects on rural communities. There is a trade-off between efficient land use and social well-being. Traditionally we have measured agricultural success in terms of increased yields. Social factors must be taken into consideration also.

Biotech should not be viewed as a solution in itself. It is a tool to be blended with other improved management practices. Its usefulness should be judged on a case-by-case basis.

There is need for more funding for research for smaller projects with emphasis on alternative agriculture.

On one hand, it was suggested that biotechnology be viewed as a tool that has potential in organic as well as conventional agricultural production—the biotech solution to root rot has a potential role in organic agriculture, for example. On the other hand, such statements are viewed as industry propaganda, in conflict with the views of organic farmers.

In view of the fact that traditional breeding has not been deemed anathema to organic agriculture, clarification was sought regarding resistance to genetic engineering. In response, concerns were voiced about gene transfer across species barriers.

The Roundup Ready® technology has been credited by farmers as providing more free time, which has broad social implications. Growers who previously worked full time may now seek off-farm employment—since farming profit margins are lean—which could result in increased unemployment in rural communities.

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There is need for more funding for research for *smaller* projects with emphasis on alternative agriculture.

Research on transgenic organisms continues to be objected to on the basis of ethical/religious concerns: in the opinion of many, scientists are making decisions that are the bailiwick of the deity. On the other hand, it was suggested that the critical boundary was crossed, not in the 1980s and 1990s, but 10,000 years ago when growers began selecting for superior characteristics, thus altering the genotypes of plants grown for food. It was suggested that one way to improve dialog between the pro- and anti-GM camps is to not use morality judgments. On the other hand, for some, ethical/religious views dictate *approval* of GM crops from the point of view of potential to increase agricultural productivity where it is most needed: in the developing world.

Undeniably, there are problems with modern agriculture, but is the system described by Frederick Kirschenmann without difficulties? Is it a choice of problems? Kirschenmann's system is less capital-intensive, and, to a greater degree, uses resources found within the farm, accessing strengths within natural systems. Organic farms are more labor- and management-intensive and thus are more costly in those terms.

Given that the agriculture industry is in need of pragmatic solutions, it makes no sense to use expensive technologies to increase production of

commodities that are already overproduced. In particular cases, however, biotech has an important role, *e.g.* as in saving the Hawaiian papaya industry.

As stated above, one significant advantage accruing from the Roundup Ready® technology is the fostering of reduced-tillage systems, with significant savings in time and energy. The question was raised as to whether "sustainable" practices may reduce tillage even more. In fact, monocrop systems in particular benefit from reduced tillage. It was stated that multi-crop systems are even better than reduced tillage approaches, because they continuously change the system dynamics. Climate change may mitigate against monocropping. If monocropping persists, it is possible that hypoxic zones will increase in size.

There is a need to move to perennial crops—perhaps to 40 to 50% trees and grasses. On the other hand, it would be difficult for conventional farmers to make such changes. Genetic engineering of perennial crops would meet with the same opposition as with annuals.

The question was raised as to whether "sustainable" systems are scalable. The problem is not the size of the farm but rather the structure of the system. The industrial agricultural approach, generally viewed as highly efficient, is not necessarily the most efficient, nor is it impossible to change.

Monsanto did not foresee that the Roundup Ready® technology would greatly increase the adoption of no-till agriculture, and thus be such a time-saver for farmers. It's an example of simplification, the value of which is difficult to calculate. Certainly the value of time saved is much greater than the cost of the technology. Rootworm *Bt* biotechnology may further simplify farming; in not having to apply granular pesticide while planting, twice as much area may be sown per unit time, and buying, storing, and handling of insecticides (for control of corn rootworm) is expected to be reduced.

Labor is an important issue on the farm. Organic agriculture is more labor-intensive than its conventional counterpart, often requiring long hours worked by laborers. How many are willing to work 12 hours per day in the field? Land and capital are more plentiful in the midwest, favoring the less labor-intensive system. On the other hand, if labor is plentiful, there is less need for capital. The situation differs from society to society. But, even in South Africa, *Bt* cotton has been readily adopted because of the reductions in labor and pesticide applications that it fosters. In tropical environments many constraints exist beyond those met by farmers in the United States—year-round insect-predation and disease, poverty, and food shortages. Particularly because the high-input

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Green Revolution bypassed Africa, biotechnology is viewed there by some as an additional tool to reduce constraints and increase productivity. But could there be an EU-market backlash—rejection of African commodities? Intra-regional trade is far more important in Africa than intercontinental. Any commodities exported to Europe would probably have to be non-GM.

Achieving sustainability in agriculture, by definition, requires a long-term view, taking account of externalities like soil erosion, hypoxic zones, and effects on wildlife. Can conventional farmers be made to alter their practices to achieve greater sustainability, in the absence of direct financial incentives?

The contentiousness between the "organic" and "biotech" camps leaves little opportunity for finding common ground. In general terms, Frederick Kirschenmann's approach is to adjust to the flow of change, and the alternative is to shortcut the natural flow. Yet, the two need not be mutually exclusive. It was suggested that *Bt* technology will be accepted as a component of organic agriculture within 10 years.

With the fundamentally different anti and pro-biotech mindsets, is it possible to agree to disagree and move on to consider problems of global dimensions in the hope of finding common ground to form the basis of progress? For example, greenhouse gas mitigation. Does biotechnology impact it, and, if so, how? Again the point was made that, this meeting is not broadly representative. We need to seek means of obtaining broader representation at NABC meetings. Norman Borlaug has stated that it takes a lot of people to start something that can then be stopped by just a few. Another problem of global dimensions is whether we can sustain the growing population; does biotechnology have a useful role to play?

As stated above, the prevailing agricultural system is not closed to the concept of change. Farmers have to be adaptable to survive, and many will try sustainable approaches if they make sound economic sense. No one solution fits all. We must move away from polarization and view the total array of technologies and systems; every grower has unique challenges and needs to be able to select the best combination of technologies available. We must set policies that maximize grower choice.

There is a strong need for funding for long-term research that is independent and not linked to criteria related to industrial profits.

Economists say that, partly as a result of GM crops, commodity supplies have been increased, forcing prices down. GM canola reduces food cost by $0.50/year per person—an undetectable change. Biotechnology is one of many factors contributing to decreased food prices. However, a discussion on the high cost of packaging would be more meaningful.

The EPA does not view GM foods as inherently risky. They examine for risks and determine how to manage any that are identified.

Consumer Issues and Trade

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Because nature is dynamic, some feel that it will be impossible to contain transgenes indefinitely and that, sooner or later, the products of unwanted transgenes will enter the food supply; we may be heading for a consumer catastrophe. On the other hand, it was pointed out that transgenes, like all others, are already throughout nature. One objective of the "terminator" seed technology was to help control gene flow.

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There is no consumer demand for GM food. Biotech is benefiting industry and conventional farmers, not consumers. On the other hand, organic farmers are under threat—although it should be borne in mind that the GM "taboo" as it relates to organic food was insisted upon by the organic industry. Eventually, tolerance levels need to be established that will foster co-existence of conventional with organic farming. Organic standards were drawn up with the precautionary principle in mind.

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What is the role of the land grant universities?

"Reductionist" scientists tend to miss sight of the system as a whole. Conventional farming isn't working for growers, pointing to the need to look at alternatives in terms of farming systems and new ways of making money.

If GM crops are substantially equivalent to their non-GM counterpart, on what basis are they patentable? This question was posed several times in the workshop and plenary sessions. Substantial equivalence lies in the harvestable component, whereas patentability results from the transgene that confers, for example, resistance of the crop as a whole to insect predation.

What is the role of the land grant universities (LGUs)? Some argued that the LGU mission—doing research for the common good—has been lost. On the other hand, the transgenic papaya research was done at LGUs, with direct benefit to the people of Hawaii. That consumer expenditure on food has been decreasing for many years is an indication that LGUs are working in the public interest, perhaps too successfully.

That consumer expenditure on food has been decreasing for many years is an indication that land grant universities are working in the public interest, perhaps too successfully.

Adoption of biotechnology in agriculture has been faster than what the public can understand—causing significant confusion and concern. There is a need to advance the debate, to foster mutual understanding. It is important to note that adoption of GM crops has not been limited to industrial agriculture; rates of adoption are rapid also in China and other developing countries, resulting in reductions in application of insecticides. Some feel that the successes of biotech need to be tempered with publicity on its failures.

One participant suggested that although consumers want labeling, industry is resisting because it will lead to consumer questions. Various industries joined forces to fight a labeling initiative in Oregon—why? Consumers with ethical

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and other objections to GM food need information to avoid what they do not wish to eat. In addition to ethical objections, others wish to avoid GM foods because the FDA does not require tests for allergenicity or other hazards in food deemed to be substantially equivalent. Some feel that a leaf should be taken out of the European book—Americans should be circumspect when it comes to all GM foods. Again, it was suggested that those wishing to avoid GM foods should eat organic. One participant made clear that, notwithstanding the activist mantra, none of the alleged StarLink™ health concerns were borne out upon testing by the National Academy of Sciences. It was suggested that the Europeans are labeling for reasons other than for safety, *e.g.,* politics, and to satisfy activist-group demands. Although at least one poll has shown that the overwhelming majority of American consumers want labeling of GM foods, it was pointed out that survey results are strongly influenced by how questions are asked.

Respect for the elegance and complexity of natural systems is not limited to the organic paradigm and could provide common ground for meeting participants and society as a whole. Other fundamental points that met with consensus were that we must protect our planet and agriculture must be

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sustainable. Despite idealogical objections and other concerns related to genetic engineering, we must emphasize agreements in related areas and build constructive dialog from there. Genetic engineering has become a lightning rod—the biotech industry should not have to answer for all of agriculture's ills.

The biotech industry views itself as the provider of biological improvements, moving away from chemical-based agriculture, which should meet with the approval of the "organic" community. Mergers and consolidations—viewed with suspicion—were, at least in part, simply acquisitions of seed companies driven by needs for commercial channels for business products. The agriculture industry's tendency to concentrate is not new. Consolidation is everywhere—*e.g.*, retail supermarkets. Monsanto controls only 12% of the seed-corn trade. There was consensus that Monsanto should not be the sole focus of debate. Major concerns that should not be laid primarily at Monsanto's door include gene escape, biopharming, and genetic engineering of trees.

Increasingly diverse plant pharmaceuticals are under development, requiring discussions involving scientists so that society will understand the processes and products.

Synthesis

Six key themes emerged from the discussions.

- Systems
- Risk
- Rights
- Perceptions
- LGUs
- Crossroad

Systems

One overarching theme was the need to take a systems perspective or utilize an ecological framework for long-term sustainability. An important issue within that theme was the role of modern reductionist science and technology, and particularly biotechnology. An underlying question that continued to surface involved the complementarity or antithetical relationship between a systems perspective and logical positivism and biotechnology. At the same time, some tension was expressed between those who seek to reduce complexity, to simplify, and to specialize, and those who embrace complexity. One person observed that "complexity breeds expense" (and expense is to be avoided), whereas another noted that "complexity breeds delight." With those distinctive orientations, participants questioned whether biotechnology could be compatible with the goal of sustainable systems and enhance the capacity of the community to renew itself.

It was suggested that to use biotechnology in a systems framework, one must avoid employing the technology as a shortcut to address a symptom or problem in the system, but should, instead, use the new technologies to expand our understanding of complex systems. It was noted that there is beauty, elegance, and complexity in agricultural systems. We should support research that helps us understand those systems, even if we disagree on specific technologies.

Risk

A second theme was risk and a number of issues surrounding it. It was acknowledged that risk characterization, risk assessment, and risk management are distinctive yet interrelated, complex and often-controversial activities. A critical component is risk characterization and definition. What should be considered within the framework of risk assessment? There was general agreement that it should encompass human-health and environmental risks, broadly defined to include allergenic proteins, insect resistance, non-target organisms, and gene flow. Some participants, however, believed it should include economic, social, and ethical risks, such as those associated with corporate control of the food system, inequitable distribution of benefits and

Public participation in the overall process is essential to the success of risk-assessment, management, and policy decisions.

risks, as referenced in a 1996 National Research Council report, *Understanding Risk: Informing Decisions in a Democratic Society.*

Some noted that risk assessment is often framed by experts in technical terms that biological and physical scientists can address, ignoring some of the broader and more diverse concerns of society, and, thereby, undermining the public's trust in risk analysis. As a consequence, a number of people suggested following the precautionary principle in making decisions in an uncertain world. More specific issues included the time frame and timing for risk assessment, since certain risks may not surface until months or years later or when a particular activity or process is scaled up. Others noted the importance of improved communication and access to information and reports. Finally, public participation in the overall process was seen as essential to the success of risk-assessment, management, and policy decisions.

Rights

A third theme was the broad question of consumer rights, consumer information, and consumer safety. Embedded in that issue was the specific topic of labeling, which was recognized as being very complex. Should it be part of the regulatory process? Should labeling be required as part of the "pride in ownership" chain of the product? Concern was expressed regarding the complexity of labeling in the food-supply chain, from seed, to processor, *etc.,* to multi-ingredient products. How can labels be exact, correct, yet informative? Should they be related to the process or the product? Should they address composition, content, derivation process, characteristics? Should there be symmetry in labeling other products? Is this simply a marketing ploy, or is it a mechanism to allow choice for consumers? Several discussants noted that organic foods are, in effect, providing choice. Perhaps. Tolerances need to be incorporated into the approval process. Others wondered if labeling is often a substitute for direct contact between producer and consumer. Since survey data have been mixed, it was unclear whether consumers really want labels. Labeling may be just one of a number of tools needed to inform and empower consumers.

Perceptions

A related issue, and fourth theme, was consumer perceptions, acceptance, and preferences. There have been many surveys of consumer attitudes to, and

perceptions of, agricultural biotechnology. Efforts to address these attitudes and perceptions must begin with an understanding of the diverse reasons why people hold those views. Some studies have shown that people have particular perceptions of biotechnology based on issues as diverse as human and animal health, environmental sustainability, economic concentration, social justice and equity, sanctity of nature, and religious values. Moreover, some cited studies have shown that, as public knowledge increases, perceptions both of benefits and of risk/costs of the new technologies increase. In review, a facilitator recalled the point being made that the more people know of GM food, the less they like the idea. Finally, some participants noted that the focus needs to be on what the public and consumers want, rather than on what they will accept. However, what they want—and why—is very complex.

LGUs

A fifth theme was the role of the public research system and the land grant universities. The LGUs have a significant role to play in biotechnology, sustainable agriculture, organic agriculture, minor-crop research, environmental and resource management, nutritional and dietary health, and community and economic development. However, there is a lack of funding for these institutions, and, in particular, for organic farming, alternative farming approaches, ecology, long-term sustainable systems, and non-proprietary research. One question raised was, "Is science for sustainability possible in an era of specialized, expert knowledge and commercialized, private knowledge?" A strong, independent public-sector research system was identified as a critical component for generating knowledge in these important areas.

Crossroad

Finally, the overarching theme of the meeting, *Science and Society at a Crossroad* was revisited at many of the break-out sessions. Major changes are occurring in population, the environment, climate, energy, science, and the food system, and various groups from government, industry, university, non-profit organizations, and producer communities have often talked past each other and their positions have become polarized. We are at a crossroads and need to find areas of common ground for the common good. We need to focus on how we can communicate and work together to pursue common goals. Several participants noted that we need to think not in terms of "either/or" but rather in terms of "both/and."

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THEMES, DISCUSSION LEADERS, AND RECORDERS FOR THE BREAK-OUT WORKSHOP SESSIONS.

Theme	Discussion Leader	Recorder
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PART III

MODULE I – KEYNOTE ADDRESSES

BIOTECHNOLOGY: SCIENCE AND SOCIETY AT A CROSSROAD

MODERATOR: *NEAL VAN ALFEN*

Lessons Unlearned: How Biotechnology is Changing Society

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Agricultural biotechnology has come a long way over the past two decades. While talk of 10-foot-high cows, 2-foot-long ears of corn, and nitrogen-fixing cereals has all but disappeared, crops that are herbicide tolerant and insect resistant are now a common feature of the landscape in several nations. Nevertheless, when one compares agricultural biotechnology with pharmaceutical biotechnology, the differences in the public perception and reception of new technologies are painfully apparent. Pharmaceutical products are embraced worldwide, while resistance to agricultural biotechnology can be found everywhere, not least in the United States. This is unfortunate, as agricultural biotechnologies have the potential to be quite beneficial in a number of ways.

In a recent article in *Technology Review*, Daniel Charles (2003) noted the potential for biotechnology to produce apomicts, *i.e.* crops that would breed true, generation after generation, thereby providing farmers in developing nations with easily reproducible high-yielding varieties. But Charles also noted that it is highly unlikely that this will come to pass. The recently restructured agricultural biotechnology industry would find such varieties threatening rather than desirable, and would be unlikely to invest in them.

Let me make clear the central thesis that I will pursue here: agricultural biotechnology, despite a few successes here and there, has thus far been a failure. It has failed to live up to the hyperbole, of course, but—more importantly—its proponents have failed to enroll citizens and consumers, and even the food processing and retailing industries around the world. Indeed, it is fair to say that probably no group of technologies has produced the rancor, the protests, the opposition, that agricultural biotechnologies have. Moreover, it need not have been this way. The phenomenal successes of pharmaceutical

biotechnologies, of personal computers, of consumer electronics, stand in clear relief to the resistance generated with respect to biotechnology for agriculture and food.

I will begin by discussing the nature of innovations. Then, I will discuss specifically the cases of Roundup Ready® and *Bt* seeds, and will suggest that the purveyors of agricultural biotechnologies are on a path that is quite likely to lead to their demise. I will conclude by noting some lessons that, if learned, might yet turn the industry around.

Thinking about Innovations

There is a school of thought that argues that innovations simply diffuse through society much like objects in a vacuum (Latour, 1987; Rogers, 1995). Once released, according to the diffusion theory, such innovations encounter no friction, no resistance, no stumbling blocks. The British biologist, Hugh Bunting (*passim*), described this approach as the researcher shooting an arrow through the extension agent into the farmer.

In contrast, I would like to suggest another metaphor. Put simply, like stones in curling, innovations require sweepers; but the work of the sweepers is usually invisible. What this means is that upstream innovations need to satisfy everyone in the complex network of relationships between production of the innovation and the acceptance and use of that innovation among final consumers. Those along the trajectory that the innovation follows have to be willing to engage in the invisible work of sweeping—eliminating the friction that can slow or stop an innovation in its tracks.

If one looks at the pharmaceutical industry, it is clear that all products have to satisfy

- the companies producing them (with respect to cost of production, efficiency and consistency of production, demand for the product, *etc*.),
- the government regulators (who must find credible the claims of efficacy and lack of side effects of the drug in question),
- pharmacies responsible for selling the drug,
- physicians who will prescribe the drug,
- insurance companies that will pay for (at least a part of the cost of) the drug, and
- patients who will purchase the drug using prescriptions provided by their physicians.

If any of these actors in the supply chain fails to support the production, regulation, distribution, sales, or consumption of the drug, the product will not reach its final consumer. Similarly, agricultural biotechnology innovations have to satisfy all the actors in the supply chain. To date, this has been only partially the case. Let us examine the cases of Roundup Ready® and *Bt* crops as examples.

The Cases of RR and *Bt* seeds

Plant biotechnology got its start during the Reagan administration, in the early years of deregulation. From the vantage point of Reaganites, regulation stifled innovation, slowed business, and otherwise restricted growth of the market. In 1986, Monsanto executives visited with Vice President Bush with the unusual request that the government regulate the new agricultural biotechnologies (Eichenwald, 2001). While the administration was reluctant at first, it soon began to understand Monsanto's position: without regulation, public opposition was sure to mount. Regulation would enhance public confidence in the new products. And, not incidentally, it would reduce biotechnology companies' liability were adverse effects to arise, and it would weed out the weaker companies, who would be unable to afford the costs of the regulatory process.

Furthermore, it was agreed by all, that executive decisions were far better than the possibility of Congressional hearings. The existing laws enabling regulation by the Environmental Protection Agency, the United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA), would be cobbled together to create a so-called "coordinated framework."

As Kurt Eichenwald (2001) put it:

> *It was an outcome that would be repeated, again and again, through three administrations. What Monsanto wished for from Washington, Monsanto—and, by extension, the biotechnology industry—got. If the company's strategy demanded regulations, rules favored by the industry were adopted. And when the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing.*

Among the first products to emerge from the company's efforts was bovine somatotropin (BST). A public furor soon occurred; company officials were apparently unaware of the importance of enrolling the general public in their projects. As Monsanto CEO, Richard Mahoney, noted (Charles, 2001):

> *We got into BST like we got into a lot of things. We'd been making agricultural chemicals for years. You increase the productivity of the farmer; you keep half (of the profits) and give him half. So what's the big deal? There wasn't even one discussion of the social implications. I never thought of it.*

A year later, another company engaged in field trials of an engineered bacterium named "ice-minus," designed to increase frost tolerance in plants. The media quickly broadcast photos of researchers in space suits tending the field. Not surprisingly, these images did not inspire confidence.

While, prior to 1990, Monsanto attempted to engage the critics, things changed when Robert Shapiro was appointed CEO. With missionary zeal, he

pulled out all the stops. Monsanto would change the world for the better, and make a fortune doing it. By 1992, Monsanto had successfully lobbied the Bush administration to speed up the regulatory process. Like most of the biotechnology-industry leaders, the administration echoed the belief that science demonstrated that bioengineered products were safe. Some FDA scientists raised concerns not unlike those noted earlier by industry scientists, but they were now ignored both by the government and by industry. Moreover, labeling was ruled unnecessary. It was argued that labeling would raise unnecessary concerns among the general public.[1]

As former CEO of Pioneer Seeds, Thomas Urban, argued (Eichenwald, 2001):

> *Monsanto forgot who their client was…If they had realized their client was the final consumer they should have embraced labeling. They should have said, "We're for it." They should have said, "We insist that food be labeled." They should have said, "I'm the consumer's friend here." There was some risk. But the risk was a hell of a lot less.*

Not surprisingly, the lack of labeling created widespread opposition by small farmer, animal welfare, consumer, and environmental groups. By the late 1990s, these groups had begun to receive both membership dues and foundation funds to challenge the biotechnology regulatory regime, if not the technologies themselves.

Moreover, industry pressure hardly let up. With industry backing, the Clinton administration pressured Europe during trade negotiations, arguing that European concerns were unfounded and based on outdated traditions. Protests erupted in Europe.

Farmers

But if Monsanto was paying relatively little attention to final consumers, it was beginning to woo farmers. This was particularly the case in the development of two types of genetically modified (GM) crops—those tolerant to Monsanto's herbicide Roundup® (glyphosate), and those modified to enhance insect resistance through the addition of genes from *Bacillus thuringiensis*, a common bacterium often used as a spray by organic farmers and in forestry. While farmers did not see significant yield increases[2] (and in some instances they experienced yield decreases), Roundup Ready® and *Bt* crops demanded far less

[1]Current FDA regulations have the effect of making labeling of non-GM foods nearly impossible. But a recent USDA publication, reporting experimental economic research on consumers' willingness to pay, suggests that when independent scientific information about GM products is presented, differences in willingness to pay between GM and non-GM foods is negligible (Tegene et al., 2003).

[2]Ervin *et al.* (2000) suggested that when examined worldwide, transgenic crops account for a mean yield increase of no more than two percent.

management. Roundup Ready® plants offered the ability to spray for weeds nearly throughout the crop cycle, while *Bt* crops offered reductions in insecticide use. Given the press of time in contemporary farming, it is of little surprise that farmers embraced these technologies. As countless articles have noted, farmers rapidly adopted both types of genetic modifications.

At the same time, Monsanto's carrots were backed up with several sticks. Toll-free hotlines were established so that farmers suspected of violating the licensing agreements could be reported to the company. State legislatures were lobbied (without success) to require licensing of seed cleaners (Charles, 2001).

While most farmers were, and remain, optimistic about GM crops, organic farmers have shown far less enthusiasm. Given that the USDA-prescribed[3] organic standards prohibit genetic modification, organic farmers have been understandably concerned that GM crops would restrict and even eventually eliminate their markets. And, given the propensity of pollen to drift, GM crops pit organic farmers against conventional farmers as never before.

Seed Companies

Somewhat less obvious is why seed companies were so keen to join the biotechnology bandwagon. After all, seed companies wishing to sell GM crops had to deal with farmers on a daily basis—farmers who were likely also their neighbors—and tell them that they had to sign a complex contract with lots of fine print in order to grow these crops, and that they would no longer be able to save seed as many had done in the past. One need not look too far to find the answer.

It should be remembered that the seed industry in the United States was, until very recently, made up largely of small, mom-and-pop businesses. Moreover, the seed market was stagnant. With little variation, farmers purchased about the same amount of seed every year. Of course, one could build market share at the expense of other companies, but only the larger companies had the capital to expand in that manner. What GM crops offered seed companies was an opportunity to expand their businesses by as much as 20 to 30% as a result of the "no-replant" clause in farmer contracts.

Consider the case of soybean. The seeds are relatively easy to save, as they are large in size and easily cleaned. Throughout much of the latter half of the twentieth century, farmers saved 63% (1960) to 33% (1991) of their seed (USDA, 1963; Doane Agricultural Service, unpublished data). Moreover, large-holding farmers were most likely to save seed. After all, those with larger farms had more capital, were likely to be more educated, have greater skill in seed-saving, and have the most to gain financially by successfully saving seed for planting the following season. Based on unpublished data from Doane

[3]In response to requests from the organic industry.

Agricultural Services, we estimate that seed-saving declined from 33% in 1991 to 10% in 2001, largely as a result of the "no-replant" clause. This translates into $391,770,000 in additional gross profits in 2001 for seed companies and their biotechnology partners—a huge windfall, to be sure. Moreover, the seed companies could shrug off farmer complaints by noting that it was the biotechnology companies, not they, who demanded that seed-saving be halted. Separate pricing for the seed and the "technology fee" aided seed companies in that argument (Charles, 2001).

In short, the agricultural biotechnology industry did an excellent job of enrolling (most) farmers and seed companies in their projects, and was, and continues to be, highly successful in getting the US government to do their bidding in a variety of ways.[4] But, further downstream in the supply chain, trouble has been brewing for some time.

Manufacturers

Manufacturers have been wary of GM-food products. They have had little to gain by accepting GM raw materials and potentially a lot to lose. To date, perhaps the most visible fiasco surrounding GM food has been the *Bt* potato. Developed by Monsanto through its NewLeaf division, it was designed to be resistant to the Colorado potato beetle, a major pest. But, not long after it was released, Frito-Lay decided that it did not want the NewLeaf™ potato for its chips, while McDonalds determined that it preferred to avoid them for its fries (Nation's Restaurant News, 2001; Pollack, 2001). With the two largest buyers of potatoes rejecting the new product, it was not long before Monsanto was forced to withdraw NewLeaf™ from the market. To my knowledge, there are no plans to reintroduce it.

Similarly, GM flax—with the unlikely name of Triffid[5]—was withdrawn from the Canadian market when it was discovered that European buyers, who purchase 60% of the crop, did not want to buy it. The same story applies to the sugar-beet industry, where, despite US government approval, refiners have advised farmers to avoid the GM crop. Hershey and Mars, major customers for the refiners, both expressed serious reservations about using it (Kilman, 2001).

The StarLink™ fiasco of 2000 (Lin *et al.*, 2001–2002) and the more recent Prodigene affair (Gillis, 2002) have upset the relatively pro-biotechnology food-processing industry as well. After the Prodigene incident, both the Grocery Manufacturers of America and the National Food Processors Association issued

[4]In contrast, the agbiotech companies have had mixed success in Canada—although herbicide-tolerant canola has been well received, BST is still prohibited—and they have largely failed in Europe where popular opposition has trumped company lobbying.

[5]In John Wyndham's book The Day of the Triffids (Doubleday & Colliers, 1951), dangerous carnivorous plants wander the earth!

press releases indicating their desire for a go-slow policy with pharmaceutical crops (Simon, 2002). Surprisingly, several months later, a Monsanto representative presented a paid seminar at the 2002 annual meetings of the American Association for the Advancement of Science in which the company unveiled its proposal to develop pharmaceuticals in corn. Particularly ironic about the proposal are the heroic lengths to which the company proposes to go in order to ensure that the pharmaceutical corn is segregated from food and feed corn. The electric fences, security guards, video cameras, global positioning systems, dedicated planting, harvesting, and transportation equipment that are to be used to ensure segregation appear more suitable for a nuclear power plant than for a field of corn.

Consumers

With respect to consumers, considerable unease still exists. On the one hand, consumers are still frustrated by the lack of labeling. Biotechnology companies spent at least $5.2 million to successfully defeat a 2002 Oregon ballot initiative that proposed that GM foods be labeled. As Business Week columnist, Julie Forster (2002), argued:

> *That's shortsighted. The food industry would be better off educating the public about the safety and benefits of genetic modification. Their fear of a labeling law only means they have done a lousy job so far.*

In contrast, industry spokespersons have argued that labeling would be seen by consumers as a warning about dangerous substances. Economists at the USDA noted that economic theory also argues against food labeling of this sort (Golan *et al.*, 2000). But evidence from numerous surveys shows that US consumers overwhelmingly want GM-food products labeled as such. Indeed, in one recent national study, an astonishing 92% of respondents were in favor of such labeling (Wimberley *et al.*, 2003). Rarely is such a level of consensus found on any issue. Mounting campaigns to avoid labeling make it appear that the industry has something to hide. And, appeals to economic theory ignore the fact that labeling is as much about politics and public relations as it is about economics.

On the other hand, to date, no whole foods have been genetically modified. Genetically modifed soybeans are largely used as ingredients in other food products, and are often unrecognizable to consumers. Most GM corn is used for animal feed, the rest for food ingredients. But, already, considerable concern is building around GM wheat, the release date for which has been delayed several times.

Finance

The banking, finance, and investor communities have not been silent about GM foods. Not too long ago, when the future looked quite bright for agricultural

biotechnology, most of the major chemical/pharmaceutical companies had agbiotech units. In 2001, most of those units were spun off. Pharmacia jettisoned Monsanto. Novartis dropped Syngenta. These decisions were made in large part based on profitability. Compared to the bright future in pharmaceuticals, agricultural biotechnology looked rather unimpressive. Since then, Monsanto has stumbled with losses large enough to force the resignation of CEO Hendrik A. Verfaillie. Syngenta recently closed its Torrey Mesa Research Institute in San Diego, largely due to poor sales of its products. Several years ago, Deutsche Bank downgraded its ratings for agricultural biotechnology (Deutsche Bank, 1999). And, recently, the Innovest Strategic Value Advisors, an investment firm, issued a report suggesting that Monsanto was a risky investment (Brammer *et al.*, 2003).

Recent Developments

Of late, the biotechnology industry has been leaning heavily on the US government to get European nations to stop their virtual ban on GM foods. In a rather bizarre turn of events, President Bush made the indefensible argument that there is a direct connection between the use of GM food and the elimination of hunger in Africa (Becker and Barboza, 2003). In point of fact, to date, no significant yield increases have been associated with GM crops. Moreover, the food crops that have been successful—maize, soybean, canola—are not widely grown in most developing countries. In addition, in many African nations, productivity is low because farmers have nowhere to sell surplus production, and United States and European Union subsidies keep world market prices depressed. Furthermore, hunger is largely dependent on lack of access to food, not on overall production figures. Indeed, as countless persons have pointed out, there is already more than enough food in the world presently to feed the entire population.

In addition to possibly leading to the collapse of the entire global trade edifice constructed painstakingly over the last decade, the effort is largely futile. In Europe, consumers have virtually no interest in buying GM foods, as food retailers there know that all too well. Indeed, one retailer, Iceland Foods, has developed an advertising campaign around the fact that its private label products are not GM (Iceland Foods, 2003). Other EU supermarkets, such as Carrefour (Carrefour, 2002) have banned GM foods from their shelves. The French chain Monoprix (2003) has a policy of replacing "products likely to contain GM organisms with existing substitutable products." Still other firms, such as Royal Ahold (2003), insist on labeling. And, food processors are also sensitive about GM foods. For example, Heinz UK prohibits use of GM raw materials in their processed foods (Heinz, 2003). Thus, even if the United States wins at the Dispute Settlement Process of the World Trade Organization, the biotechnology industry will ultimately fail in its efforts to get Europeans to eat GM foods. The situation in Japan is hardly much different.

Moreover, US farmers have borne the brunt of the effects of consumer rejection of GM foods. The US share of the world soybean market continues to fall, in part due to consumer preferences in the European Union and Japan for non-GM varieties. One recent estimate puts yearly losses at $300 million (Wolfson, 2003). Yet, most large farm organizations fail to recognize the first rule of marketing: give the customer what he or she wants.

Genetically modified wheat is nearing release in the United States and Canada, although its acceptance is far from certain. On the one hand, it is more than conceivable that domestic millers and bakers may reject it. After all, it poses new logistical problems for them. Some might argue that those who wish to pay a premium for non-GM wheat will compensate the millers and bakers for the extra costs of segregation (although it remains unclear whether adequate segregation is practical). This is certainly possible, but the magnitude of rejection of GM wheat is a large unknown. That means that, at least in the short term, millers and bakers might well be hit by heavy losses.

On the other hand, foreign buyers of US wheat appear far more skeptical. In February, in testimony to the Montana state legislature, Iowa State University agricultural economist Robert Wisner noted that thirty-six nations currently require labeling of GM products and that without some beneficial health implication, prices received for exported wheat are likely to decline to feed levels (Montana House of Representatives, 2003). In a related paper, Wisner (2003) noted that importers will be able to get non-GM wheat at much lower cost from other supplying nations, where expensive segregation is unnecessary.

Moreover, we would do well to remember that Eastern Europe was the center of world wheat production a century ago (Buller, 1919). That position ended as, first, Russia, and then most of the rest of Eastern Europe, were removed from the world market. Today, with re-entry into the world market, Eastern Europe once again has the potential to become a major competitor for the United States. Genetically modified wheat might be just the impetus necessary to bring capital investment to Eastern Europe to reestablish it as a major wheat-exporting region. This would cause wheat prices to fall by as much as one-third (Wisner, 2003). A Canadian research group has reached similar conclusions (Furtan *et al*., 2002).

At the same time as the biotechnology industry has been struggling, the organic food industry has been growing by leaps and bounds. Organic food sales continue to increase rapidly. In the United States, they have doubled since 1997 to reach $7.1 billion in 2001 and are expected to double again to $14 billion by 2005 (Nutrition Business Journal, 2003). Although only a small percentage of total food sales, virtually every supermarket chain now has space dedicated to sale of organic products. In Europe the situation is even brighter.

Supermarkets specializing in organic foods, such as the Whole Foods chain, are doing very well, and many, if not, most major US food processors, including Heinz, Coca-Cola, Kraft, and Mars, now have an organic line. Gerber's, a wholly

owned subsidiary of Novartis, advertizes that its products are organic. The irony, of course, is that the biotechnology industry has been the subject of enormous government largesse and correspondingly high corporate research expenditures, while the organic industry has been, and remains, the stepchild of government- and industry-supported research.

Conclusions: Lessons Unlearned

So what lessons can be drawn for the agricultural biotechnology industry and for other industries desirous of public acceptance of their products?

- *Enroll all actors in the supply chain*. The secret of success in innovation lies not merely in getting the next actor in the supply chain to adopt your product, but developing a product that is viewed positively by all actors in the supply chain. This means that the product must, at the very least, not increase the costs—economic and otherwise—of downstream actors. Ideally, it should increase the benefits for every actor in the chain. Remember all those invisible sweepers out there!
- *Compete and cooperate*. While economic textbooks dwell on the virtues of competition, good management and marketing textbooks give equal weight to competition and cooperation. Adam Smith (1994 [1776]) might not have liked this as he was convinced that associations of all sorts were the enemy of the market. But history has proven him wrong. One only need glance at the *Encyclopedia of Associations* to realize that cooperation has a major role in organizing both our economy and society. Moreover, the encyclopedia does not even include the myriad strategic alliances, cross-licenses, and contractual arrangements that are a central feature of the modern business landscape. Competition without cooperation is usually a dead end.
- *Gain by sharing*. Trying too hard to capture all or the lion's share of the market is often a recipe for failure. At the very least, it creates enemies—enemies with political clout, deep pockets, a great desire to invent around whomever has control of the market, and lots of lawyers.
- *Regulate through the entire supply chain*. The current regulatory system is clearly a piecemeal affair. By avoiding public hearings and debate, by patching together a system using existing law, we have created a system that appears to constantly break down. In particular, it fails to recognize that GM organisms wind up where they should not be, either as a result of the normal processes of nature or through the all-too-human processes of production, processing, transportation, warehousing, retailing, and consumption. An effective regulatory system must take the entire supply chain into account.
- *One needs to line up all the ducks in order to effectively sell products*. All actors in the supply chain must both compete and cooperate. If any one

actor engages in behavior that inflicts damage on another actor, the aggrieved actor will surely attempt to block that behavior. Marketing of agricultural biotechnology products without considering this crucial point will continue to be an uphill battle.

Finally, I should note that holding innumerable debates about the pros and cons of agricultural biotechnology will not resolve the issues raised here, as long as the problem is framed as a lack of knowledge. As Les Levidow noted recently, "'Public debate' and 'input from society' are sought mainly as a means to restore the legitimacy of science and technology, not as a means to reconsider innovation processes" (Levidow and Marris, 2001). The future of agriculture cannot and should not be limited to a simplistic debate in which (1) one is either for or against what are in fact a wide range of new technologies, not all of which are necessarily desirable, and (2) other technoscientific trajectories are ignored, written off, or bypassed in a mistaken effort to find the one "true" solution to the problems of food and agriculture.

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Biotechnology: Cause and Consequence of Change in Agriculture

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As I was growing up in rural northwestern Minnesota in the 1940s and 50s, the major—if not, only—considerations by farmers of whether or not to adopt a new technology were based on whether it would raise yields, save labor, or otherwise pay economically. I recall the adoption of 2,4-D herbicide in the early 1950s, for control of broadleaf weeds on our family farm. I remember the images of mustard blooming in our fields of small grains only where application had failed, whereas, beforehand, the entire field would be yellow when the mustard was in bloom. At that time, the only hints of an environmental movement were from soil-conservation programs of the United States Department of Agriculture (USDA) and Cooperative Extension Service. In the wake of the "dust bowl" and "dirty thirties" of slightly more than a decade earlier, these programs had promoted contour and strip farming, neither of which paid economically, nor did they work well enough to stop the erosion caused by a typical Minnesota summer thunderstorm.

The environmental movement in progress today, with its focus primarily on the elimination of chemical pesticides, undoubtedly has multiple origins, but traces most visibly to Rachel Carson's *Silent Spring,* published in 1962. This watershed book caused farmers, scientists, and the agricultural industries to look beyond the economics of new farm practices. Economics was no longer the only factor to consider. The result has been an avalanche of change, including more research on biological control and integrated strategies for management of pathogens and pests. Agribusinesses have redirected their R&D

to products with specific targets as replacements for broad-spectrum pesticides. There now are requirements that every pesticide applier maintain updated training and be licensed. Comprehensive record-keeping by growers, and intensive "market basket" sampling and testing of fresh produce by the Food and Drug Administration for off-label chemical residues are now the norm. *Silent Spring* may also be considered one of the origins of the social awareness that agriculture must now consider when adopting or continuing a new technology, practice, or system.

Today, growers are finding various ways to balance and integrate three drivers of the sustainability. These are *economic*, including ability to compete in a global economy, *environmental*, *i.e.*, be in compliance with environmental requirements, particularly clean water and air, and *social*, *i.e.*, meet the safe-food and other demands of consumers and customers specifically and of society more generally. If a product or practice fails the test of acceptability for any one of these three factors, it may continue in the short term, but will not be sustainable in the long term. Biotechnology has been a boon to the environmental and, to some extent, the economic drivers of sustainability, but, clearly, the jury is still out on its broad acceptance in society.

It is often said that agricultural biotechnology would be more readily accepted by society if the benefits to consumers were more obvious, as they are with medical biotechnology. Wider benefits are forthcoming, including novel raw materials for the manufacturing industry that currently depends on petrochemicals, more-digestible animal feeds, foods higher in essential nutrients or lower in allergenic proteins, and plants as cheaper ways to meet the needs of medicine for specialty proteins (pharm plants) to treat chronic human diseases. Because of public resistance, fear of rejection by foreign customers, or other consumer/customer/societal issues, I am concerned that agbiotech companies might abandon the currently available applications of so-called "in-put" traits that benefit the producer (and hence the consumer) economically and that also benefit the environment and natural resource base, and concentrate instead on second- and third-generation "out-put" traits (products) with their more direct and readily apparent benefits to society. It is here, essentially still at the "starting gate"—as much as or more than any other application of biotechnology—that science and society are at a crossroads. This paper is, therefore, focused on how and why biotech fits into the dynamics of change down on the farm, where its adoption is as much a consequence as it is the cause of this change.

Outcome Measures of Modern Agricultural Systems

Rather than a single-issue focus on biotechnology, the changes in agriculture are better considered in terms of outcome measures and the recognition that farming, regardless of its label—conventional, organic, subsistence, industrial—is a *system*. In this context, biotechnology is but one of several innovations that

are both cause and consequence of change in agriculture. Other major innovations include the use of direct seeding or "no-till" farming, precision-agriculture technologies, and information technology. Not surprisingly, each of these changes has met with resistance.

As one outcome measure of the farming systems in place today in North America, there likely will not be another "dust bowl" on this continent, thanks to a 60-year trend towards technologies and management practices developed and adopted to save, and even rebuild, soils. These changes started with physically altering the landscape: the contour and strip farming mentioned above. These approaches to soil conservation have been increasingly complemented or replaced by mulch-tillage, minimum tillage, strip-tillage, ridge-tillage, and now direct-seeding. Direct-seeding—the placement of seed and fertilizer directly into undisturbed soil with no prior seedbed preparation—not only prevents soil erosion, it increases sequestration of carbon dioxide and helps farmers reduce fuel and labor costs while protecting water and air quality and providing habitats for birds and other wildlife. While identified with large-scale farms in developed countries, direct-seeding is also coming into use on small-scale farms in developing countries (CIRAD, 2002; Javier, 2002). As a bonus, the accumulation of soil organic matter in direct-seeded fields represents sequestered carbon as an offset to carbon dioxide emitted by cars and coal-fired sources of heat and energy.

Merkel (1998) defined sustainable growth as:

> *The use of natural resources no faster than they can regenerate themselves, and the release of pollutants to no greater extent than natural resources can assimilate them.*

Direct-seeding leads dramatically to conservation of soil, water, and fossil-fuel resources while allowing minimal transfer of soil sediments, dust, pesticides, plant nutrients, and greenhouse gases to other environments, and, therefore, is clearly consistent with the goals of sustainable growth.

One-third of the 75 million acres of soybeans in the United States is now direct-seeded (Table 1). More than 60% of US soybean growers interviewed by the Conservation Technology Information Center (CTIC) credited herbicide-tolerant (Round-up Ready®) varieties for weed control as the key factor in their decision to reduce or eliminate tillage. Of course, some farmers use direct-seeding but not herbicide-tolerant varieties and the converse; and the limited area of direct-seeded wheat in the United States (10–12% of the acreage) is done without herbicide-tolerant varieties. On the other hand, there is little doubt that reaching the next plateau in adoption rates of direct-seeding for wheat and barley will almost certainly follow the availability of herbicide-tolerant varieties. An even higher adoption rate for wheat and barley will follow the availability of varieties with resistance to the root diseases favored by direct-seeding (Cook, 2001).

TABLE 1. AREA OF DIRECT-SEEDING FOR SELECTED CROPS IN THE UNITED STATES IN 2002 (CTIC, 2002).

Crop	Total	Direct-seeded	%
	millions of hectares		
Corn	78.6	15.0	19
Sorghum	9.5	1.4	14
Small grains (spring)	32.5	4.1	12
Small grains (fall)	43.3	4.7	10
Soybean (full season)	69.8	23.1	33
Soybean (double-crop)	4.8	3.0	62
Cotton	14.6	2.0	14

As another outcome measure of today's farming systems, the world market for pesticides, valued at $30 billion in the 1990s and at about $20 billion in 2003, is dropping at the rate of 2 to 3% per year (Kishore, 2002). The National Center for Agricultural and Food Policy (NCAFP) estimated that just eight transgenic crops currently grown in the United States resulted in a reduction of 46 million pounds of pesticides used in 2002 alone (Gianessi *et al.*, 2002). Most of this reduction occurred with the adoption of cotton cultivars with the *Bt* gene for resistance to insect pests. In China, insecticide use on cotton has been reduced by thirteen spray applications per hectare per season because of the use of *Bt* varieties, saving $762/ha per season (Huang et al., 2002). *Bt* cotton is also now grown in Australia, South Africa, and India, and may soon be in use in Egypt. According to James (2002), the majority of farmers adopting *Bt* crops globally operate small holdings.

ENVIRONMENTAL SAFETY ISSUES EXPAND TO INCLUDE THE CROP VARIETY

To my knowledge, throughout the approximately 100 years of variety development by conventional plant breeding based on an understanding of Mendelian genetics, the question of whether or not the new variety itself—or the gene that made the variety special—might have a negative impact on the environment has never been addressed. Instead, our understanding of environmental impacts and efforts to reduce them through science, education, regulations, and innovations have been based on two principles.

- It is the management used to grow the variety, *i.e.*, the intensity of tillage, pesticide use, planting date, irrigation, *etc.*, and not the variety itself that has impact on the environment.
- Each new crop variety usually leads to changes in the management system used to grow that crop.

A new high-yielding variety may require more fertilizer or pesticides to attain its full potential, as was the case with the IR8 semi-dwarf variety of rice released by the International Rice Research Institute (IRRI) in the 1960s. In this example, *management*, especially fertilization and pesticide application, changed in response to needs of the variety. The breeding programs that followed up on this breakthrough in yield potential, and that continue to this day, have worked largely to develop replacement varieties that maintain the high yield potential but also have genes for resistance to diseases and pests as well as improvements in other agronomic traits and quality measures. The replacement varieties may have no higher yield potential, but rather—and often just as important—they allow the crop to be produced with management that is both more economical and has less impact on the environment. In the example of direct-seeding to protect soil, water, and air resources by preventing soil erosion, the change in management happened first, and is now being followed by the development of varieties that fit the management, such as soybeans with herbicide-tolerance.

Again and again, changes in agriculture worldwide have followed a pattern of varieties bringing about new management and new management making it necessary to develop new varieties. Herbicide-tolerant varieties have been adopted because of their fit with direct-seeding and the *Bt* hybrids of corn and *Bt* varieties of cotton with their genetically-based resistance to insects are replacements for insect-susceptible hybrids and varieties that preceded them—like the disease- and insect-resistant varieties of rice that have replaced IR8 and its successors over the past 40 years.

There seems little reason to doubt, based on all of the evidence to date, that the principle—*it is the management used to grow the variety and not the variety itself that has impact on the environment*—holds just as true for transgenic as for conventionally bred varieties. Nevertheless, developers of transgenic crops and the scientific community more generally are now attempting to assess the impact, if any, of the *new crop variety itself* on the environment. Thus far, other than pollen flow between varieties of the same crop (Rieger *et al.*, 2002), all claims of potential adverse or unwanted non-target environmental effects of transgenic varieties remain hypothetical, unconfirmed, or have been disproved. For example, Sears *et al.* (2001) concluded, following an extensive, multi-location, multi-investigator field study, that management practices such as planting date, control of milkweed with herbicides or cultivation, and insecticide applications, affected monarch butterflies, but that *Bt* hybrids of corn themselves had no measurable or significant effect on these insects. Similarly, Saxena and Stotzky (2001) found no measurable effect on earthworms, soil bacteria, or soil fungi of *Bt* protein released into soil from roots of transgenic corn.

One of the greatest challenges with any study intended to assess the environmental impact of a specific crop variety—*e.g.*, a transgenic variety—is the choice of a control. Even without the research, no one would expect to

conclude that plowing the soil, irrigating the crop, rotating corn with soybean, or just growing corn, has no measurable effect on earthworms, soil bacteria, or soil fungi. On the other hand, documenting the environmental impact of even one crop as a crop, whether corn, soybean, wheat, tomato, potato, or any other, as the baseline or background against which to compare the effects of that same crop with a transgene could rival or exceed the scope of the human-genome project. The Environmental Protection Agency (EPA) avoids this challenge in the case of transgenic resistance to pests and diseases by requiring tests specifically with the gene product based on protocols developed for chemical pesticides. Such tests would be impossible for conventionally bred resistance in wheat to, for example, Russian wheat aphid, green bug, or Hessian fly—all of which are in use in the United States—because there is little knowledge of the mechanism(s) of resistance and no knowledge of the gene products responsible.

The introduction of the next generation of transgenics into cropping systems—especially varieties transformed to produce novel proteins for use in medicine—presents a much greater unknown in terms of potential environmental impact. In this respect, experience gained and the techniques already developed to measure and monitor the effects of transgene products can provide the science-base needed to measure and monitor environmental effects, if any, of genes responsible for novel out-put traits. However, while the market potential for out-put traits, especially proteins for pharmaceutical use, no doubt can pay the high costs of the tests and evaluations required by the regulatory agencies, thus far only the market potential for applications such as herbicide tolerance and *Bt* resistance in the major crops has justified the regulatory costs needed for approval of in-put traits. Herein exists another reason for my concern that the use of biotechnology in agriculture will pass over the almost unlimited array of available and potential in-put traits that would benefit the efficiency and environmental sustainability of production agriculture and pursue instead the development and production of novel and readily marketable out-put traits.

Models Based on Genetic Approaches Used for Pacific Northwest Wheat and Barley

The Pacific Northwest (PNW) region has long been committed to genetic approaches to improving its wheat and barley industries economically, environmentally, and socially. Given below are six examples of genetic approaches in use, or that could be used for the net benefit of the PNW wheat and barley industries and the environment. They appear promising but are not entirely without risk.

Introduction of Dwarfed Varieties of Wheat

The PNW was the first region in the western world to grow dwarfed varieties of wheat. In the late 1940s, Orville Vogel produced a dwarfed breeding line by

transfer of the *Rht* dwarfing gene (Figure 1) from a variety obtained from Japan. He then used this new line in conventional plant breeding, and he shared it with wheat breeders worldwide, including Norman Borlaug, CIMMYT, Mexico.

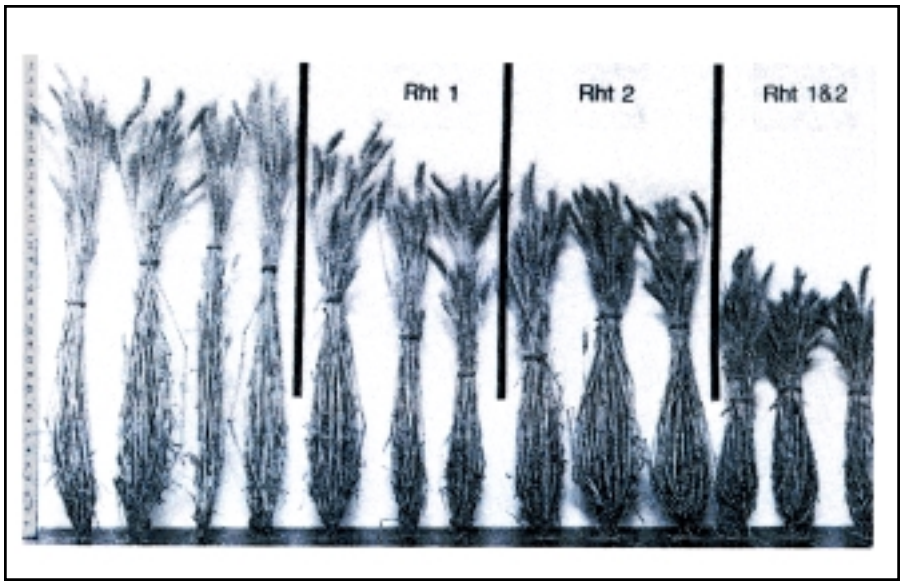

Figure 1. Examples of the effects of the Rht1 and Rht2 dwarfing genes alone and combined on the height of wheat. (Photograph by R.E. Allan, with permission of R.E. Allan and the American Phytopathological Society.)

The 30 to 40% higher yields from semi-dwarf 'Gaines' and 'Nugaines' varieties were estimated to increase the income of Washington farmers by $50 million per year, starting in the early 1960s when these varieties were introduced. Like the example of IR8 rice given above, the risk that accompanied the widespread and rapid adoption of these new high-yielding varieties was that the management needed to obtain their high yield—early seeding on summer fallow and heavy use of nitrogen fertilizer—favored stripe rust caused by *Puccinina striiformis,* foot rot caused by *Pseudocercosporella herpotrichoides,* and crown rot caused by *Fusarium pseudograminearum* and *F. culmorum.* Crown rot was brought largely under control on winter wheat by changes in management practices, namely later seeding on summer fallow and limiting the rates of nitrogen so as to not induce premature water stress (Cook, 1980). Stripe rust and foot rot, on the other hand, were brought under control initially with the aid of fungicides, and are now managed by planting genetically resistant varieties (Jones *et al.*, 1995; Line, 2002).

Management of Stripe Rust

Since the late 1960s, all varieties of wheat released by PNW breeders have had one or more genes for resistance to stripe rust (Line, 2002). Two kinds of resistance have been in use:

- race-specific, single-gene, immunity expressed at all stages of plant development, in which the genetics of the host-pathogen interaction follows the gene-for-gene model;
- race-nonspecific, multiple-gene partial-type resistance expressed largely or entirely in adult plants, and in response to high temperatures, also known as high-temperature, adult-plant resistance.

Race-specific, single-gene immunity is readily defeated by the pathogen, with the result that each new gene deployed in a new variety selects eventually, and sometimes quickly, for a new race of the pathogen. Approximately ninety races of the stripe-rust pathogen now exist whereas only one was known in the 1960s (X.M. Chen, personal communication). Nevertheless, through a combination of varieties with high-temperature adult-plant resistance, the use of several sources of single-gene resistance in isolines mixed to provide a multi-line (*e.g.*, the multi-line 'Crew') and deployment of combinations of single genes as stacked genes, stripe rust remains largely under control through plant breeding (Line, 2002). This is one of many success stories worldwide of a plant disease managed by host-plant resistance.

Management of Foot Rot

In the 1970s, Robert Allan, a wheat geneticist then with the Agricultural Research Service, located at Washington State University, obtained a breeding line of wheat developed in France with the *Pch1* gene for resistance to the psuedocercosporella (strawbreaker) foot-rot disease of winter wheat caused by *Psuedocercosporella herpotrichoides* (Jones *et al.*, 1995). This breeding line was a product of an interspecific cross between common wheat and the *Pch1*-donor, *Aegilops ventricosa*, a wild relative (Maia, 1967). After nearly 15 years of research, the variety 'Madsen' was released (Allan *et al.*, 1987) to become the first variety of foot-rot-resistant winter wheat available to growers in the PNW. Within a few years, this variety became the most widely grown winter wheat in the region. It also eliminated the need to treat some 500,000 acres annually for foot rot, providing a cost savings estimated at $40/acre (Jones et al., 1995). This was only the first of several foot-rot-resistant winter-wheat varieties released by PNW plant-breeding programs at Oregon State University, University of Idaho, Washington State University, and the USDA at Pullman. Breeding for resistance to this disease is now done largely by screening seedlings in the laboratory for an endopeptidase gene closely linked to *Pch1* (McMillan *et al.*, 1989), providing one of the first examples of marker-assisted breeding.

Management of Stem Rust of Barley by Genetic Engineering

In 2003, scientists at Washington State University and the University of Minnesota reported the successful transfer of the *Rpg1* gene for resistance to stem rust in barley (caused by *Puccinia graminis* var. *hordei*) to a rust-susceptible variety of barley by genetic engineering, making the latter resistant to stem rust (Hovarth *et al*., 2003). This gene has been used in North America as a source of such resistance in barley for more than 60 years—remarkable durability compared to most sources of resistance based on a single gene. The *Agrobacterium*-mediated transformation system opens the way for updating popular varieties for resistance to rust by direct and precise transfer of *Rpg1*. Moreover, because it has been cloned and its sequence known, the gene itself becomes the marker for marker-assisted breeding.

Ironically, commercial production of a barley variety with the *Rpg1* gene requires approval by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if the gene is introduced by transformation, but not if introduced by conventional breeding. Similarly, based on national organic standards developed by the USDA, a barley variety with *Rpg1* is acceptable for organic production if introduced by conventional plant breeding, but not if introduced by the method used by Hovarth *et al*. (2003). These policies exist in spite of the repeated conclusion from studies and white papers of the National Academy of Sciences (NAS, 1987; 1989; 2000; 2001) that assessment of the risks of any new variety of crop plant should be based on the nature of the variety itself (the product) and not on the modification process.

Herbicide-Tolerant Wheat by Mutagenesis

For the first time, certified seed of herbicide-tolerant varieties of winter wheat were available to PNW growers for the fall seeding in 2003. These varieties have tolerance to the acetolactate synthase (ALS)-inhibiting family of herbicides, a technology owned and patented by BASF as Clearfield® technology. Unlike Roundup tolerance, which involves introduction by plant transformation of a glyphosate-insensitive variation of the gene for production of the enzyme 5-endopyruvylshikimate-3-phosphate (EPSP) synthase, tolerance to the ALS-inhibitory family of herbicides involves the use of mutagensis of the plant's gene for production of ALS. Four Clearfield®-type varieties of winter wheat have been developed thus far by PNW wheat breeders. Of these, three are herbicide-tolerant selections of existing varieties, *i.e*., 'Madsen,' 'Stephens,' and 'Coda,' produced by exposing mutagenized seed to lethal doses of the ALS-inhibiting herbicide imazamox and picking the survivors. The fourth, developed by Oregon State University by conventional breeding and released as 'ORCF-101,' is the product of a three-way cross involving the herbicide-tolerant CV9884 (produced in France by mutagenisis of the French variety 'Fidel') as the donor, and the PNW winter-wheat variety 'Madsen' and a 'Malcom'/

'Stephens' hybrid (Peterson, 2003). These varieties are expected to provide new tools for growers to manage grass weeds that are currently problematic with winter wheat.

Obviously, the economic and environmental risks of pollen-mediated transfer of herbicide tolerance to other varieties or weedy relatives of wheat (*e.g.*, jointed goatgrass), and selection of herbicide-tolerant weeds through overuse of one herbicide, must be monitored and managed, whether resistance is induced by mutagensis or introduced by genetic engineering. On the other hand, societal and consumer concerns, nationally and internationally, over food from genetically modified crops using transformation technologies does not apply to Clearfield® technologies. The market and societal acceptance (or indifference) to Clearfield® genetic modification means that growers, the agrichemical industry, and the PNW wheat industry can concentrate on how to manage herbicide tolerance almost exclusively in the context of the economic and environmental drivers of sustainability.

Management of Root Rot in Barley

Rhizoctonia root rot, the most important root disease affecting direct-seeded wheat and barley in the PNW (Cook, 2001), is caused by *Rhizoctonia solani* AG8 and *R. oryzae* (Paulitz *et al.*, 2002). Both induce root rot also of pea, lentil, chickpea, canola, yellow mustard, and safflower, thereby rendering crop rotation ineffective as a method of control. Extensive screening of the gene pools of wheat, barley, and their relatives has failed to produce a useful source of resistance (Neate, 1989; Smith *et al.*, 2002a; 2002b). *Dasapyrum villosum*, a distant relative of wheat, shows evidence of some resistance (Smith *et al.*, 2002b), but, thus far, it has not been possible to transfer it into wheat by conventional methods, including by chromosome substitution and manipulation. Several cultural practices make it possible to reduce the risk of root rot, but even direct-seeded wheat, grown with best management, yields only 80 to 85% of the crop's potential with healthy roots (Cook *et al.*, 2002). The fact that it is delaying the adoption of a better way of farming, that it cannot be controlled by crop rotation, and that there is no useful or accessible source of resistance available for use in conventional breeding makes *Rhizoctonia* root rot a logical candidate for control by genetic engineering.

Transgenic resistance to both species of *Rhizoctonia* has been produced in barley by transfer of the *ThEn42* gene from the fungus *Trichoderma harzianum* (Wu, 2003). This gene encodes an endochitinase that softens the cell walls of the pathogens. Barley was selected as the vehicle for testing this gene because a) it is more susceptible than wheat to *Rhizoctonia* root rot, b) being a diploid, the genetics are less complicated than that of hexaploid wheat, and c) a transformation method is available and in use for barley at Washington State University (Hovarth *et al.*, 2002). Even if not also used in wheat, through genetic engineering of barley, PNW farmers could someday have the first

rotation crop for management of *Rhizoctonia* root rot in direct-seed systems. Of course, achieving the end result of a *Rhizoctonia*-resistant variety of barley for use by PNW growers will be much more expensive and complicated than simply backcrossing the *ThEn42* gene from a transgenic line into an agronomically acceptable line, as done to produce the semi-dwarf 'Gaines,' root-rot-resistant 'Madsen,' and herbicide-tolerant 'ORCF 101' described above. Use of *ThEn42* will also require arrangements and, presumably, compensation for ownership of intellectual property needed to produce the *Rhizoctonia*-resistant barley, and clearance of federal regulatory hurdles will be necessary because the source of resistance is a transgene.

Role of Public-Sector Institutions

Barley resistant to *Rhizoctonia* would greatly facilitate the adoption of direct-seeding and give farmers peace of mind that root rot will not produce the next "wreck" on their farms. However, it is not likely be needed on more than 500,000 acres of PNW farmland. Multinational corporations are unlikely to develop a transgenic technology to control one disease on only a few hundred thousand acres, and small plant-breeding programs are unlikely to have the capital to invest in obtaining the necessary regulatory approvals. Whether 100, 1,000, or 500,000 acres, all represent "minor use," especially for an agronomic crop such as barley. Indeed, "minor use" describes the majority of future and potential applications of biotechnology for disease and pest control by transgenic technologies, as has been the case since the beginning of modern breeding for disease and pest resistance. "Minor use" includes virus-resistant varieties of squash and papaya listed among the eight case studies in commercial use and assessed by NCAFP (Gianessi *et al.*, 2002), but which make up less than 1% of the acreage of transgenic crops (James, 2002).

In 2001, the NCAFP estimated that 950 USDA-funded and land-grant university projects were underway on use of transgenic resistance to insect pests and plant diseases (Silvers, 2001). Moving even one new variety with transgenic resistance into application would be a formidable undertaking for any one land-grant university, considering the costs of regulatory approvals, intellectual property issues, and public education. On the other hand, how else will the benefits of this technology be made available for use in minor crops or minor uses in major crops such as wheat and barley if not with the involvement of public-sector institutions? Moreover, what better platform for public education by university extension programs on the risks and benefits of biotechnology to agriculture than with a proposed release of a university-developed transgenic variety? Opportunities for public-sector institutions are unlimited. Opportunities for the private sector are unlimited as well, including partnerships with smaller seed and plant-breeding companies, following the lead of public-sector institutions.

Achieving the vision for public-sector leadership for "minor-use" applications of biotechnology will require teamwork involving the traditional USDA/land-grant university partnership, the professional scientific societies, federal regulatory agencies, state departments of agriculture, environmental groups, the international agricultural research centers, and grower organizations, to name the most obvious potential team members. The formation under leadership of the Rockefeller Foundation of the Public Intellectual Property Resource for Agriculture (PIPRA, www.pipra.org), as a means for public institutions to share or limit the cost of intellectual property for developing new varieties, is a model for what might be done to share safety data and limit the costs of federal regulatory approvals. The USDA and land-grant university IR-4 project for obtaining data needed to register minor-use pesticides is another model by which promising transgenic technologies could be moved through the testing and regulatory processes for EPA, USDA, and FDA approval.

With the great majority of the costs needed to develop and facilitate the adoption of transgenic crops still largely ahead for both public-sector institutions and private companies, one question specifically in relation to the development of pest- and disease-resistant varieties should remain front and center: what is the appropriate level of additional oversight for pest and disease resistance developed using transgenic technologies compared to pest and disease resistance developed by mutagenisis, chromosome substitution/manipulation, and conventional plant breeding?

As stated above, the National Academy of Sciences and, more recently, a group of seven national academies of science, have espoused the principle that safety considerations for genetically modified crops should be based on the product and not on the modification process. In 1996, eleven United States-based professional scientific societies, representing the plant, soil, microbiological, entomological, and food sciences, challenged the EPA policy to regulate transgenes and their products under FIFRA when the transgenic trait is intended for pest or disease control (IFT, 1996). This *ad hoc* group endorsed the principle of regulating product and not process, and suggested that a strengthened variation on the current land-grant university variety approval and release process would be adequate for most transgenic crop varieties developed for resistance to pests and diseases. A blue-ribbon panel assembled by the Council for Agricultural Science and Technology (CAST) similarly endorsed the principle of regulating product not process, and concluded that regulations of genes and their products as pesticides was inappropriate (CAST, 1998). Dialog among the many and diverse stakeholders on this issue must continue, but with the clear goal to deregulate those biotechnology applications that, based on the body of scientific evidence, represent no apparent risk to the environment or to people. A technology intended to control one disease or pest of one crop, and a minor crop at that, cannot justify the high costs of regulation that, so far, are justified based on perception of risk and not on weight of evidence based on science.

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Module I Panel Discussion and Q&A Session

Moderated by Neal Van Alfen
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Davis, CA

Panel Discussion

Eugene Rosa (Washington State University, Pullman, WA): The first question is for Larry Busch. Your presentation was both informed and stimulating, and, as intended, highly provocative. We thank you for it. Unfortunately, it created many more questions than we could ever cover in the time here, but let me throw out at least one. You and I, as social scientists, have been looking at the glass of agricultural biotechnology water—you longer than I—and I have concluded that in the case of the United States the glass is half-full while your presentation could be interpreted as saying the glass is half-empty. In particular, you observe that public resistance to biotechnology can easily be found in the United States, whereas I see the resistance as more sporadic, unorganized, and not widespread, especially in comparison to Europe, where there is clearly a great deal of resistance to these products. What empirical evidence might we look at to resolve our differences over what, in fact, is the current level of public acceptance of, or resistance to, agricultural biotechnology in the United States, and how might we assess those data as trends on the potential for its future adoption?

Lawrence Busch: The long answer is a couple of books in length. The short answer is that National Science Foundation surveys show pretty much a steady concern among about a third of the population over agricultural biotechnology, as compared to about two thirds in Europe. Now, that said, there are enormous variations within those very crude numbers. If the question is: why is that less articulated in the United States than in Europe, the answer is fairly straightforward and has to do with the US governmental system and the fact that we have a presidential system with two parties tends to move all debates towards the center, wherever the center happens to be at that particular point in time, whereas, in most European countries with parliamentary systems, more factions are heard at any given point in time. It has nothing particularly to do with biotechnology. I think this is true across the board for almost all issues.

Karla Chambers (Stahlbush Island Farms, Corvallis, OR): I am not an academic. My husband and I farm and we have a food-processing facility. I recently spent 8 days in Tokyo talking to our customers, and that's the majority of what I do in our business—talking to customers internationally as well as domestically. We sell products throughout the United States and in fourteen export countries. So, my comments reflect that experience—spending thousands of hours with people who buy our food products. I might suggest to both of our speakers that the debate is not about science today. The scientific debate, in many ways, is past. The current discussion I'm having with my customers is on traceability, on isolation, on documentation, on how are we testing our seed corn, how are we testing our finished product, how are we creating buffer zones, and—bottom line—how am I going to guarantee them, my customers, that our products are GMO free and free from any contamination. If you don't have this traceability documentation and this testing program to guarantee them this control, then those markets will move to those players who do. My question: is science putting our US growers in conflict with our international and domestic markets and consumers? Should the scientific community try to influence the market or should the scientific community respond to markets?

James Cook: I would totally agree that the debate has moved beyond science. If you attend a conference of scientists anywhere in the world—Europe, Japan, North America—they will be on a completely different track from what we have here. We're looking at the next breakthroughs, and where science is going from here, with a lot of excitement. As to whether the scientific community should address the markets—I don't know the answer to that, Karla. I'm worried about scientists trying to do other than what they do best, which is to put new knowledge into the marketplace, and that knowledge is being generated as much in Japan as it is in Europe, as it is in North America. Ultimately, this knowledge will become part of the fabric of what society understands. Within the National Academy there is a huge effort looking at K–12 education, which is such a long process. I really don't think we can wait that long. We've got to find a way for the scientific community to be able to communicate better. We have been totally ineffective in getting our message out. Some scientists don't even believe that it is their job to get the message out. I will say this about the Japanese market: from what I understand, it has been more generous on tolerance limits than has the European market. But that tolerance—if a product is to be marketed as GMO free—if there is a carryover product in there, say up to 5%, then even that has to be approved by their regulatory system. A tolerance level does not apply to just any biotech product, but, in fact, to one that's been approved. So, I think there are some possibilities. At the same time, it took Washington State 20 years to begin to market apples in Japan over issues such as the coddling moth, and we may be looking at a similar long-term process with respect to biotech products. I really don't know whether it's the scientist's

job to try to address the marketplace or not, but I certainly feel it's our job to put the best knowledge that there is—not that it's always without flaw, but always double-checking ourselves, and reworking our own data—to make sure that the best possible information is out there for the public to understand.

Busch: We are in agreement that this is not entirely about science. I would go so far as to say that science cannot do anything other than influence the marketplace. When they first invented automobiles, the people in the carriage industry were quite upset. Most of them went out of business. That's the nature of business. That said, it is important to remember that there are always far more problems that scientists can address than there are scientists available to address them. So, questions about public and private policy enter in here in terms of determining which problems people are going to work on, where is funding coming from, and who is going to do the work? Moreover I'd emphasize that even in the decisions on the part of the Japanese to determine that they want low levels, or ideally no, genetically modified organisms in their food supply, obviously that is a scientifically impossible thing to achieve, at least in areas where GM crops are grown. But, even in those areas, science is implicated because science has to design the tests, has to develop the standards, has to determine the sampling procedures, has to determine the reliability and validity of the tests. There's no way to get around it. Science is involved in all these things.

Philip Bereano (University of Washington, Seattle, WA): I'll combine a couple of questions. In September of this year apparently, the Cartagena Protocol on Biosafety will come into effect. It will regulate the international movement of GMOs, including those for food, feed, and processing, among those countries that sign it. The United States will not be a party to the protocol, and, presumably, will be banned by some of its provisions in terms of countries that previously took our exports. The Biosafety Protocol requires for foods a less rigorous procedure than it does for GMOs, but it recognizes, of course, that every sovereign country can decide what is required for non-foods and that's to say risk assessments will be needed. Now in the international negotiations that I've been involved in, such as of the Protocol and the Codex Alimentarius, the US delegation, including scientists, industry, and government types, constantly refer to the US regulatory system as being science-based. Those of us who are students of it and knowledgeable about it, know that this, of course, is not the case. There have been no risk assessments with publicly available information because of FDA's announcement in 1992, at the bequest of the Council on Competitiveness under the first Bush administration, that GM foods would not be regulated because they were "substantially equivalent to non-GM foods." Substantial equivalence is nothing more than the doctrine of analogy. By definition, analogous items are different as well as similar. *A priori* it was said

that the similarities outweighed the differences, without any scientific investigation of any of the GM crops under consideration. So we are heading for a confrontation if one of these countries, 1) insists on doing a risk assessment, 2) asks for the US data. This is from the *Washington Post* 2 days ago. I'll read this and then ask the speakers to comment on it:

> *The FDA reviews biotech foods for safety and the agency's action on a new biotech crop is often characterized in press accounts as approval, but legally it isn't. The FDA operates a voluntary system under which biotech companies decide on their own how to test the safety of their products, submit summaries of their data—not the full data—to the FDA, and win a letter that says, in so many words, that the agency has reviewed the company's conclusion that its new products are safe and has no further questions. In most cases, the data on which the safety conclusion is based remain secret, confidential business information. It is a much less rigorous system than the FDA procedures for reviewing new drugs or food additives, in which the agency will spend months, if not years, going over company claims in detail.*

The role of science in all of this has been a bit of a sham, because the scientists are not disinterested enough to have blown the whistle on this a long time ago. Gunther Stotsky's research was published 5 years after *Bt* corn was commercialized and planted on millions of acres in this country. Is that science? In a rational, scientific, regulatory procedure, I would think—and I'm interested in your comments on it—that Stotsky's work would have been required first and then the agency, on behalf of all of us, would have made a determination on the basis of that sort of research whether the crop should be put out, because they did or did not present a risk to the environment. I believe that a short-term economic interest is driving this whole thing, and the scientists have not had the spine to stand up and blow the whistle on it.

Cook: In the scientific community, we have our own doubts about whether the current regulatory system is, in fact, science-based. We consistently try to put the best science on the table, fully recognizing that what comes out in the way of policy can be reflective of the politics as much as of the actual science. Now, in terms of whether we are doing the best job we can to understand potential risks to human health or to the environment, reflecting on Gunther Stotsky's work—which I think is really where this question is going—we have followed the same procedures that we have always followed, only with much more rigor since transgenics came on line. For example, we have in use today in North America wheat varieties with genes for resistance to Russian wheat aphid, genes expressed for resistance to Hessian fly, and genes expressed for resistance to green bug. What are the effects of those genes on non-target organisms? Has anybody looked? Was there a reason to look before the varieties were released,

in this case by land-grant universities? Should we have looked at the root exudates of those varieties to see what they are doing to non-target organisms? It comes back to Larry's comment: a tremendous amount of research can be done, and we can hold this technology up indefinitely. Every new variety that has been released by Washington State University ultimately revealed its weakness after it was scaled up. If it revealed any weakness before it was scaled up it was usually pulled unless there was some really important reason to push forward. The same questions could be asked about orange juice: whoever proved that it was safe? What clinical trials were done to establish its safety? If orange juice is safe coming from a tree without the citrus-canker gene would it still be safe it if came from a tree with the citrus-canker-resistance gene? The substantial equivalence model has argued that, in fact, the changes are so slight relative to what we've done all along with conventional breeding, where you can create all kinds of variation in anything you want to measure, but it is hardly worth the expense although certainly the questions can be raised. Now, I believe that, with respect to transgenic crops, there has been more intensive measurements of things that I never imagined we would have to measure—hundreds of proteins between the transgenic crop and its corresponding, non-modified, counterpart. And it's true that a lot of this is confidential business information, and I think that's unfortunate in the sense that more of it cannot be put into the public domain. I would be delighted to see it in the public domain. The National Academy of Sciences is looking at ways to bring some of it into the public domain in the same way that they publish treatises on nutritional values of feeds and so forth. But, the questions that have been raised—and there is no limit to these questions—continually fall back to the standards from which we have worked for many years. The *Pch1* gene that was put into wheat: what would it do if it were transferred to the goat-grass population? What if Orville Vogel's *Rht2* gene had transferred to the goat-grass population? Would this goat-grass have made more seeds, making it a bigger weed problem? These are issues that were not addressed, although they could have been addressed. They are being addressed with transgenics, but are still not being addressed with conventional cultivars, which we assume are safe because of years and years of experience with them.

Busch: Let me add a minor point. It seems to me that one of the problems we have right now with the regulatory system is that, even when we do careful risk analyses, we ask scientists to do things that they don't have any special competence to do. First, we ask scientists to determine what the risk is given what are probably relatively incomplete data. That's fair, because we need to know it now. We can't wait until all the data are in. But we also then ask the scientists to tell us whether that is a risk worth taking, and scientists have absolutely no special competency to answer that question. That's an ethical question, to which every single person has an equal ability to come up with an

answer—something has to be publicly negotiated. We do science a disservice when we have scientists trying to answer the ethical question and making a claim that somehow the question of whether a particular risk is worth taking is a scientific claim.

Rosa: It is now a truism in the risk literature, which is large and growing, that perceptions about risks and the willingness to incur risks are shaped as much, in some cases even more, by the qualitative features of risk than by the objective "probabilities" of undesirable outcomes. So, for example, people get quite concerned about voluntariness control, scientific knowledge, and a whole variety of issues. One such qualitative feature, the feature that is essentially of concern to people, is not so much the risk itself but who is managing the risk and, in fact, can that institution or organization be trusted. In fact, I would argue that your example, Larry, of the success of the pharmaceuticals compared to transgenics would be, in part, a function of the trust that is embedded in the medical profession, pharmaceuticals, and so forth. To what extent do you perceive that resistance to agricultural biotechnology is a function of mistrust of the institutions, and other actors and stakeholders in this scientific application, and to what extent do you see mechanisms for reversing that mistrust? By the way, as an add-on issue—I think it's quite important—a frequent solution of these problems that occurs, and I'm sure Phil will tell you the same, over and over again in technological controversies, is the answer: educate the public. The risk information that I've just given typically argues against that. It tells us that that's a fairly typically, somewhat superficial and unrealistic solution to the problem, that the problem is much deeper and has much more complicated features to it than simply getting people information or education. And the expectation is a normative one, that once they have this information they will adjust their attitudes and their perceptions to be in line with what the scientific information is.

Busch: Your question is hardly an easy one. It's a tough one. Let me see if I can at least frame an answer, which I would be happy with. It seems to me, first of all, that a key issue in terms of doing any kind of risk assessment is defining what the risk is, and that is only partially a scientific issue. In fact the issue that you raised a few moments ago about how we do certain kinds of things for transgenics and we don't do them for crops produced through conventional plant breeding is a good example of how, in the one instance, there has been a desire to frame these things in one way and in another instance to frame them quite differently. That said, of course we know that through conventional breeding we can produce instances in which toxicity to humans or environmental problems could emerge. There are examples out there. If my memory is correct, a potato plant was developed about 10 years ago that luckily never made it to the market place because the breeder himself decided to try some

and got sick. So the point is: the question of how the risk is framed in the first place is critical, and I think the problem we have here, from at least the skeptical public's point of view, is that we don't fully know how to frame risks that have to do with transgenic crops. We haven't come up with a good way of doing that. In turn then, shall we say, there's a kind of bouncing back to the question about crops in general. Are there kinds of things we ought to know? Other kinds of environmental questions? Other kinds of food-safety questions? Now, all that said, I don't see anybody out there, in either the public or the private sector, who is deliberately trying to produce something that is unsafe or will create environmental problems. I think we can, for the most part, argue that if those things occur they are the result of accidents or stupidity, or trying to move so fast that you make a fool of yourself. But it all does come back to the trust issue that Gene raised, and I think he's absolutely right. The US public, for the most part, trusts the FDA when it comes to doing tests on pharmaceutical products. We are comfortable with that. Even though the FDA has occasionally made mistakes, it has had relatively little effect on the public trust. I'll come back to the point about labeling that I made earlier. Part of the issue here is if you say "trust us, we won't even tell you if it's there," it seems to me you are asking for trouble. You are creating a situation which produces distrust. After all, I know these folks want to sell something to me. They want me to buy it, but they're not going to tell me what it is. That's a very problematic situation.

Van Alfen: Could we have some short questions and short answers, and then we'll turn this over to the audience?

Chambers: The last five investments we have made in our farming operation have been electronic and technological in nature: GPS satellite tractors, aids that will improve our efficiency of harvest of strawberries about 200%, and automated cultivators. Is it possible that we are missing or overlooking possibly the next revolution? The focus today is biotechnology where we substitute chemical inputs into the plant rather than application to the plant in many instances. Might a more powerful consumer-friendly tradeoff be technological and electronic substitution rather than chemical input? Let me ask specifically: pattern-recognition technology in exchange for herbicides could be enormously powerful in our daily farming operation and we are very close to making that happen. Would either of you have a comment on that?

Cook: I think these technologies are tremendous. And, as I tried to indicate at the beginning of my talk, many emerging technologies are coming together to improve the farm operation. The electronic technologies are emerging very fast, weed recognition for example. If any one of the three drivers—economics, environmental or social—fails, then a new technology will not be adopted. Could a wheat farmer afford it? Right now maybe not. But I think we are going

to need all of these. Those of us who work on the systems end and in production agriculture are constantly looking for the best combinations of tools, and if they, in fact, get the job done, then that will mean that genetic approaches in some cases will simply be redundant or irrelevant. But, I think we are going to need them all. We have a lot of crops. We have a lot of diseases and I would qualify what you said about making a plant produce its own chemical. There are compatibility aspects to deal with when we talk about rust resistance and so forth. Yes, they come down to chemicals. Our own bodies are making chemicals in our defense against pathogens, but we think of these more as compatible/incompatible than we do the pesticide made by the plant to stop the pathogen. Just wanted to clarify that.

Busch: The blueberry industry has a major problem in Michigan with the Japanese beetle. There's no food-safety problem here, of course, because beetles are totally edible. In fact they provide a nice source of protein apparently, but most people just don't like to eat beetles. One of the results is the development of photo-optical sorters that every blueberry passes through, which can guarantee that the industry has something close to completely zero tolerance for Japanese beetles. It's all a matter of electronics.

Bereano: Larry, the thrust of your remarks was summarized in the statement "it need not have been this way," and I want to focus on that and challenge it, because I think that statement ignores the realities of monopoly capitalism in the current era. Tomorrow morning when the FCC announces rules that further consolidate media control and ownership in yet a fewer number of hands, I think we'll see that the story of Monsanto going to the Reagan administration was not an aberration. It was in fact a paradigm. A paradigm of what is behind this whole technology as short-run corporate-driven. Your chart, which had your sweepers, had the consumers at the end; there was no consumer demand, in my understanding, driving this technology. This was a technology looking to create consumer demand and I would say the same to Jim who had something near the end of his talk about demands of consumers. At the UN Sustainable Development Summit in Africa, I was debating US Agency for International Development Assistant Administrator Emmy Simmons about food aid to African countries and their refusal to take the genetically engineered maze. It was a heated debate, as people might be able to imagine, which continued after the cameras stopped rolling. Simmons said to me, virtually wagging her finger under my nose, "What you don't understand is that in 4 years we will have gotten South Africa to plant enough genetically engineered crops that the pollen will have contaminated the whole continent." It's a corporate strategy. It's not adventitious contamination, it's intentional. It's a corporate strategy that the government is in cahoots with. This whole idea of feeding the world using genetically engineered crops is yet another way to contaminate the ancient land

races and we are complicit in it. It's clear that, to those of us who study world hunger and work with peasant organizations, genetic engineering is not needed to feed the world because, in our own country where we have enormous excesses of crops, engineered and not engineered, we have millions of hungry people. Hunger is clearly a function of economics, of politics, and social factors. Genetically engineered crops are patented, which makes them even more an issue of corporate control. I think that this technology and this kind of scientific pure view of this technology is fundamentally naïve. In reality, it is a corporate-driven mechanism to increase control and profitability by a relatively small number of people using techniques, like appeals to public sympathy to feed the world, as a way to foster their control over the food supply. And I think that it "need not have been this way." It need not have been this way if people organized against it, but I'd like you to comment on that because I think that that's the way the world is working these days.

Busch: Well, as you say, it need not have been this way if people had organized against it. I agree of course. That's precisely the point that I wanted to make. I agree with you that the issue of hunger is largely an economic question especially in the short run. In the longer run perhaps one can make a case for increased productivity and production, but, certainly in the short run, the issue has got nothing to do with that. In fact, just a brief footnote to this: about 5 or 6 years ago I was wandering around in Mali as a part of an evaluation team of INTSORMIL, the sorghum millet collaborative research support program funded by the US Agency for International Development. I came across a farmer who had planted some new improved sorghum seeds, and he had them right alongside the ones that were not improved and the difference was astounding: two or three times as much sorghum seed on the plants. I said, "What do you think of these?" And he said, "This is absolutely fantastic seed." I said. "Well, would you buy these if you had to?" He said, "Oh of course not." And all the people who were there were shocked, because this guy was supposed to have said, "Yes of course." And I said, "Well why not?" He said, "Because there's no place to sell the surplus." And the reason there was no place to sell the surplus was because of US and European farm subsidies. It was far cheaper to buy wheat in the capital city of Bamako than it was to buy sorghum produced locally. So, these problems are exceedingly complex. They are a combination of, shall we say, corporate and government policy, and I believe they are not going to change rapidly. On the other hand, it need not have been that way.

Cook: First of all, it's interesting that neither Larry nor I mentioned this technology as a means to feed the world, although I think—

Bereano: That's why I brought it up, Jim.

Cook: It usually raises a red flag and it diverts the discussion. I would say that, with respect to the minor-use application that I got into, this, in itself, can make a huge difference in developing countries as is already happening with virus-resistant sweet potatoes, and so forth. But, let me back up and make another comment. I do not accept that the biotech companies and their monopolies are deliberately trying to spread pollen around. Every time we put a new variety of corn out, a new hybrid, its pollen has moved around whether from the land-grant university way back in the early days, or the hybrid seed from Pioneer or Syngenta or whoever. That pollen is going to move because it is just a natural thing. One more point: this technology has enormous potential. You can tell by my enthusiasm for it. I would say that whatever we would want to raise in the way of questions about transgenics we could just as well raise them with respect to conventionally bred cultivars. And I would also say that, if this issue is about corporate monopoly, how come it was so easy for McDonalds to get that NewLeaf™ potato back on the shelf at Monsanto? It showed that Monsanto was absolutely helpless against McDonalds and Frito-Lay, and that corporate control over farmers is not what we think it is. I might also add that the real down-in-the-trenches battle that's going on within corporations is over market share, but if you look at some of the business reports that have come back and who is making money, companies that continue to depend entirely on a pesticide market for their products are, in fact, showing little or no margin of profit, whereas those that have moved into biotechnology—although I agree that things are a bit more shaky right now—were, in fact, the ones that were making a profit. The real battle that's going on is among the multinationals in the marketplace. When Monsanto takes over 70% of the acreage on soybeans all the companies that did have a share in that market making herbicides suddenly are letting their employees go and are scaling back on their R&D. But if somebody said, like McDonalds, we're not going to take those soybeans, that'd be the end of it, the same way it was with potatoes. So, there are many checks and balances in this system.

Q&A

David Schmidt (International Food Informational Council, Washington, DC): My question is for Dr. Busch regarding the survey question on labeling. You may know that our organization has commissioned eight surveys since 1997, approaching the labeling issue differently from the survey you cited. I don't think you cited the source, but I've seen similar data quoted. I'm going to describe how we go about it and then ask whether the survey you cited gives consumers enough context to elicit intelligent responses. In our most recent survey, in early April 2003, we asked the question, "Is there any information not currently included on food labels that you'd like to see added?" Some

75% of Americans could not think of anything. Others, about 7%, said, "Ingredients, nutrition information." About 1 or 2% mentioned anything related to biotechnology. Later in the survey we actually described the FDA labeling policy, which explains no special labeling is required unless there is a change in the products composition, *etc*., and found that 62% of Americans supported the current policy. My question is: does a question about labeling, "should genetically modified foods be labeled" give enough context for consumers? In this case you cited, I think, 92% answering in the positive.

Busch: First of all, let me say that the survey I was referring to is one that is on a website at North Carolina State University, Wimberley is the first author and about thirty people were involved. It is my understanding that, yes, it did provide some context. But, I think all surveys should be taken with the "lies, damn lies, and statistics" approach. Certainly the way in which you frame a question is going to affect the answers. On the other hand, plenty of other surveys have given similar results to those of Wimberley's study. Certainly, how a question is framed is critical.

Brewster Kneen (the Ram's Horn, Sorrento, BC): I would like to raise a concern in the form of a question. This discussion so far, and its framing—the whole event—is focused entirely on industrial production agriculture, essentially on monoculture. I am concerned, Professor Cook, at the emphasis on the scientific community as a monoculture. You speak of "we in the scientific community" as if there were only one science and only one scientific community. As I look around the room, I think that this is a very North American grouping here. What about the rest of the world? What about other ways of knowing? There is more than one science. I cannot accept that there is *a* scientific community. I think one of the problems that we face, here, is understanding that we do not represent the world's people. We represent an elite and a small minority of the global population who do not now, and I don't think ever will, feed themselves with industrial agriculture or biotechnology, or GPS or any of these other things, because our system is not affordable. It's not affordable for us and it's not affordable for the world. Do you really think that there is only *a* science and that we have all the answers or will have in due course?

Cook: Well, of course not. There is a scientific community and huge debates go on all the time within it. It's interesting to look at the differences between where science is within this spectrum and where society is in terms of beliefs or expectations *vis-à-vis* the origin of life, human cloning, global warming, reproductive biology and so forth. This is where I was heading when I said there's science and then there's politics, which reflects the perceptions of lots of people and ethics and on and on, and policy comes out as a balance of those two, and I fully accept that policy will not be driven only by science. Now, as

far as developing countries are concerned, I quoted Clive James, who in the 2002 ISAAA report indicated that the majority of farmers growing *Bt* crops operate smallholdings—in China, India, Egypt, and so forth. The beauty of some of these technologies is that a single gene can be put into a popular local variety like "Meekers" raspberry to keep it healthy in the context of how local farmers prefer to grow it. Industrial agriculture has its own baggage. Personally, I don't think, even in eastern Washington state, I'm working in what would be called industrial agriculture. You might call it that, but I'm working with family farm businesses that are large in order to stay in business. As I go around the world, farmers ask the same question: "How can I control this disease? I did everything right and still got it." That's where the genetic approach—including through the international centers—has been able to deliver solutions to these problems case by case, one by one, to the benefit of local farmers. So, if I gave the impression that all scientists are of a like mind, believe me that is not what I intended. The scientific community is debating within itself on all of the issues I just mentioned, but making progress all the time. At one time there was disagreement as to whether the sun went around the earth or the earth went around the sun. Society believed one thing, Galileo and his followers believed something else, and it took a long time before the two came together. We don't even think about that any more. We have to allow all of this discussion and all of the process to work. I am not here to say we should speed this thing up and short circuit it. We must allow the process to work. Everybody in this room has a legitimate stake in this issue and has the right to be heard.

Gabrielle Roesch (Western Washington University, Bellingham, WA): My question has to do with what was said in terms of not knowing how to fully frame the risks associated with biotechnology. If we are not aware of how to frame the social, environmental, cultural, political, or economic risks, I'm curious as to how we can justify continuing at full force to commercialize more and more biotech crops and to spread the technology throughout the world.

Busch: If you look at how all risk questions are framed, both science and politics are involved. We have probably jumped ahead of the game on biotech crops, in the sense of not checking certain environmental risks out more carefully. That's my personal view. Others will disagree. But, you can see the same problem even in areas that are well established. For example, the United States and France test cheese for *Listeria* and the US bans unpasteurized cheeses that are less than, if my memory is correct, 60 days old. In contrast, France does not. Now the data are the same, and one of the interesting ironies is that more cases of listeriosis are associated with US cheese than with French cheese on a *per capita* consumption basis. The risk is relatively well framed, the data are not really in dispute, yet the public policies differ radically. Although there is no such thing as a risk-free world, one has to be careful with technologies

that are radically new, and it seems to me that some of the biotechnologies *are* radically new, others are not.

Cook: I haven't thought much about the science of risk assessment, which is where the question is coming from. Within the US regulatory system, the USDA has oversight to assess environmental risks and fill in the blanks. If a gene intended for pest control is moved from one barley to another by genetic engineering, EPA has to ultimately approve that variety for commercial use. The FDA would look at that barley and say, "Well it's still barley and it's still the same gene that was previously moved by a traditional method, so we will not go any further, we will say that it is substantially equivalent." Thomas Edison had to go up against the gas industry in order to introduce the light bulb. Could we have projected that his light bulb would have led to huge demands for electrical energy including coal-fired plants that dump carbon dioxide in the atmosphere, dams on our rivers that would affect salmon, and nuclear power plants that would carry all kinds of risks? Would you vote today that we not go forward with electricity based on what you know in hindsight? And we can go over and over this with the airplane, with the automobile, with manufacturing, with recycling of wastes. Agriculture has done a tremendous job in providing a safe food supply for the American people, moving evermore into environmentally-friendly methods of production, and, yes, you can always look ahead and say, "But, you didn't answer this question." Where do we draw the line? Let's go forward. A tremendous amount of work was done before we began to move into the field. I served with Europeans, North Americans, Australians and Japanese on a task forces that looked at the science that countries would use to develop their own regulations. We had a tremendous amount of debate on this, but, in the end, we said, "It's time to scale up. We've got the bases covered." Yes, there will be questions. I don't think you should worry that much about framing all of the risks because we've done everything we can and the benefits are just so great that it's time that we try it.

Elliott Peacock (University of Washington, Seattle, WA): You showed impressive data and pictures of substantially improved crops and it makes a lot of sense to apply biotechnology to agriculture from an economic standpoint. But we live in a democracy and this technology will affect different people in different ways, not just in this country but also in the world at large. What political, social and cultural considerations should be part of the decision-making process? Who should be involved in that decision-making—is it part of our responsibility?

Busch: Do you want the 2-hour answer or just the 30-minute? The industrial democracies of the world have failed to democratize science and technology. We have assumed that science and technology are essentially ethically neutral with respect to the rest of the world and, therefore, are not subjects of concern for

democratic governments. I would argue that we need to address that. I would argue that NABC haltingly moves in that direction. I suspect that Ralph Hardy would agree with me. But we have not come up with satisfactory means for dealing with technological changes that have sweeping distributive effects and that might infringe on the rights and obligations of various citizens. I think this is a critical issue and it's one we have tended to try to brush under the rug. For a variety of reasons, biotechnology is one of a few areas in which there has been a lot of noise, yet we have still not come up with some good mechanisms, and I'm talking here about organizations and institutions to allow us to adequately address those questions.

Cook: We are using the terms "science" and "technology" interchangeably. Science says, "Hey, it's the earth that goes around the sun. Genes do this. The human genetic code is that." Technology then takes advantage of knowledge to develop new tools, like the light bulb and electronics and, of course, genetically modified crops. Each new technology carries with it a certain amount of resistance because someone is adversely affected by it. The internal combustion engine had a huge impact on the horse-carriage industry, for example. Biotechnology brings with it many changes. Providers of fungicides right here in the northwest may go out of business or have to find new ways to make a living. That is how technology leads to change. But science is the knowledge base that we should all embrace to bring the eyes and ears of society to how things work in nature.

Busch: I would argue precisely the opposite—that a distinction between science and technology is no longer tenable. Any distinction is more conceptual than practical. If research geneticists were totally disconnected from the people who actually applied the genetics then the position you took would be correct. But, they are not disinterested. The scientists are involved in a variety of ways—from being part owners of companies to receiving grants from companies to wanting to make a difference. It's perfectly reasonable for someone such as yourself to want to make a difference in agriculture. I presume that's one of the motivations that got you into science in the first place. So, it seems to me that a sharp distinction between science and technology simply doesn't exist.

Cook: But, there still is a distinction. You are right that they are blending, but more so in medicine than in agriculture. Yet we have great comfort with medicine and not with agriculture.

Cathleen Kneen (The Ram's Horn, Sorrento, BC): My question follows from Brewster's. Dr. Busch, I suspect I was not the only person who felt a little uncomfortable at the slide you showed on the dissemination model with an arrow going in one direction. That doesn't describe my understanding of where

innovation in agriculture comes from nor, in fact, does it describe my understanding of the appropriate relationship between the farmer and the scientist. I'd like to have you comment on that. I assume that this was a slip of the tongue or a slip of the pen on your part and that, in fact, you would agree that that doesn't describe the model accurately. If not, could you say a few words about how then you approach genetic engineering, which itself is clearly not something that has been developed by farmers working in the fields, to try, as they have for millennia, to deal in a creative and sustainable way with the challenges that Mother Nature throws in their faces.

Busch: There are two separate—maybe not entirely separate—questions there. First, of course, I was not arguing in favor of that diffusion model. I was simply saying that many people believe that it is a very nice unidirectional model. In fairness to some of the people who have worked on this, there is often an arrow going in the other direction, usually labeled feedback, which is an interesting term since in engineering it usually means "squeal." I wear hearing aids, and every so often I get feedback and it's not something that I want. The problem, and in fact the reason that the term feedback is used in that model is because it's a one-way communication. It's, "Here, I have this particular thing, do you like it? Oh you don't, I'll try again. I have this thing do you like that? Oh, you don't." And you keep working until you find the thing that somebody wants. It's a very, very inefficient means of innovation. That said, let me move to the second part of your question. Innovation can originate at any part of the supply chain. Look at the invention of frozen foods, which are enormously convenient. You could argue, certainly, that fresh foods are better than frozen ones and I wouldn't disagree. But I would probably argue that frozen ones taste better than canned ones and so on down the line. The point is, innovation and invention can occur at any point in the supply chain between the input supplier and the producer. What I think has happened to agriculture over the last couple of hundred years, with both positives and negatives, is that things that used to take place on the farm now take place elsewhere and a lot of things that used to be farm-based processes are now industrial processes. A group of geographers in California, Goodman, Sorj and Wilkinson, wrote a book on this and argued that two things have been going on: substitution on one hand—we substitute say margarine for butter—and appropriation on the other—instead of producing butter on the farm we produce it in a dairy. We live in a highly industrial society and are probably going to wind up with a wide range of ways in which products move between producers and consumers. I'm not sure I like all of them, but that's partially in the nature of the beast. Now this comes back to the point that Phil Bereano raised earlier about corporate control. Actually, I would argue that, if there is concern about corporate control, it should be focused at the downstream end in terms of the shift in power in the food system away from input suppliers and processors to supermarket chains. As I

mentioned, three supermarket chains now dominate worldwide, Wal-Mart, Carrefour and Ahold. It is interesting, however , that the nice simple suggestion that these are three evil giants actually tends not to make much sense. When you look at what is going on, you discover that these three giants are sensitive to all sorts of issues having to do with the public, and they trip over each other in many, many ways, Wal-Mart perhaps less so than Carrefour and Ahold. But, they trip over each other in many ways in order to respond to rather slight shifts in the public's view of them, because they are paranoid that they are going to lose one or two percent of their market share. So, I'm not sure I know where this is going. I do know that it's definitely not the world of 50 years ago or certainly not the world of 100 years ago.

John Browne (Judd Creek Nursery, Burton, WA): I'm a local horticulturist. I figured that in a room full of scientists I might get an answer to, "At what proximity to Washington DC does politics trump science?" But I haven't heard it yet. I heard earlier redundant, irrelevant systems mentioned and I was thinking that they will maybe go away. I also remember technologies that we developed that we didn't use. I was in high school when Atoms for Peace, in the Eisenhower years, was proposed as a super way of excavating. In any event, if scientists don't bear the burden of ethical decisions and one doesn't choose to leave it to politicians, isn't it paramount that as much truth in labeling as possible be provided to the ultimate consumer so that we can make our own ethical decisions? What you are dealing with isn't simply something that affects the genus and species that is providing it, but a wealth of other organisms that actually have no political base. Some of them may have an economic base, but that's in the eye of the beholder.

Van Alfen: Do you have a question?

Browne: That's it.

Cook: I'm not sure what the question was. It would be uncharitable to leave this room today thinking that scientists aren't conscientious about what's going to be done with the knowledge base that they put in place. In fact, they are constantly in a checks-and-balance system within the scientific community through the peer-review process and so forth. At what distance from Washington DC does politics trump science? Well it happens a lot. But, we in the scientific community understand that we put the best science out knowing that it's not perfect but it's as far as we've gone, and then the policies are decided, whether it be on human cloning, reproductive cloning, whether it be on global warming issues, or what have you, including GM foods. Society has a huge stake in this and society has called the shots over and over again—not science. We put the best knowledge out there. A lot of times we more thoroughly

explain something that was already accepted but nobody knew how it worked, which results in the development of new applications.

Eric Sachs (Monsanto Company, St. Louis, MO): A lot of what we have been talking about today is perception versus reality. I'm hearing a lot about concerns from the speakers. I'm hearing concerns from some that have come to this microphone. What are the sources of these concerns and should we stop moving forward. Should we address those concerns and, if so, how?

Cook: Absolutely, we need to address the concerns and they are legitimate concerns. Things are moving fast and it is a little scary. I can understand that. There are other areas of my life where things are moving fast that I don't understand, and I might be in the same boat that some of you are here asking me as a scientist to comment. Where I do get frustrated is when I run into misinformation like, "They're putting chicken genes into my wheat." That's not an exact example, but you've heard similar statements. The human genome initiative has revealed that we humans already have about 250 microbe genes in our genetic code. We've worked really hard to address concerns over safety. One issue had to do with, "Well you're going to put this antibiotic resistance gene into my food," so we took that marker system out of the tool box. I could give other examples of where the scientific community has backed away from something. We said, "Would you accept it if we did this?" To which some said, "You don't understand. We just don't want it." How do we go forward from that? I believe we have to go forward and we have to listen to concerns. There are huge social concerns, most of which are in terms of, "How will this affect me personally?" I had a person say to me, "I wouldn't mind having my dog genetically engineered if I could win a championship with him." That's a true example. And I thought, "Yeah, it's got to come down to personal benefits." I believe, though, that most of the public would be supportive of farmers doing things that are making their life easier, making it easier to combine their corn, giving them more time with their families. I believe that society would accept that. For the most part, agriculture has got a dirty name. How did that happen? And genetic engineering is getting caught up in that baggage. We have a huge job to do, and most of my colleagues don't even think it's their job because they are so busy writing their proposals and teaching their courses. I think we can all relate to that. But you raise a very good question. We have to go forward. If we stop—and I know there are people in this room who think we are just going to stop—we're not even going to let WSU move that gene from one barley to another by the engineering method because it's just downhill from there. I hope the rest of this meeting will give us more information on how to answer that question.

Module II

Sustainability, Environmental, and Production Issues

Moderator: Terri Lomax

Technologies for a Sustainable Future: Therapeutic Intervention Versus Restructuring the System[1]

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> *The real problem of food production occurs within a complex, mutually influential relationship of soil, plants, animals, and people. A real solution to that problem will therefore be ecologically, agriculturally, and culturally healthful . . . a bad solution solves for a single purpose or goal, such as increased production. And it is typical of such solutions that they achieve stupendous increases in production at exorbitant biological and social costs.*
>
> —Wendell Berry

> *I had a strange feeling that a paradigm deeply embedded in modern biology was being chipped away at, and bits and pieces of an earlier paradigm were being revived.*
>
> —Harold Morowitz

As we enter the twenty-first century, we face at least seven major challenges that are likely to transform agriculture on this planet. Population growth, persistent poverty, energy needs, environmental degradation, food security, climate change, and an unprecedented explosion of infectious diseases all will likely force us to rethink the assumptions about food and agriculture that we have taken for granted for at least 50 years.

The United Nations estimates that the world's population, now more than 6 billion, will increase to 9.3 billion by the year 2050. Furthermore, the additional 3.2 billion people will be born in the developing world, many in poor rural areas. Seventy-two percent of the world's poorest people now live in rural communities (Brown, 2001).

[1]Portions of this paper were presented at the Iowa State University Department of Agronomy Baker Council annual meeting, March 25, 2003.

Currently, 1 billion of the world's population live on less than $1 a day and an additional 1.6 billion live on less than $2 a day. The number of people living in poverty increased by 100 million during the past decade and the United Nations predicts that another 100 million people will live in poverty by the year 2015 (Lee, 2002).

As population grows and poverty persists, the natural resources that have fueled the production increases of the past 50 years are in a state of decline. Industrialized agriculture, which enabled us to double and triple the yields of cereal grains, is largely fossil-fuel driven. Crop inputs, the manufacture of farm equipment, traction fuel, and the breeding of crop varieties that are responsive to chemical inputs and irrigation are all highly dependent on fossil-fuel energy. As fossil-fuel resources decrease, and, therefore, become more costly, this mode of production will become increasingly difficult to sustain.

At the same time that the natural resources that fueled industrial agriculture are declining, the natural sinks that absorbed the accompanying agricultural wastes are filling up. There are now fifty-three hypoxic zones on the planet, all of them related to watersheds that support industrial agriculture. Hypoxic zones are not isolated aberrations, but visible indicators of the larger environmental degradation that is inherent in industrial agriculture systems.

Masae Shiyomi and Hiroshi Koizumi have, in fact, argued that the combination of the decline of fossil fuels, and the increased environmental degradation caused, in part, by fossil-fuel-based agriculture, will necessarily *force* agriculture to change in the decades ahead, and they suggest that a shift toward an ecologically based agriculture may well pose the most viable alternative for the future (Shiyomi and Koizumi, 2001):

> *The present system of agriculture, which depends on consumption of tremendous quantities of fossil-fuel energy, is now being forced to change to a system in which interactions between organisms and the environment are properly used. There are two reasons for this transformation. The first is the depletion of readily available fossil-fuel resources. The second is that consumption of fossil fuels has induced deterioration of the environment. Is it possible to replace current technologies based on fossil energy with proper interactions operating between crops/livestock and other organisms to enhance agricultural production? If the answer is yes, then modern agriculture, which uses only the simplest biotic responses, can be transformed into an alternative system, in which the use of complex biotic interactions becomes the key technology.*

A fifth challenge facing agriculture is the increased interest in recognizing food as a basic human right. Not only is the world evolving into a global economy, but it is becoming a global civic society as well. Such a society carries with it increased awareness that a stable global community can be achieved

only if all its inhabitants are food-secure. Securing food as a basic right for all of the planet's citizens, therefore, presents an additional challenge that global agriculture must face in the decades ahead.

The precise role that climate change will play in agriculture's future is not yet certain, but indicators suggest some formidable challenges. A recent report from the Soil and Water Conservation Society focused on just one climatic variable: precipitation. The study indicated that anticipated increases in precipitation due to climate change, together with the likelihood of more violent storms, "heighten the risk of soil erosion, runoff, and related environmental and ecological damages" (Soil and Water Conservation Society, 2003).

A recent Iowa State University study revealed similar concerns. Computer modeling suggested that the upper Mississippi River basin (UMRB) is likely to see significant increases in precipitation by 2050. The "model system produced an increase in future-scenario climate precipitation of 21% with a resulting 18% increase in snowfall, 51% increase in surface runoff, 43% increase in recharge, and 50% increase in total water yield in the UMRB" (Jha *et al.*, 2003). It is unlikely that Iowans will be able to continue growing massive quantities of annual crops such as corn and soybeans under these circumstances.

Finally, the unprecedented explosion of more than thirty-five new infectious diseases in the past 30 years presents agriculture with yet another challenge. The Institute of Medicine, a research arm of the federal government, recently convened a panel of scientists to discuss why this outbreak of infectious disease has taken place. They attributed the phenomenon to thirteen changes, a substantial proportion of which, according to Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, "relate to man's manipulation of ecology" (Borenstein, 2003). Agriculture, of course, has been a major contributor to such ecological manipulations.

The Role of Technology

What kind of agriculture can meet the requirements of an exploding human population in the face of entrenched poverty in a post-fossil-fuel era that must restore the ecological health of the natural resources on which agriculture depends, while the climate is changing, global society insists that food is a human right, and increased infectious diseases require that we attend to the ecological ramifications of human activities?

And a question for this conference is whether or not technology—especially transgenic technologies—can meaningfully address these challenges?

The complexities involved in meeting these challenges are, by now, readily apparent. Simply increasing food production, we know full well, will not solve the problem of hunger. If that were the case there would *be* no hunger today since we already produce enough food to provide the necessary calories for every person on the planet. And even if we were able to invent technologies that could put food in every new person's mouth, how do we address the

problem of providing sufficient quantities of fresh water to support such a population, especially when agriculture currently uses 70% of the planet's freshwater resources? And how do we sufficiently shrink the ecological footprint of each global citizen to prevent further loss of the biodiversity that is so essential to the ecological health of global ecosystems? In his recent book, *Our Final Hour*, Martin Rees, Professor at Cambridge University and Fellow of the Royal Society, suggested that the planet simply could not sustain even our present population if everyone consumed as much as middle class Europeans and North Americans (Rees, 2003).

Furthermore, since populations are exploding primarily in poverty-ridden rural areas of the developing world where farmers live on fragile lands, inventing new technologies that they cannot afford and that do little to address local ecological issues will not serve to solve the problem. As Jeffrey McNeely and Sara Scherr pointed out (McNeely and Scherr, 2003), if…

> *…food is to be accessible to the rural poor, then much of it must be produced where they live, and in ways that increase both their consumption and income. Yet food-producing systems throughout the world are already stressed by eroding soils, declining freshwater reserves, declining fish populations, deforestation, desertification, natural disasters, and global climate change. These and various other factors are making it increasingly difficult to maintain, much less increase, food production in many areas of the world.*

Simply inventing a new technology—whether transgenic or non-transgenic—is not likely to address that multifaceted set of circumstances.

The problem, in other words, is quite complex, therefore, we cannot reasonably expect to solve it simply by introducing a few new technologies to increase the yields of a handful of crops. And we should stop misleading the public into believing that the problem can be solved with such simple technological innovations. Such misrepresentation is immoral even by the most rudimentary ethical standards of any civic society. We should end such deceptive rhetoric *now*!

Does this mean that technology, even transgenic technology, has no role to play in meeting agriculture's future challenges? Of course not.

The question we face is *not* whether we will use technology to help shape the new agriculture required to meet future challenges. Clearly we will. Nor is the pertinent question what *kind* of technology we will use. We likely will use all of the available technologies that hold any promise for developing an agriculture capable of meeting these challenges. The more important question is *how* we will use the technologies available to us.

To determine how best to use technology to meet these challenges, it might be useful to reassess *current* use of technology in agriculture.

Throughout most of the industrial era we have used technologies almost exclusively to perform one-dimensional, single-tactic functions. We developed and applied pesticides to control a target pest. We manufactured and applied fertilizers to replace nutrients. We produced and injected antibiotics to fight disease. It is a methodology that Joe Lewis, pest management specialist with the USDA's Agricultural Research Service, called "therapeutic intervention" (Lewis *et al.*, 1997). This approach uses technology to intervene in a system to alleviate a problem. It almost never uses technology to understand *why* the problem emerged or how inherent strengths within ecosystems could be enhanced to solve the problem. Based on field experience, Lewis argued that the therapeutic intervention approach has failed.

This is not to deny some short-term successes using single-tactic technologies. We dramatically reduced the labor required to produce essential crops. We increased the yields of those crops beyond anyone's expectations. And we made it possible for citizens of the United States to spend less of their disposable income on food than any other nation in the world—only 10% in 2001, according to USDA/ERS estimates.[2]

Ecological Failure

This one-dimensional approach has, however, led to unforeseen consequences that have prevented us from solving some of agriculture's most persistent problems, and it has not prepared us to meet the challenges of the future. Manufacturing and applying nutrients to overcome deficiencies allowed us to ignore the larger issues of deteriorating soil quality and erosion. We are not likely to see many new yield gains in the future without addressing the complex issue of improving soil quality. Good quality soil, in turn, can provide a range of benefits to healthy, resilient production systems while making major contributions to water quality (National Research Council, 1993). Soil erosion not only seriously depletes our ecological capital but, together with excess nutrient application and highly specialized production systems, it fosters nutrient pollution of streams and rivers that eventually contributes to hypoxic zones in major bodies of water, like that in the Gulf of Mexico. Poor-quality soils also require increased irrigation, which further depletes aquifers and increases soil salinity.

Land degradation has reached epic proportions. By some estimates, 36% of the world's cropland is losing topsoil at a rate that is undermining its productivity (Brown, 2001). This does not bode well for meeting the twin challenges of feeding a growing population while reversing environmental degradation.

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[2]One should be cautious about translating the percent of disposable income spent on food into a "cheap food" claim, however. What Americans pay per calorie of food consumed is more than what 95% of the rest of humanity pays according to some estimates. See Charles Benbrook's unpublished manuscript, Principles Governing the Long-Run Risks, Benefits, and Costs of Agricultural Biotechnology (available from the author).

The use of broad-spectrum pesticides to control target pests has similarly failed to acknowledge ecological connections within the system in which the pesticide is applied. The results, once again, yield unintended side effects. As we now well know, pesticides not only kill the target pest, they also harm many beneficial organisms that previously kept other pests in check, creating new pest problems. Since a pesticide never kills all the target pests, those that survive become resistant to the pesticide and produce a new population of hardier pests. In the process, the *source* of the pest problem often is ignored, leaving the system ripe for pest resurgence. Meanwhile, the correlations among soil quality, nutrition, and plant protection remain largely unexplored, and too often the potential human and wildlife health effects of the pesticide are ignored.

Despite these signs of need for change, the culture of one-dimensional approaches to solving production problems continues. In introducing a new generation of technologies (transgenics, robotics and nano-technology), we continue to subscribe to the same paradigm that fueled earlier technologies. Most applications of transgenic technologies, for example, are still intended as single-tactic approaches to problems—designing corn plants to resist the corn borer; designing soybean plants to resist a broad-spectrum herbicide to control weeds; designing pharmaceutical crops to produce specific properties as therapeutic intervention in disease. Lewis *et al.* (1997) argued that since the new transgenic technologies follow a similar blueprint to yesterday's chemical technologies, they are likely to meet with similar constraints. In the process, he argued, they will actually *hamper* our progress toward the development of more ecologically sound strategies:

> *As spectacular and exciting as biotechnology is, its breakthroughs have tended to delay our shift to long-term, ecologically based pest management because the rapid array of new products provide a sense of security just as did synthetic pesticides at the time of their discovery in the 1940s . . . the crops engineered to express toxins of pathogens are simply targeted as replacements for synthetic pesticides and will become ineffective in the same way that pesticides have.*

Lewis's observation is now being corroborated, not only by the appearance of pest resistance to transgenic technologies in the field, but also by a growing awareness among scientists that genetic mechanisms are much more complex than biological determinists previously assumed. Richard Strohman (2002), molecular biologist at the University of California, described the matter succinctly:

> *Molecular biologists have rediscovered the profound complexity of the genotype-phenotype relationship, but are unable to explain it: Something is missing. The missing element was described 35 years ago by Michael Polanyi, who characterized live mechanisms and*

information in DNA as "boundary conditions with a sequence of boundaries above them."

Harold Morowitz (2003), professor of biology and natural philosophy at George Mason University, also acknowledged this complexity and the paradigm shift it portends:

> *[There] is a startling change in the paradigm of genetics following from the dogma of molecular biology. It suggests bionic laws at the level of phenotype and a somewhat noisier background of genes that are required to reify these laws in a not overly precise way. It tends to turn the present paradigm rather on its head . . . All of this suggests the possibility of a substantive change in the paradigm of biology and a reconsideration of how we are spending our research funds.*

This growing awareness within the field of genetics will, as Evelyn Fox Keller (2001) has suggested, "necessitate the introduction of . . . other ways of thinking about biological organization, thereby loosening the grip that genes have had on the imagination of life scientists these many decades." She also states that this "success" will finally teach us the necessary "humility" that will lead us to appreciate, and perhaps honor, the complexity and interdependence of the living systems of which we are a part. In other words, we might begin to take ecology and evolutionary biology seriously in all of our human endeavors. And these new discoveries in the functions of biology and ecology may impose a significant paradigm shift on agricultural research.

It would seem prudent, therefore, on countless ecological fronts, to begin the shift from a one-dimensional strategy to a multi-dimensional systems strategy as the guiding principle of our agricultural research agenda. This shift would lead to the development of systems that focus on "harnessing inherent strengths within ecosystems," as Lewis *et al*. (1997) put it, rather than continuing to invent single-tactic solutions.

All of this suggests that the principal benefit from genetic research for meeting the challenges facing us in agriculture's future may not lie in the invention of specific transgenic technologies that modify plants and animals, but in the discoveries that help us better understand how systems function and, therefore, better utilize the strengths that are inherent in natural ecosystems.

Understanding Networks

Some of the insights garnered from network theory in the past decade or two also may be instructive. While we are, perhaps, still a long way from achieving scientific consensus with respect to the science of networks, one aspect of the theory is gaining widespread acceptance—namely that systems cannot be understood solely in terms of their component parts, and that it is often the "weak links" in a system that hold the key to understanding systems functions (Barabasi, 2002; Buchananan, 2002; Watts, 2003). Some of these findings may

be instructive as we continue to struggle with the question of how to make the best use of new technologies in agriculture.

The practice of reducing a complex phenomenon into simple constituents is, of course, an important and time-honored convention in the scientific enterprise. And such reductionism certainly continues to be an important part of the work of science. The problem is that we often jump to the conclusion that a system can be fully understood in terms of its parts, when in fact it is important to understand *not only the parts but also the interactions between them*. It also may be important to acknowledge, as Mark Buchanan (2002) put it, "that the interactions between the parts of a complex network often lead to global patterns of organization that cannot be traced to the particular parts," and that there is, in fact, a "network architecture" that is the "property not of parts, but of the whole."

Why is this important to the question of how to use technologies in agriculture? It is important in at least two respects. First, if the existing network architectures are the property of the whole rather than of the parts, then we have to begin paying attention to how the network architecture is affected by our technological innovations and not just how component parts respond. In other words, if network architectures exist, we could succeed in increasing the productivity of a component part (a soybean plant, for example), while ignoring the fact that the ecosystem architecture is being affected in ways that are altering the ecosystem's productive capacity.

Isn't that exactly what happened when we increased the yields of wheat and rice by employing the single-tactic strategy of introducing varieties capable of higher yields through the use of fertilizers, pesticides and irrigation, but failed to see that the architecture of productivity was being compromised as a result of soil degradation, increased salinization, depleted aquifers, and compromised biodiversity? Are we paying any more attention to network architecture now as we introduce our new generation of technologies? I don't think so.

Second, if food webs consist of ecological communities that are tied together not only by connections that are obvious—like major predator/prey relationships—but also by many inconspicuous weaker links that go unnoticed, but often provide stability to entire ecosystems, then it might behoove us to use much more caution in introducing technologies that alter the functions of a specific organism.

Buchanan (2002) cited an instructive example. When Atlantic cod populations collapsed due to over-fishing, the Canadian government suggested that hunting expeditions be organized to kill North Atlantic harp seals, which were known to eat cod. The assumption was that by eliminating the seals, the principle cod predator, more cod would survive and, therefore, cod populations would recover. What the Canadian government failed to realize, however, was that the cod/seal relationship was affected by many other less prominent species in the system. Consequently, reducing the number of seals could affect cod

populations in unpredictable ways by virtue of the many relationships among the cod, the seals, and the other species. Seals, for example, feed not only on cod but also on close to 150 other species, many of which also feed on cod. So, there is no way of knowing whether modifying the system through the single-tactic approach of reducing the number of seals would actually produce *more* cod or *fewer* cod. As Buchanan said, "It's anyone's guess." Since ecologists estimate that, in food chains involving as few as eight species, there are "more than ten million distinct chains of cause and effect that would link the seal to the cod" (Buchanan, 2002), it is impossible to predict the outcome of such a modification.

The seal/cod example serves as an analogy for production agriculture. Plant and animal agriculture consist of networks of organisms linked in numerous ways that we cannot readily comprehend. Can we anticipate all of the ways that millions of soil organisms may be affected by the introduction of a corn plant genetically redesigned to attack the corn rootworm, for example? What are the weak links in the complex system that service the stability of soil-microbial networks? It's probably anybody's guess. Given the millions of distinct chains of cause and effect that may link them together, there is simply no way to know.

Ecologist Kevin McCann suggested that the lessons for conservation implicit in such networks are obvious (quoted in Buchanan, 2002):

- if we wish to preserve an ecosystem and its component species then we are best to proceed as if each species is sacred; and
- species removals (that is, extinction) or species additions (that is, invasions) can, and eventually will, invoke major shifts in community structure and dynamics.

The lessons for agriculture may be just as obvious. Introducing technologies that significantly modify, disrupt, or otherwise alter network architecture could severely diminish production agriculture. And altering such networks is something that can be done quite inadvertently since we *do* not, and likely *cannot*, understand the many subtle connections that link organisms together into ecosystems.

Once again, it makes much more sense to use technology to increase our understanding of how natural systems function and to harness inherent strengths within those ecosystems than to invent technologies to modify components of the system to achieve single-tactic effects.

Economic Consequences for Farmers

It is now evident that one-dimensional technologies also have failed to provide *economic* sustainability for farmers. Richard Levins, Department of Applied Economics at the University of Minnesota, and Michael Duffy, Extension Economist at Iowa State University, each recently have demonstrated this with unusual clarity. Levins (2001) pointed out that "the one consistent part" of the farm economy story of the past 40 years is that "farmers, as a group, have been

left out of the enormous growth in the value of what they sell." Levins pointed out that while *gross* farm income grew dramatically since 1960, *net* farm income remained essentially flat (Figure 1).

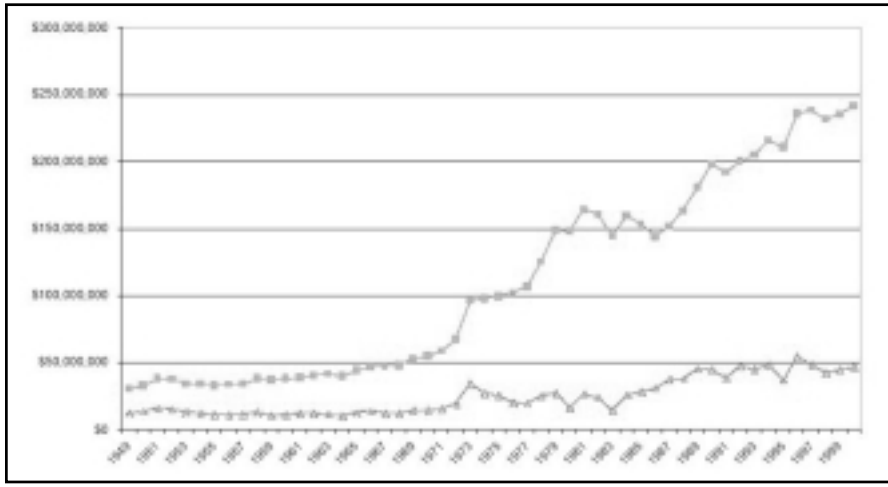

Figure 1. Gross (❑) and net (Δ) farm income in the United States.

Duffy demonstrated similar findings for Iowa farmers. His research demonstrated that, although they succeeded in dramatically increasing gross income between 1950 and 2001 (albeit with the help of government subsidies), their net income remained essentially flat. His study revealed that nearly all of the farmers' yearly gross income was used to pay the expenses required to produce the income (Figure 2).

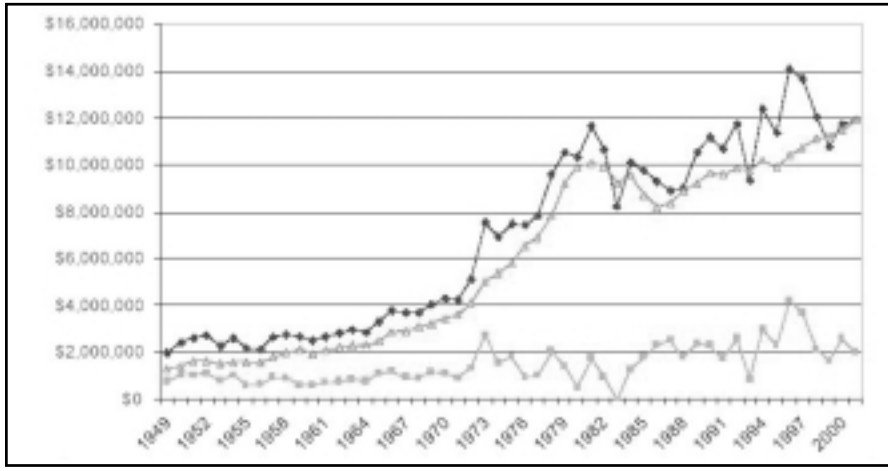

Figure 2. Total output (◊), total expenses (Δ), and net income (❑) for farms in Iowa.

The reason for this continuing dysfunction in the farm economy is not hard to pinpoint. Purchasing single-tactic solutions that fail to address the source of production problems and failure to take advantage of the inherent strengths in the system places farmers on an input-purchasing treadmill that requires them to buy more and more of the solution. That treadmill, furthermore, puts farmers under constant pressure to add more units (animals and/or acres) to their farms each year to generate more gross income just to pay the previous year's bills. It is the only way to stay in business.

As a consequence, of course, farmers are increasingly forced into predatory behavior, using any competitive advantage to acquire their neighbor's land, to borrow ecological or social capital from their communities, or to collect public subsidies. These are the only survival strategies available to them.

Anticipating the Future

In his enlightening biological study of human history, Jared Diamond helped us understand why, throughout history, some societies flourished while others perished. Two factors consistently seem to play a prominent role in the outcome—local conditions and getting a head start. Prosperity, it would seem, goes to those who best interpret the changes taking place in their local environments and get a head start in taking advantage of them. The changes *per se* are largely beyond our control (Diamond, 1999). Diamond's analysis may provide some clues for determining how to use technology in agriculture to meet the challenges facing us. One thing seems certain: if we continue to insist on using technologies in accordance with old paradigms that seem unlikely to meet the challenges of the future, they will fail us.

In a comprehensive study of pioneering agricultural research in the developing world funded by the McKnight Foundation, Richard Manning concluded that our efforts to feed the world can never be successful if we fail to take into consideration the complexity and diversity of local cultures and local ecologies. Within the context of that complexity, Manning suggested that transgenic technologies may have a role to play, but they will be only one tool in a whole-systems solution. He conceded that the "genetic engineering business is going to get all the headlines," but added that attending to the needs of local culture and local ecology is "potentially far more earth-shaking. If there was a key mistake of the Green Revolution, it was in simplifying a system that is by its very nature complex" (Manning, 2000).

Understanding such complexity is surely part of the task of correctly assessing our local situation. Focusing at least part of our research agenda on the development of technologies and management practices that enable farmers to understand and take advantage of the inherent strengths in ecosystems, instead of continuing to have to buy technologies that address only one-dimensional components of the problem for only short durations, seems like a reasonable way to get a head start.

Broadening the research agenda to attend to such systems approaches is consistent with recommendations in a recent National Academy of Sciences (NAS) report, *Frontiers in Agricultural Research: Food, Health, Environment and Communities*, which recommends that the USDA refocus its $2 billion annual research budget, shifting emphasis from the singular objective of increasing food and fiber production to include environmentally sound farming alternatives, quality of life in rural communities, diet and health, food safety, and the impact of globalization on farming in the United States (National Academy of Sciences, 2003).

The NAS report writers were well aware that these new demands on agricultural researchers would tax the ability of the land grant system on many fronts. In a coda to the report, they warned, "To meet new demands, established processes and partnerships in agricultural research must evolve without losing their unique value. Those tensions in the research agenda can be managed only through sustained vision, leadership, and political will" (National Academy of Sciences, 2003).

All of this suggests that more of the research focused on the challenges facing twenty-first century agriculture should be devoted to solving for pattern, rather than developing single-tactic solutions. It may well be, therefore, that poet-philosopher Wendell Berry had it right all along. In an essay on "solving for pattern," published in 1980, he suggested (Berry, 1983):

> *A good solution acts within the larger pattern the way a healthy organ acts with the body. But it must at once be understood that a healthy organ does not—as the mechanistic or industrial mind would like to say—"give" health to the body, is not exploited for the body's health, but is a part of its health. The health of organ and organism is the same, just as the health of organism and ecosystem is the same.*

Or as Morowitz (2003) put it, in more scientific, but less poetic language:

> *The primary metabolic chart of every species maps onto the universal metabolic chart . . . The metabolic chart is part of the phenotype of every organism. The phenotype . . . has a robustness in spite of the constant buzz of noise in the underlying genomes.*

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Biotechnology on Rural Landscapes

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In my former career as a university professor, between 1985 and 1995, I strived to help crop producers design environmentally sound cropping systems in, and adjacent to, some of the world's most pristine estuarine resources, the Albemarle and Pimlico Sounds in eastern North Carolina. Those efforts ranged from small-plot work to designing an organic research station to help growers produce more birds on their properties as they farmed. People ask me why I gave up—as my wife would say—the last secure job in America, the tenured full professorship. In any case, I gave it up and went to work at Monsanto because I felt it was an organization that had an opportunity to expand the frontiers of science and do the kinds of things that I learned about back in my graduate-school days when working with Ralph Hardy, Bill Jackson, Dick Hageman, and others. Those names may be unfamiliar to many, but they were preeminent scientists in their day—ethical, moral people who intended to do good with what they were trying to accomplish.

Eight Truths

My third career will be retirement. Some work harder in retirement than they did when they were employed. I am going to write a book: "Things That I Know to be True." Some of the discussion at this conference has clearly been based on poor information. So, before starting my presentation proper, I want

to list eight things that I know to be true and, although ancillary, are worthy of consideration particularly in relation to biotechnology.

- Technology crosses boundaries in response to capital.
- Complexity breeds expense. The more complicated something is the more expensive it is to deal with it.
- When I taught at NC State, I used to have at least one person stand up every day and say this to remind people: a dollar today is worth more than a dollar tomorrow.
- People respond to incentives.
- The more we do something, the better we become at it, which speaks to Dr. Kirschenmann's concepts of the commodity business.
- It's far easier for a small group of people to stop something than it is for a large group of people to accomplish something.
- It costs today, about $80+ million to commercialize a biotechnology trait in 8 years. Four years of that activity and about $8 million dollars are dedicated to the regulatory process that establishes food, feed and ecological safety.
- Finally, I'm going to define science because that word has been used a lot. Science is a conversation that changes over time wherein the correctness of an answer is swayed by the preponderance and the quality of the evidence.

Plus ça Change…

Samuel D. Champlain, as he explored the northeast territories, stated in his diaries: "These savages all along the coast where we have been, said that birds, which are very large, come along when the corn is ripe. They imitated to us a cry which resembled a turkey." This shows that when the Europeans arrived, the Indians were already interacting with wildlife in their agricultural fields. The Europeans brought along tourism and economical development based on natural resources. It's the same today as yesterday—the issues are similar.

A footnote, dated 1907, at the bottom of the page in the book I used says, "The wild turkey, long since extirpated"—which means removed—"in New England, is still found occasionally in Canada and frequently in the southern States." Although clearly abundant when Champlain came along, in 1930 there were only 30,000 wild turkeys in the United States. Today there are 30,000 turkeys in the state of Vermont alone. Therefore, that species has been rejuvenated, and there are several similar examples. All kinds of issues and discussions go along with this, but the issues, again, remain the same.

Fundamentals

I am a fan of Thomas Friedman, the foreign affairs writer for the *New York Times*. I don't like his politics, but, from my perspective, he is very bright and

understands how the world's markets and financial instruments are interconnected. The title of his book, "The Lexus and the Olive Tree," is metaphorical: the lexus is global capitalism and the olive tree is the sense of local culture that everyone is trying to hold on to. Dr. Kirschenmann said it's not enough to be a good technology person, or a good reductionist scientist; to be effective in the modern world you have to understand culture, finance, environmentalism, politics, and national security. It's a multi-dimensional information albatross. Furthermore, sometimes events occur and technologies develop that nobody has foreseen, yet great things result.

While studying biology in high school, my daughter had the opportunity to dine with James Watson. She said that he was funny, but she wasn't sure if he understood how she thinks. I said, "Welcome to the real world. Sometimes you get your best ideas from the fringe, and so you should always listen and figure out how you want to operate." If you look at biotechnology today—keeping in mind that it's a very immature industry (the first transformed plant was produced in 1983) and when things are young, like my daughter, you don't always know how they work—we do know for a fact that it can increase grain and fiber yields. We know it can decrease operating costs. Remember, the more we do something the better we become at it; when you're in a global commodity business, every time you double global output, the price comes down 15 to 25%. If you put it into deflated dollars on a logarithmic scale, the decrease is linear. The real values of corn, soybean, and wheat have been declining consistently since 1962. Biotechnology offers an opportunity to go back and change the rules and add value. Accordingly, reduced soil erosion extrapolates to enhanced water conservation and anybody who travels in this country knows that water is the big issue. Decreased pesticide spraying means that growers make more money; they adopted *Bt* technology at unprecedented levels because it creates value.

Conservation History

It has been said that the environmental movement started with Rachel Carson's book "Silent Spring," but I think that's incorrect. In my opinion, the new testament, if you will, of the conservation movement is "A Sand County Almanac," which Aldo Leopold published in 1949. The old testament was Herbert Stoddard's work in the red hills of Southwest Georgia in the 1930s, in which he criticized cotton producers.

Unknown to most people, the number-one person at Monsanto in the 1930s and 40s, the person who established it as a science and technology company was Edgar Queeny, who wrote "Prairie Wings" and shepherded the development of the waterfowl industry in the upper Mississippi belt.

Clearly, there is a long conservation history, but I want to speak to how agriculture, economic development, and environmental benefit may occur on the same landscape.

Landscape Demographics

When I was growing up in North Carolina, there was a wonderful commercial called "North Carolina, Variety Vacation Land": 3 hours from the beach, 3 hours from the mountains, pristine the whole way. Today, economic development, tourism, and agriculture all share the same landscape. As we look at landscapes, one of the things that I used to complain about as an academic was that when you really want to do something everybody starts arguing about definitions, so I prefer to say don't look at how you define it, look at what I'm planning to do. This is a definition from an agency of biological integrity: body, composition and structure and functioning, a genetic organism in community levels comparable with historic conditions, including the natural biological processes, shape genomes, organisms and communities. That sounds like a good definition to me, although I have one question: what does "historic conditions" mean? Does it mean when Champlain came along? Does it mean when Leopold was writing or when Edgar Queeny was in Arkansas? Or does it mean today?

Rather than worry about that definition, I am going to try to address today's challenge, to create working farms in which crop, forest, and wildlife resources are integrated as agronomic systems that preserve water quality, enhance wildlife habitat, and contribute to the rural economy.

I heard a wonderful presentation from a gentleman in Arkansas some time ago who talked about the 66/66 rule, for which there is no sound scientific basis, or so I thought. The 66/66 rule is that 66% of the farmland in this country is controlled by people over 66 years of age. While looking at a Web site late in the evening preparing for this presentation, I discovered documentation for this, from the Iowa Department of Natural Resources: 86% of Iowa landowners are 55 years or older—and there could be "a major shift in ownership in the next 10 years from farmers to middle-age absentee non-farmers who could have different ownership objectives for their resources."

Also, I heard a fascinating presentation recently about the companion-animal industry. (The definition of a companion animal is one that has a name.) People spend $2,300 a year per companion animal in addition to food costs. People are moving out of the town that I live in and are setting up farms close by, of 10 to 40 acres. Part of the evidence for this, as stated in our local newspaper, is that small-tractor sales now far exceed those of large tractors indicating a reorganization of the agricultural landscape in the next few years with great opportunities for organic farming. Companion-animal customers are highly educated and likely to be female, wanting to know the science underpinning how things work. This will constitute the largest transfer of wealth in this country in the next 10 years. I know a representative of the Nature Conservancy who is fascinated by this, seeing it as an opportunity to teach these people about conservation.

What will agriculture look like in that scenario? I would suggest that those individuals will expect certain things, bearing in mind that water is the issue. Ecological benefits are possible from biotechnology. In some Illinois watersheds, where corn herbicides have been an issue, replacement of conventional corn with Roundup Ready® corn in 1999 to 2001, has resulted in dramatic decreases in numbers of samples above 4 parts atrazine per billion—a very real environmental benefit of importance to those living on that landscape in terms of drinking-water quality.

The hottest growing business outdoors today is the wildlife plant-material industry. These plant materials attract wildlife, thus supplementing habitats. Although some scientists have issues with this, it's a fast-growing business because of the changing demographic on the landscape and demands for recreational opportunities. In the fall 2003 meeting agenda for the American Society of Farm Managers and Rural Appraisers—farm managers who represent absentee landowners, certainly an increasingly powerful group—the number-one topic was recreational use of farmland. It's a growing industry resulting from the changing dynamic on the landscape.

Therefore, what's the hot ticket in wildlife food crops? It's Roundup Ready® corn and soybeans. Why? Because they are simple to use for people who don't routinely farm, but want enhanced wildlife habitat. Public and private agencies and state wildlife agencies in North Carolina, South Dakota, Iowa, Nebraska, are utilizing *Bt* both on public and on private lands with input from scientists who understand the risk assessments that have been done. The YieldGard® root-worm technology is also attractive for those who are moving out from town, by way of ensuring pesticide reductions and improvements in water quality.

A Cotton Case Study

Cotton became a dirty word in wildlife circles because of intensive tillage in the late 1800s and early 1900s. I can remember J. Fulton Luce, the pioneer of soil conversation—I took his course—telling me about the erosion that occurred when cotton covered western North Carolina. In *Cotton Today*, Roger Leonard and Ron Smith at Auburn University recently discussed impacts of Bollgard® (*Bt*) cotton. Benefits of $168 million have accrued to Monsanto, to growers, and ultimately to consumers. Some 104 million pounds less insecticide active ingredient have been used. And, most importantly, it has saved 41,250 10-hour workdays on the farm and eliminated 2,150 10-hour aerial application days. The really interesting story is how biotech cotton contributes to growers who have ecological values.

One of the things I like to say to people is, "You travel on farm landscapes; draw me a picture of what it will look like in 10 years." Very few even try. If you don't know what it's going to look like, then you don't know how to address what you are going to do over the next few years. At Monsanto we have been

trying to convince farmers (and sometimes landowners because most farmland is rented) to get away from mowing ditches and disking fields and move towards managing ditch banks and crop residues. There are opportunities for managing farmland in the United States today for biodiversity improvement by not cultivating ditch banks, headlands, and other unprofitable areas. Wes Burger at Mississippi State University has done a great job of putting these into a GIS system so that you can tell where they are. You can put your production map from your yield monitor right over the top of your economic map and come up with a negative layer and take it out of production.

It is likely, as a result of the movement of people onto the farm landscape, that the next two Farm Bills will focus upon paying farmers to create public good through conservation. Clearly there's hope and opportunity for ecologically sound approaches. But don't underestimate how difficult it is to move into a farm culture and get them not to mow that ditch—professional stature is frequently based on how clean a farm is and, in my neighborhood, how neatly manicured your yard is and how good your roses look.

How do you package something that includes intensive agriculture and maintains an ecologically sound landscape? First, you manage the non-crop areas for biodiversity and wildlife. I am just old enough to have plowed with a mule and have a strong memory of the landscape mosaics of the 1950s. The Farm Bill will offer opportunities to manage agricultural landscapes intensively simultaneously with non-crop areas managed for biodiversity; in my opinion you can have it all.

Conservation Tillage and Wildlife

Conservation tillage increases the quality of brood habitat for quail chicks. It's a good story from John Carroll at the University of Georgia. Cotton growers today care about these things; they use biotech cotton and conservation tillage and they manage their noncrop habitats to increase bird numbers. At the NILO plantation in southwest Georgia, 8.4 coveys of wild birds per hour have been reported—very high numbers. The manager, Ernie Iler commented, "It appears that the *Bt* gene is an asset to quail because of the insects we don't have to kill." Quail have to grow feathers and fly within 2 weeks of hatching to avoid predation. Insects available on the soil surface provide a high-protein diet, and 20 inches of cover provide protection from aerial predators. The shorter the period of time spent fertilizing and raking with conservation tillage, the better is bird survival. Quail are found 200 yards or more into cotton fields, hence 8.4 coveys per hour.

Biotech has done much for conservation tillage, as was described by Jim Cook. Some 63% of soybean growers who have reduced their tillage since 1996 cite the herbicide-tolerant technology as the key factor. The benefits on rural landscapes are huge. Farmers who do not use herbicide-tolerant seeds are not likely to engage in conservation tillage. It is largely black and white.

In answer to the question, "What has Bollgard® cotton done for wildlife on your farm?", 31% said that *Bt* cotton increased wildlife and in areas where people know most about that, *e.g.* northeast Georgia and Tennessee, it was 59%.

Furthermore, Roundup Ready® corn is expanding the range of wild turkeys in North America and it's being used by wildlife agencies to enhance pheasant habitat.

Nonpecuniary Benefits

With regard to the recently deregulated YieldGard® technology to combat rootworm, what will a farmer pay above the cost of insecticide in order not to be exposed to organophosphates? How about $1.79/acre? What will a grower pay to know that his farming activities relative to corn rootworm and organophosphate application, have no offsite impact?: $1.46. These data are from Julian Austin and Michelle Merrer. We know that YieldGard® protects yield potential, as do most IPM tools. We know it provides superior control in comparison with insecticides; it's more consistent. What will growers pay for the fact that corn may be standing up straight at harvest where otherwise it might be curved or crooked over due to rootworm? How about $5.29/acre? I thought that would be the highest because, during 20 years working for *Foreign Farmers*, they talked yield but they bought standability. What would they pay for peace of mind through consistent performance?: $4.03/acre. And what would they pay just for the pure simplicity of not having to calibrate or fill an insecticide applicator?: $1.94 and $1.57/acre.

Future Global Village

In a hypothetical exercise at Monsanto some time ago, we asked what a village of 100 people would look like in 2020: fifty-seven Asians, twenty-one Europeans, fourteen from the western hemisphere, and eight Africans; seventy other than white and thirty white; seventy other than Christian and thirty Christian; 50% of the wealth will be in the hands of six people, all US citizens; seventy will be unable to read; fifty will suffer from malnutrition; eighty will live in substandard housing; and one will have a college education. So, when you are dealing with global economics, and you are dealing with foreign cultures, it will be a hard job to sell the benefits of any new technology even to people to whom benefits may accrue. It will be a challenge, but I believe that that there will be opportunities for biotechnology to contribute both to ecological health and to economic health on many landscapes.

New USDA-ARS Research in Biotechnology Risk Assessment

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The Agriculture Research Service of the United States Department of Agriculture (USDA-ARS) is making many contributions in the field of agricultural biotechnology. These include conserving and improving genetic resources, and developing new genomic information and molecular tools. Increasingly, USDA-ARS research includes biotechnology risk assessment and mitigation.

Genetic Resources and Genome Databases

Core responsibilities of the ARS include conserving, safeguarding, and characterizing genetic resources. The ARS manages the US seed and germplasm collections through the National Plant Germplasm System (www.ars-grin.gov/npgs/). These collections, which include over 10,000 plant species of agricultural value, are stored, evaluated, and regenerated at germplasm repositories at over twenty locations. Over 120,000 accessions are distributed annually, many to biotechnologists. Researchers are tapping these germplasm resources to identify valuable genes and to understand crop evolution. High-throughput genomics strategies are providing new, precise methods to identify genes for disease resistance, tolerance of extreme weather conditions, and improved nutritional value. The genetic base of many US crops is narrow, therefore, strategies to integrate novel genes offer the possibility of enhancing genetic diversity.

Much current ARS research uses conventional breeding methods aided by new molecular tools. Genomics information provides molecular markers to accelerate breeding and make it more efficient. Centralized Web sites

providing crop-genome information are supported in cooperation with the National Science Foundation Plant Genome Program. These crop-genome databases include: MaizeGDB (www.maizegdb.org), Gramene (www.gramene.org), GrainGenes (www.graingenes.org), and SoyBase (http://soybase.agron.iastate.edu/).

ARS researchers are also protecting US agriculture and food safety by employing molecular tools to develop sensitive detection tests.

ARS Biotechnology Risk-Assessment Research

As genetically engineered (GE) crops become more prevalent in the United States, ARS researchers—including geneticists, entomologists, and microbiologists—are increasingly applying their expertise to evaluate their use in farming systems. Much of this work is part of regional evaluation projects that incorporate both conventional and biotechnology methods.

Many of the concerns and questions about GE crops and foods could be asked about any new variety or food product. However, the public has more experience and confidence in conventional plant breeding and food-product development due to many years of largely problem-free experience. Reviews by the National Academy of Sciences have confirmed the safety of GE crops, but have indicated need for more evaluation of environmental effects. Topics identified by the Academy as needing more research attention include:

- development of resistance in pest populations,
- effects on non-target insect species,
- gene flow from crops to surrounding vegetation.

Biosafety research at the USDA addresses priorities identified by the National Academy and by consumer groups. Two agencies are involved: the Cooperative State Research, Education and Extension Service (CSREES) and the ARS jointly administer the Biotechnology Risk Assessment Research Grants Program (www.reeusda.gov/1700/funding/04/rfa_brag_04.htm). This program, authorized in the 1990 Farm Bill, provides 2- and 3-year research grants funded by a 2% set-aside from all USDA biotechnology research projects. In FY 2003, it exceeded $3 million.

A new initiative to support long-term ARS projects in biotechnology risk assessment was funded by Congress in FY 2002 with additional money in FY 2003. Total funding in FY 2003 was $5.4 million. Other ARS projects are incorporating biosafety-related research activities into their objectives due to the increasing prevalence of GE crops and increased interest in long-term effects on the environment.

The ARS conducts biosafety research as part of its responsibility to supply needed information to regulatory agencies. All research results are submitted for scientific review and are publicly available. Examples of current ARS biotechnology risk assessment and mitigation research projects follow.

Preventing Development of Resistance in Pest Populations

Cotton farmers have suffered multi-million dollar losses from insect pests, particularly the tobacco budworm and the bollworm. Those losses have been reduced by the use of biotech cotton with *Bacillus thuringiensis (Bt)* genes that produce insecticidal proteins. The cotton industry is using strategies to reduce the evolutionary pressure on the tobacco budworm and other pests to acquire resistance to *Bt* cultivars

Researchers at the ARS Southern Insect Management Research Unit, Stoneville, MS, are monitoring tolerance of insect predators of cotton as part of efforts to insure that *Bt* remains an effective means of control (Hardee *et al.*, 2001). They are evaluating caterpillar specimens, collected from cotton-growing areas, that are reared first without *Bt* and then are grown on *Bt*-containing feed. Growth comparisons are made with insects raised on control diets. Changes in susceptibility to *Bt* have not been observed, but monitoring continues; data are used to design and evaluate production practices and federal regulations that will prolong the effectiveness of *Bt* cotton.

Control of the devastating corn rootworm requires extensive use of pesticides. Monsanto has developed a *Bt* corn that is toxic to the rootworm. Wade French and Mike Ellsbury at ARS, Brookings, South Dakota, are partnering with industry researchers to evaluate use of seed mixes as a strategy to slow the evolution of rootworm resistance to *Bt*. Various mixtures of conventional and GE corn are being tested. The advantage of seed mixtures is that rootworms grown on conventional corn plants will not be subject to evolutionary pressure to acquire tolerance, and will continue to mate with rootworm beetles previously exposed to the *Bt* plants. Monitoring includes measuring root damage, plant lodging, and numbers of adult rootworm beetles caught in emergence cages (Anonymous, 2003).

Effects on Non-target Species and Gene Flow into the Environment

Do *Bt* crops harm beneficial insects? ARS researchers are helping to address that question with long-term studies on non-target species. Pitfall traps, with timed daily interval units, are being used to collect ground beetles in corn and soybean research plots and private farms as part of a national pest-management project. The results will alert researchers to any risks to beneficial species (Anonymous, 2003) as well as provide new information about numbers and feeding activities of ground beetles.

Concern over effects of *Bt*-corn pollen on monarch butterflies was raised several years ago. ARS researchers participated in a series of public meetings in 1999 to 2001 to identify research needs to determine if *Bt*-corn pollen is hazardous to monarchs. ARS and industry groups, along with Canadian sources, then provided $200,000 in grant funding to twenty-nine scientists to

address the biotechnology risk research needs. Entomologists, weed scientists, geneticists and other researchers coordinated experiments to provide comprehensive evaluation of risk. Effects of *Bt*-corn pollen on monarch butterflies in the field were thoroughly evaluated, with little indication of risk. Data were made public and published in six comprehensive papers in the October 9, 2001, *Proceedings of the National Academy of Sciences* (*e.g.*, Hellmich *et al.*, 2001)—a good example of cooperative research by the public sector to evaluate biotechnology risk.

New ARS research projects are being initiated to mitigate and confine the expression of transgenes. Efforts are focused on expression of transgenes only in tissues where they are needed and not in plant organs that are harvested. Priorities include identifying gene promoters and other molecular tools that confer precise and predictable transgene expression. Promoters that confer new pest and disease resistance in the shoots and growing ears of grain crops are needed to withstand devastating diseases of cereals such as scab (fusarium head blight). Molecular tools are needed that increase virus resistance in the vegetative tissues of potato without expression in the tubers. A major benefit of this research will be the development methods and tools with public accessibility.

Tissue-specific expression can provide nutritional and health benefits. A project is being developed to enhance calcium levels in potato tubers. And promising new strategies are being used to reduce food allergens. Recently, a transgenic soybean was developed with the major soybean allergen removed (Herman *et al.*, 2003). Reducing allergens in a commodity as widely used as soybean will significantly benefit those with food allergies.

Other ARS projects are focused on precise and predictable transgene expression. Technologies to consistently and precisely insert transgenes are being developed. Such technologies offer the opportunity to stack or combine beneficial genes into one insertion event. Other possibilities are to combine beneficial genes, say for pest resistance, with "domestication" genes that can slow gene flow into wild species.

Summary

The ARS and USDA are increasing research efforts in biotechnology risk assessment and biosafety. Many projects are addressing long-term effects of GE crops in agriculture production systems and on the environment. Other projects are focused on mitigating transgene expression in food and feed. Precise and predictable methods are being developed to express transgenes. These technologies can enhance pest resistance and weather-stress tolerance in plant tissues only when needed. Similarly, nutritional enhancement and allergen reduction can be focused where it will be most beneficial.

New ARS biotechnology risk assessment and mitigation research is addressing biosafety priorities identified by the scientific community and

consumer groups. The results of research by public sector scientists will be made publicly available and will be used for science-based regulation of transgenic crops and food products.

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Module II Panel Discussion and Q&A Session

Moderated by Terri Lomax
Oregon State University
Corvallis, OR

Panel Discussion

William Boggess (Oregon State University, Corvallis, OR): Fred, you indicated that, philosophically, you often see the "question behind the question." You also mentioned that, in the next 47 years, there will be another 3.2 billion people in the world to feed and most in the rural, underdeveloped areas of the world that face many agricultural challenges. My question behind the question is: do you actually anticipate feeding these people or at least attempting to feed them, or do you see this as not being a possibility?

Frederick Kirschenmann: Whether or not that population increase occurs will depend on whether or not current circumstances stay in place. There's the question of infectious diseases and what role they will play. It will depend also on what kinds of intervention we use. We know that education of women has been one of the most effective tools for stabilizing population, for example. But, assuming that the increase will occur, simply producing more food is not going to solve the problem because we will run into water shortages before we run into food shortages. Also, we will run into the problem of ecological impact; how long we will continue to insist on consuming will be a part of the equation. Many challenges face us, and simply developing technologies to produce more food will not solve the problem. Having said that, there are some examples of how we can, in fact, increase productivity without increasing yields, by developing multi-species systems that actually produce more from the same acreage. My favorite example of that is a farmer in southern Japan, Takao

Furuno, who, instead of just producing rice as he did up until 1987, also produces duck meat, fish meat, duck eggs, and fruit from the same acreage. This multi-species system has created synergies such that he no longer needs to buy pesticides, he no longer needs to buy fertilizer, and his rice yields have increased. So my question is: why aren't we devoting at least some of our research money to understanding such systems? What's the ecological equivalent for Washington State? What's the ecological equivalent for Iowa? For Africa? I'm convinced that, with such complex highly productive systems in place, farmers would no longer be on the technology treadmill and would, in fact, increase the production and diversity of food so we wouldn't have the problem of nutrient deficiencies because we're concentrating on increasing the yields of particular crops, namely rice or wheat. We need to explore some of those options.

Boggess: Kay, do you think that this emphasis on risk assessment, which is being taken as a portion of the ARS and USDA mission, is actually addressing profound hazards or is this part of seeking a risk-free world and environment as part of our society?

Kay Walker Simmons: We are addressing biosafety research needs identified by scientists under the aegis of the National Academy of Sciences as well as other scientific forums. At the same time, we are mindful of concerns expressed by consumers about the need to assess the long-term impact of crop biotechnology on the environment and plant genetic diversity.

Boggess: In light of that, I was wondering—I think the numbers are correct here—do you have any information that would support that $3 million is enough to support 2- to 3-year studies on resistance management and effects on non-targets or gene flow?

Simmons: That amount funds competitive grants on an annual basis in each of the priority areas identified as biosafety research needs. These grants are awarded by the USDA CSREES Biotechnology Risk Assessment Research Grants Program. Additionally, there is the new Biotechnology Risk Assessment and Mitigation Initiative within USDA-ARS that supports long-term biosafety research projects. ARS funding increases in 2002 and 2003 ($5.4 million total) support this long-term research on effects on non-target organisms, risk to the environment, and assessment and mitigation of the effects of transgenes on global gene expression.

Boggess: John, do you see Monsanto and other industry leaders in the development of biotechnology, as utilizing a systems approach, or will it be primarily a single, one-dimensional approach?

John Anderson: In day-to-day activities at Monsanto, we are organized in teams. There's a corn team, a wheat team, a cotton team. Within that process sometimes we focus on individual products. The challenge that we've undertaken, and are very capable of addressing, is how to look at the portfolio of products in a more holistic way, and how to address growers' needs—some people call them solutions—on a landscape scale. So, the good news in my opinion, having come from academia where we were organized by disciplines, is that, at Monsanto, there are entomologists, agronomists, because our products cross so many commodities and other enterprises—biofuels and those kinds of things—the expertise is there to look at things in a holistic way. But, you have to make an effort to point out that it's needed and the issues that you have to address require holistic solutions. I apologize for the Monsanto commercial, but, since we are team-based, if I need Eric Sachs or Harvey Glick to add expertise to a team to address something that is holistic, we have the empowerment being a flat organization to put that team together. I understand it sounds self-serving, but that's the way it is.

Boggess: Thank you.

Brewster Kneen (The Ram's Horn, Sorrento, BC): After 15 years or so of looking at the issues of biotechnology, I find myself having to look further and further upstream to ask, "What is the real problem here? Is what we identify as the problem really the problem or is it somewhere else further upstream?" In good reductionist tradition, we want to reduce the discussion to issues that we think we can address with pragmatic and technological or technical solutions. That approach may not address the problem at all, but we have that proclivity. We do this because, if we cast the problems as technical questions in a society that says technology and science are neutral, then we can avoid dealing with the ethical, moral, and social questions of where we stand personally and are we prepared to make life changes to actually address the problems? The problems always come in language such as, "How are *we* going to feed the world?" And I agree with Fred—I don't think *we* are going to feed the world. That's the white man's burden. I think it's high time we gave that one up and said, "Why don't we let people feed themselves?" So, I have a problem with some of the language. Of course, it becomes personal. "Am I prepared to make changes in my life to decrease the demands that keep the system of exploitation going and for which biotech is supposed to be an answer?" So I have to back up again. Let me just suggest that I see genetic engineering, biotechnology, as a cultural project, or product if you will, of a particular culture. And I am very aware that, in listening to the discussion, this is very, very North-American centered, as if it's the only culture in the world and everything is resolvable and can be dealt with in this context. I suggest that that is problem number one. Three more points: as Fred stated, production is not the issue. The issue is justice, and justice

means distribution. But that's a social question that we don't want to deal with because then we have to ask ourselves about our demands, what we expect for our livelihood, and what we think we can expropriate out of the pot. If you look at medical biotech, you see that it's a very elitist practice for a very, very small number of people to benefit by extremely expensive processes, which raises a lot of serious moral questions to me. The second point, which Fred has alluded to, is that the environment is not out there. It is not a resources for us to use. It is the world in which we live. It is the context of our lives from the gene up. The context is constantly expanding and we are part of that. We are not some separate thing that is in a position to control it. My point is that sustainability must exclude growth. Now that may sound radical. But, we assume that the problem of poverty is economic growth, not distribution. And we assume that we have to feed people with industrial agriculture, not allowing them to feed themselves with a diverse sustainable subsistent system, which is in fact the way most people feed themselves. So I guess I would ask John Anderson first, if progress isn't in fact what's killing us?

Anderson: I would answer your long question in a very direct way: I don't get up in the morning feeling guilty for consuming something, and I'm not so naïve as to think I or my employer can feed the world. But I do like to think that I can see out in front of me. Many things are going to have to change to feed those people. Wars may be fought over food and water. We have the ability and the intelligence to adapt and manage those situations in a way that is good for a lot of people. And so, if I ask myself the ethical question, "If I'm working in the biotechnology industry, am I doing something immoral or unethical?" I would say no, because traditionally people have tried to improve their quality of life by using the resources at hand and applying their knowledge to create what you could call technology to solve the problems of importance to them. So no, I don't feel guilty working in this industry. The other thing is that we have a lot of opportunity in front of us and that opportunity, whether you're an organic grower or a traditional grower, is based on markets. I'm a supply-and-demand kind of guy. If there's a need, and a compelling need, then somebody will respond to it. If they can profit from it, I don't have a problem with that, but no one has a monopoly on ethics, and if you move forward and do the right thing you can use technology and accomplish the goals at hand. I don't feel there is anything in front of us that we can't manage or that there is anything that really is terribly negative about the way we are approaching it.

Kneen: Kay, I was struck by the fact that you had one slide in which I think the text was, "As agriculture itself creates risks with conventional crops, this should be the standard of comparison." Doesn't this illustrate the point I was making, that we take industrial agriculture as normative, and is that a reasonable starting point?

Simmons: My point was that any type of plant breeding or crop improvement introduces some risk. *Any* new plant variety should be carefully compared with previously developed varieties that have performed well. For example, effects of new biotech crop varieties on non-target species should be tested in the field and compared with other commonly used varieties. Amounts of pesticides used and effects on non-target organisms should be compared. Those comparisons should be done with current farming practices, which can also include alternative farming methods.

Kneen: Fred, do you feel that the term "technology"—which you've used as well as everyone else in referring to life processes and characteristics of organisms—demeans life and reduces organisms to objects that are then fair game for our manipulation?

Kirschenmann: It depends on how this turns out. I'm trying to redeem the term "technology" so that we don't limit it to hardware or control systems. In fact, a lot of technologies, which we could access, are available in nature. Aldo Leopold has been mentioned several times today, and one of the things that we often forget about his view of the world—and it really is the underlying principle of his land ethic—is that *Homo sapiens* is not the conqueror of the land community but a plain member and citizen of it. In other words, we are not in control of the world, we are not in charge, we are each simply one citizen of the community and the other citizens comprise everything from bacteria to earthworms to every other organism. So, what technologies, what mechanisms, are available to us if we recognize ourselves as plain citizens of the community and we can access all those other resources by relating to them to make the system as a whole more productive? He also said that the objective is not to preserve the community in its present state, because it's always changing, because nature is always evolving. Nor is it to "squeeze the maximum productivity out of it." The objective should be to enhance the capacity of the biotic community to *renew* itself. Think about that for a minute. We should, in fact, be engaged in using every technology at our disposal to meet that objective, because the future—the sustainability of the whole system—depends on that one issue. I invite all of you to keep that fundamental philosophical position clearly in mind, because that's what Leopold was talking about.

Kurt Volker (Syngenta Crop Protection, Yakima, WA): Fred, the thesis I got from your paper was that not just biotech research but probably most agriculture research is not focused on the right things. It's reductionist rather than holistic. It's "single component" rather than "systems." What I didn't hear though was whether you see any unique opportunities on one hand or any unique challenges on the other that biotech may bring to your solution. Does biotech open up avenues that traditional research doesn't to better understand systems,

or does it have some characteristics that make it even less likely that we will make the shift?

Kirschenmann: I'm sorry if you missed where I tried to emphasize that, particularly in referencing Evelyn Fox Keller's work *The Century of the Gene*. One of the things that she points out, based on her research of the evolution of gene technology and gene research over the last century, is that its real value lies in the enormous capacity for better understanding how systems function. In that case, it's a knowledge-based enterprise rather than a technology-based enterprise, using the word "technology" in the traditional sense. And if we can begin to recognize that there is some real value to the knowledge that we can extract from genetic research, in terms of better understanding how systems work—on my farm, for example—I want that information because that can then help me to understand how I can manage it better to access its inherent strengths. This is important for me as a farmer, because there have been a lot of other references in the last day and a half about the benefits that farmers get from this technology when applied to a single crop to provide farmers with X number of additional dollars per acre. Yet, when you put the whole system together, farmers are not surviving economically because they are constantly on a treadmill because these technologies don't address the fundamental sources of the problem. By introducing crop rotations many of my problems disappeared. And by changing the management system of our animal agriculture, the disease problems essentially disappeared. We no longer use veterinarians on our farm. So, there is information from genetic research that could be enormously beneficial to me, and I want that information. Information will be the driving force, not specific technologies that I have to buy, which, by definition, are going to have short-term solutions because we haven't addressed the source of the problem. We've only addressed how to fix the problem and that's the point of Joe Lewis's whole analysis.

Volker: John, I am thinking back on your eight principles, one being time/value/money or the fact that a dollar is worth more today than it will be a year from now. Considering how people respond to incentives and the role of capital, which you pointed out, and that it costs $80 million to bring a technology online, explains why we've seen private companies focus on commodity crops—corn, soybeans, wheat, cotton—that have a large market size with which sufficient benefits can be captured from producers' willingness to pay for a particular interventionist-type technology. What incentives are there for Monsanto and other large companies to take on research that might lead to longer-term, sustainable systems, particularly if it means that it would be difficult to capture benefits in the marketplace? Or do you see being restricted to products from which benefits may be captured in the marketplace?

Anderson: You use the term "interventionist," I would prefer "innovation," because markets are harsh judges. The private sector takes shareholders' resources and puts them at risk, and can spend $80-plus million to commercialize a product—but it doesn't mean that people are going to buy it. You assume that you have interpreted the business landscape correctly enough to create value with that innovation. People put their scarce resources where there is the highest return, whether it's on Fred's farm or whether it's in the private sector. He's looking at how to best use his resources to accomplish his goals. The goal at Monsanto is to make money. We don't apologize for that. Because of the expertise we've assembled, we have the opportunity to address modern agriculture. Because we have entomologists, agronomists and molecular biologists, we have the opportunity to look at things in a broader holistic way. We support projects with the Nature Conservancy, with Audubon, and with other entities that espouse the need to think holistically in an ecologically sound way. I would argue that conservation tillage in tandem with biotech cotton or corn, with other ecologically sound approaches that growers might adopt, can create holistic solutions to economic problems. In a global commodity business, which farming is today, the low-cost producer always wins. We must use this technology to broaden the number of opportunities available to growers. The dynamic I talked about—people moving out of town back onto the landscape—is a huge opportunity for what the Audubon people would call community-based agriculture, and I sense that's what Fred's describing. He's shaking his head no. I'm sorry—didn't mean to intrude, Fred. That's what I thought he said. In any case, there's an opportunity here to find ways to add value and get off the commodity treadmill rather than the technology treadmill.

Volker: Kay, your last slide ended your presentation on an optimistic note: high safety standards and safeguards are in place, and will be even higher in the future. I was surprised that you seemed sure that there is no need for concern over development of resistance, unintended effects on non-target organisms, or gene flow that might have irreversible effects.

Simmons: New funding for USDA biosafety research will increase monitoring and evaluation activities to detect any development of resistance or unanticipated effects on non-target organisms or the environment. Results of this research will be openly provided to the public and be used by federal agencies to review regulatory practices for biotechnology crops.

Q&A

Craig Winters (The Campaign to Label Genetically Engineered Foods, Shoreline, WA): I want to know how the US Department of Agriculture can justify

allowing genetically engineered corn to be grown when it's apparent that it is contaminating organic corn. It's interesting to hear the Secretary of Agriculture Veneman say that if people want products that are labeled they can just buy organic, when we know that organic crops are being contaminated by genetically engineered crops. Another incredible thing is the proposal to allow drugs to be produced in crops that will be within 1 mile of food crops when we know that corn pollen travels far more than a mile. How can the USDA justify allowing organics to be contaminated and pharmaceuticals to be produced in food crops?

Simmons: The USDA Animal and Plant Health Inspection Service (APHIS) regulates the introduction of transgenic crops. including those containing pharmaceutical and industrial compounds. That agency has recently developed more stringent protocols for field testing of these types of transgenic crops.

Alan McHughen (University of California, Riverside, CA): Kay, I appreciate the work that you were describing from the USDA-ARS. The allergy-reduced soybean is a tremendous project. We all know that eventually insects will acquire resistance to *Bt*, and it's important to do that type of work and put it in the public domain. I applaud those efforts. But, $3 million simply is not enough, so I would encourage more funding for those types of projects. You referred several times to National Academy of Sciences reports and it seems to me that on those several occasions when they've offered comments they said that the risks associated with biotech are no different in kind from those associated with conventional and indeed organic production. Yet all of these studies were aimed at biotech products, and I question the wisdom of perpetuating the myth that there is something special and something inherently risky about biotechnology. Are we addressing perceived risks from society or are we addressing real risks? If we continue to work on perceived risks associated with biotechnology might we ignore real risks with conventional and organic products?

Simmons: As Fred Kirschenmann noted, the significant benefit of biotechnology has been the tremendous advance in new information at the gene level. Biotechnology is enabling us to understand the effects of altering individual genes. Much of our new USDA-ARS biosafety research will be assessing the long-term effects of introducing new pest- and disease-resistance transgenes. While these ARS projects will focus on transgenic strategies, the research results will also provide new knowledge and tools for conventional plant breeders. New information about the most effective genes, unanticipated effects from altering specific genes, and methods to minimize environmental impact and effects on non-target insects can be used by all plant breeders.

Carolina Reyes (Western Washington University, Bellingham, WA): My question is most directed to Mr. Anderson as well as Ms. Simmons. Speaking of whole-systems approaches, it has become very clear that an environmental benefit of biotech is reduced pesticide use. On the other hand, it could be said that large-scale pesticide use is made necessary by large-scale agriculture—by monoculture farming. Using potatoes as an example, is it not true to say that Monsanto has construed the problem as being the potato beetle rather than potato monoculture. This is to say, existing systems of agricultural production are left intact while the root causes of unsustainability are left untouched. Are we addressing symptoms and not the causes of our problems?

Anderson: I think you are asking, "Could crop rotations replace pesticides?" Fred spoke to that earlier. There are examples where those systems work. There are examples where insect problems break out in those systems. But, if you look at the global demand for feed grains, global demand for oil seeds, the agricultural sector has chosen to meet those demands, and be rewarded accordingly, with efficient, highly productive systems. Now, remember my comment that complicity breeds expense. Support to do that kind of work came from the 1985 Farm Bill—a lot of that effort faded away because the people working in those systems were never able to demonstrate widespread economic benefits. And so, complexity breeds expense. It's a knowledge-intensive, more difficult way—in my opinion—to farm, and it's not one that meets the demands of large markets. Over hundreds of years, not just the last 20 years, a system has emerged whereby people use the technology they have at hand to address a problem most efficiently and most effectively. That is traditionally how agriculture has approached issues. I am not saying the approach you are talking about doesn't work. I'm just saying it's hard to generate large economic benefits to large numbers of people with that kind of approach.

Phillip Schwab (USDA Cooperative State Research Education and Extension Service, Washington, DC): I appreciate Dr. Anderson's comment about definitions, and my question derives from the definition of biotechnology that we are talking about here today, which seems to be mostly focused on transgenics. From my perspective as a federal science policy person, our major investment on the federal level is in genomics and, Dr. Anderson, you referenced that in terms of encouraging your daughter to go into proteomics. As we learn more about the genomics of crop and animal species, learn more about the proteomics, the inner workings of the genetics in each of these species, won't we be able to make better intra-species crosses—better plant breeding, better animal breeding—versus reliance on interspecies transgenics. How will that affect the biotechnology debate and what do you think the relative contributions will be of genomics information *vis-à-vis* intraspecies tranformation?

Anderson: If you go back to Thomas Friedman—I like him because he understands that the late 1800s was an era of innovation based on the rapidly declining cost of transportation—the seventh largest company in this country was Central Leather. I would defy anyone in this room to tell me what Central Leather did. What we are seeing today, as I suspect you already know, is an era of biological innovation based on the rapidly declining cost of biology. Monsanto has a huge investment in genomics, as do many of the people in this room. I think the greatest benefits from genomics will come from improvements in plant breeding—molecular breeding if you want to call it that—because I can assure you that the current rates of improvement in crop productivity are nothing compared to what you will see in the very near future, maybe 10 years out. If it's not transgenic that's good news, because you circumvent the risk and the cost associated with transgenic approaches. I'm agreeing with you that the real improvements in crop productivity are going to come from molecular breeding and other things that young people understand but I don't. There's a whole language around proteomics that I'm trying to learn.

Simmons: Consider the promise of genotyping. Genomics is going to allow us to use genotyping to mine crop germplasm collections and identify genes for valuable agriculture traits for pest resistance and weather tolerance. Crop diversity will be enhanced. USDA-ARS is developing regional wheat and barley genotyping laboratories to deploy new gene discoveries for use by public plant-breeders in partnership with land-grant universities.

Steven Garrett (Washington State University Cooperative Extension, Takoma, WA): Dr. Anderson, a criticism that industry and academics producing genetically engineered crops have had to sustain is the perception of arrogance—that scientists think they know best. In fact 2 or 3 years ago, when Monsanto had a change in CEOs, the new fellow—I can't remember his name—publicly apologized for just such attitudes that had been exhibited by scientists at Monsanto and in academia. Given that public recognition that attitudes need to change in order to promote the new technologies, I was a bit dismayed to hear you talking about others within this forum having bad science, bad economics, and the general theme that you know the way things are. I think the criticism comes mostly from people who don't like to be patronized—also science is not necessarily neutral, as has been pointed out. As Fred said, there is always a question behind the question. For example, in your slide on Bollgard® cotton, you had asked the farmers if it had improved the wildlife on their farms. But, first you said that we have found that Bollgard® improves wildlife habitats on farms and then you asked if it improves it on their farms. No social scientist would load the question before asking it, basically telling them the answer.

Anderson: I understand your comments about arrogance. I don't recall the details of the apology you described, but initially at Monsanto we thought this technology was so good and the benefits would be so obvious that people would understand it. You could say we were taken aback by the fact that people didn't see the same things we did. Call that arrogance if you will, but we have no monopoly on that either. I'm a little taken aback by the fact that you say I demean people. I just pointed out that the person yesterday talking about finance needed to explore some more detail because, conceptually, it was wrong and I don't think I called him by name and I don't think I called it demeaning. But what you are really speaking to is the ability of a corporation, organization, a university to listen to your clientele and respond to their needs. I think we are past the point of arrogance in this industry in the sense that you are judged by your actions. Now, relative to the survey question I think I said before that we argued about how to ask the question. We all know that how you ask the question is important. I can take you to the growers who can give you that information. I can give you their names and addresses and show you their pictures and they'll be glad to talk to you. I have a lot of confidence that I'm correct. I've lost the end of your question, please follow up.

Garrett: I actually thought you had compelling evidence there.

Anderson: I think it's very compelling.

Garrett: In terms of Bollgard®, and I was just pointing to that particular question as to say—

Anderson: Yeah, and I pointed that out before I said it.

Garrett: —we cannot say that we scientists always do things correctly or that science is never neutral. That question was like push polling in politics. That kind of question would engender a response, so, to me, it took away the compelling evidence that you had in terms of wildlife habitat because of Bollgard®, which I have no doubt would definitely improve the habitat.

Anderson: I acknowledged before I put the slide up that the question might not be perfect. I think I said that. "Push polling" is not quite appropriate there. The key thing is that there's a body of evidence that says that biotechnology can generate wildlife benefits, particularly if they are looked at holistically on an agricultural landscape. In the wildlife conservation community—they still believe in good science and they're still very close to agriculture, and if you look at the demographics I described, they are going to be a lot closer in the future.

Gabrielle Roesch (Western Washington University, Bellingham, WA): Michael Taylor, FDA's deputy commissioner who wrote the FDA's rBGH-labeling guidelines formerly worked for Monsanto, and Margaret Miller, deputy director of FDA's Office of New Animal Drugs, was formerly a Monsanto research scientist who worked on Monsanto's rBGH-safety studies until 1989, and Susan Setchen, the primary viewer for rBGH in the Office of New Animal Drugs between 1988 and 1990 was involved in research under Monsanto-funded rBGH studies at Cornell University. Considering those connections between our regulatory frameworks and private interest, I'm curious what problems that represents to you all about the objective nature of our regulatory system.

Anderson: I suggest that it's naïve to think that Monsanto controls the FDA.

Roesch: That wasn't what I was saying, though.

Anderson: No no, but I'm going to finish. The regulatory system in this country requires tremendous amounts of research, evidence, and documentation. As was indicated in our session yesterday by the gentleman from the EPA, they brought in outside experts who didn't work with Monsanto—haven't taken Monsanto's dollars—and they listened to those people. They also have public-comment periods where you are entitled to comment, just like I am. So there's a misconception that the regulatory system in this country is broken and it's naïve to think that because someone used to work somewhere that they are still advocating a particular point of view. You can buy someone's time, but you can't buy their integrity, at least that's the way it's supposed to be. My point is, the regulatory system works; if you look around the globe there's not one that's better. If you look at the risk assessment, it is huge. Risk is assessed, and that is getting better. Transparency needs to be improved, in the sense that it is very difficult for someone who doesn't deal with it—regulatory science is a science in itself—to actually understand how it functions, and I can tell you from the discussion in our group yesterday that few people in that room understand how you take a product through the regulatory process. That's not demeaning, that's just fact.

Roesch: Does anyone else have a response to that question?

Trudy Bialic (PCC Natural Markets, Seattle, WA): I'm from a consumer-owned retailer of natural foods here in the Puget Sound area. I want to speak on the behalf of consumers, who often are overlooked in this debate, and to follow up on a couple of the comments just made. It would be a gross tactical error on the part of the biotech industry to underestimate the depth of passion that consumers have about genetically engineered foods. To suggest that we have a transparent process when we have more than two dozen examples of industry

people occupying the highest levels of the regulatory commissions, I think that would be a tactical error. I'm here primarily to encourage you to use your vast resources to transfer your skills and scientific endeavors into more medical applications and out of the food-crop industries. The advent of bio-farms is extremely disturbing to consumers. We have secret trials all around the country. Consumers know about them. We've been told that GE foods are not different enough to be labeled, but they are different enough to be patented. And I do think that it would be very valuable to heed the advice of the INVESCO report, the investment firm that reported that investments in biotech foods is a very bad risk right now—you can find that INVESCO report online—primarily because of the credibility gap between what the industry is trying to get consumers to believe and what consumers are perceiving. Essentially it comes down to an argument again for labeling. We're the only country in the world that allows rBGH milk. We stand alone. No other country in the world allows it. To think that we have that situation because we have a transparent process is fueling the organic industry at 20 to 25% a year.

Lomax: Do you have a question?

Bialic: I have a question. How do you reconcile between having foods different enough to be patented, but not different enough to be labeled so consumers can choose?

Anderson: I think there are people in the room who know far more about labeling than I, but the key to labeling, is that the label has to mean something and agreement on what that label means—when a lot of people have a lot of different opinions—is very difficult to come by. A patent is granted because someone had the insight to create something that is valuable, and the patent means you have 20 years or so to capitalize upon your discovery. It's a kind of government-approved monopoly, granted because you had creative insight. Transgenic plants are very different, in terms of the innovation it took to create them. They differ by a single gene or a single protein. They are substantially the same; a soybean is a soybean. So I don't have any problem resolving that issue. When we get to the point of having novel foods, then the discussion becomes very different and much more complex. Today we have a soybean that is very much like any other soybean except it has a single trait that allows a farmer to improve his business or his livelihood. Let me give you an example, and I hope I'm not getting into deep water. My wife works in the medical industry. She manages clinical trials for HIV. If you look at the current lack of capacity to produce pharmaceutical proteins that will improve people's quality of life, then I don't have any problem resolving the pharmaceuticals-in-plants debate. The new APHIS regulations are good, so that is almost an ethical question that I can live with. I don't see the big risk that you speak to. It comes down to being

awarded a patent or opportunity to capitalize on your creative insight and the pharmaceutical piece is basically a quality-of-life issue to me. People look forward to having therapeutic proteins available that are rationed because you can't produce enough of them. We come from very different perspectives. I don't have the risk concerns that you do, but I agree with you wholeheartedly that in this global economy, consumers have all the power. They make a market that is a very harsh judge of anything a company like ours does. They have all the power and so, if we make a mistake, the people whom we represent, the shareholders, understand those mistakes. From an ethical perspective I have no problem with pharmaceuticals in plants, from a risk perspective I have no problem. I have no problem with patents, but I think you are right in representing consumers because, in the end, you are going to decide what happens.

Kirschenmann: I'd like to add that there has been a lot of conversation around two aspects—one that was just raised about the consumer. It seems incredible to me that we are indicating that we don't have the aggregate intelligence to come up with a label to tell consumers what they want to know. I just find that difficult to believe, so I don't think that's the problem. I think there are other agendas at work here. The other things is the notion that we are going to be able somehow—with sufficient regulatory systems and control—to isolate a living organism within the environment and keep it from becoming mixed with other organisms. Everything I know from ecology and evolutionary biology tells me that that's a pipedream. Nature is designed to disperse its seed and it's going to find one way or another to do that. The notion that we're going to somehow isolate one organism from another is totally unrealistic.

Module III

Consumer Issues and Trade

Moderator: *Thomas Wahl*

Consumer Attitudes and Willingness to Pay for Genetically Modified Foods: A Cross-Country Comparison

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The introduction of genetically modified (GM) crops to world markets has created new divisions among commodity-trading countries. The United States and Canada have great economic interest in exporting transgenic crops, however, lack of public acceptance of GM-food products in the European Union (EU), Japan, and elsewhere, have already resulted in reduced or curbed demands. Many European and Japanese consumers believe that GM foods pose a threat to human health. They fear short- and long-run consequences for their own health and that of their offspring. The Chinese-consumer response is not well documented. Consumer attitudes and behavior toward GM food products are complex and differ across cultures. A better understanding is essential for designing market strategies. We have investigated factors that affect consumer acceptance of GM food in Japan, Norway, and China, and have estimated the discounts necessary for consumers to be willing to purchase GM food or the premium consumers would be willing to pay for an enhanced GM food. We have compared consumer preferences across countries.

Mandatory labeling of GM foods has obvious implications for trade. The EU has imposed mandatory labeling for some foods that contain GM ingredients. In October 1999, the EU gave preliminary approval to a law that requires labels on all foods containing more than 1% GM ingredients. In Japan, authorities have ordered mandatory labeling for twenty-nine categories of food if they contain

GM ingredients. Since June 2001, China has required that all GM products imported for research, production, or processing have safety certificates from the agricultural ministry with assurances that they are safe for human or animal consumption, and for the environment. Since March 20, 2002, labeling has been required in China for listed transgenic products. The United States has argued that there is no health-related or scientific reason to reject GM commodities and food products, and has challenged EU's mandatory GM labeling as a non-tariff trade barrier.

The Codex committees of the World Trade Organization (WTO) are working on harmonizing international standards and resolving trade disputes associated with labeling, to promote fair trade of foods while protecting consumer health. Since different countries have different attitudes toward GM-food products, the Codex framework allows each country to develop their own standards. The challenge of Codex is to set international standards for GM-food labeling that both promote fair trade and allow consumer choice. An important issue in GM labeling policy is scientific versus consumer sovereignty. Although the scientific consensus may be that GM foods are completely safe for consumption aside from potential allergens, it may be the case that a majority of the population in a given country prefers to avoid them.

Mandatory labeling forces United States producers to segregate crops to claim food products are "GM-free," which is difficult and costly. For example, many grain elevators are not physically equipped for segretation. United States producers may lose market share because consumers can reject their GM crops.

Related Studies

In recent years, the issue of GM labeling has received considerable attention. However, only a few published studies have included analyses of consumer willingness to pay (WTP) or willingness to accept compensation for food products that contain GM ingredients. Lusk *et al*. (2001) estimated WTP for corn chips made without GM ingredients. In their experimental study, junior- and senior-level agricultural economics students at Kansas State University indicated their WTP by exchanging a bag of GM corn chips for a bag of GM-free corn chips. They found that individuals very concerned about GM foods would be 50% more likely to be willing to pay a premium to exchange GM chips for non-GM chips than individuals with little concern for GM foods. However, their results indicated that 70% of all participants stated that they were not willing to pay a premium for non-GM chips. The average bid to exchange GM chips for non-GM chips was $0.07/oz. Still, 20% of participants were willing to pay at least $0.25/oz for the exchange, and 2% offered bids of $0.50/oz, suggesting that there is a potential niche market in the United States for non-GM products.

Baker and Burnham (2001) investigated American consumers' acceptance of GM corn flakes, and found that 30% of consumers based their purchasing

decision on GM content. Their analysis showed that cognitive variables (opinions, beliefs, knowledge) had a great influence on preference. The level of risk aversion, knowledge about genetic modification and opinion about genetic modification were highly significant in explaining the purchasing decision. Previous studies on the relationship between consumer characteristics and food-safety concerns generally found that sociodemographic variables (like education and income) performed poorly as explanatory variables for purchasing decisions regarding GM-food products. The exception was that women in general were more concerned with food safety.

Lusk *et al*. (2003) estimated consumer WTP for beef in France, Germany, the United Kingdom, and the United States using a variety of quality variables including whether the cattle had been fed GM corn. Their results suggested that the European consumers placed a much higher value on beef from cattle that have not been fed GM corn compared with consumers in the United States.

Our Surveys

In August 2001, we conducted 400 in-person interviews in Japanese at the Seikatsu Club Consumer Cooperative (Seikyou), a grocery-store-like setting in Matsumoto City, Japan. Matsumoto is a relatively agricultural area where about 13% of the population come from farm households compared to 2% for all of Japan. Consumer cooperatives usually focus on a marketing strategy of featuring a higher level of food safety. The Seikyou has significant power in the Japanese marketplace.

In January 2002, we conducted 400 in-person interviews in Norwegian at the RIMI Liertoppen grocery store in the Oslo area, which is the most populous part of Norway and one of the main centers of economic activity. The RIMI chain of grocery stores has chosen a low-price/limited-selection niche in the market, and has thus gained significant power in the Norwegian marketplace.

In August 2002, we performed 599 in-person interviews in Chinese in Beijing. The survey was conducted at four locations: a supermarket, two outdoor markets, and one shopping area. These locations were chosen to obtain a cross-section of the local population.

The surveys solicited respondents' demographic information, their attitudes about the environment and food safety, and their knowledge and perceptions about biotechnology. Further, respondents were asked if they were willing to pay the same price for a particular GM food as for a corresponding non-GM product. In Japan, we asked about GM noodles and GM tofu; in Norway, we asked about GM bread, and GM-fed salmon; and in China, we asked about GM rice and GM soybean oil.

Empirical Analysis

The contingent-valuation (CV) method is currently the standard approach to elicit WTP through a dichotomous choice, market-type questioning format

conducted by direct survey via telephone, mail, or face-to-face (Kanninen, 1993). Our surveys included CV questions regarding willingness to pay a premium or accept a discount to purchase GM-food products.

Consumers were first asked if they were willing to pay the same price for the GM product as for the corresponding non-GM products. If the respondent's answer was "no," (s)he was offered a percentage discount on the GM product relative to the non-GM counterpart. In China only, if the respondent's answer to the first question was "yes," the respondent was offered a percentage premium on the GM product relative to the non-GM product. For the survey in China, the discount was set at one of the following levels: 10%, 20%, 25%, 50%, or 75%. The premium for the GM rice was set at one of the following levels: 10%, 20%, 25%, 50%, or 100%. The premium for the GM soybean oil was set at one of the following levels: 5%, 10%, 20%, 25%, or 50%. Each level of discount or premium was used for one fifth of the surveys. The assignment of survey version (and thus, discount or premium) was random to the respondent. The rationale for using differing premium amounts for the GM rice versus the GM soybean oil, was that the respondent was given information regarding a *product-enhancing* attribute of the GM rice, but was not given information regarding either a *product-enhancing* or a *process-enhancing* attribute for the GM soybean oil. Hence, it was expected that those respondents willing to pay a premium for the GM product would pay more for the *product-enhancing* product than for the other.

Econometric Models

In the standard double-bounded model, there are four possible outcomes: (1) the respondent is not willing to purchase the GM product at the same price as the non-GM product, nor at a discount relative to the non-GM product, *i.e.* "no" to both bids; (2) the respondent is not willing to purchase the GM product at the same price as the non-GM product, but is willing to purchase the GM product at the random discount offered, a "no" followed by a "yes"; (3) the respondent is willing to purchase the GM product at the same price as the non-GM product, but is not willing to purchase it at a premium, *i.e.* a "yes" followed by a "no"; (4) the respondent is willing to purchase the GM product at the same price as non-GM product and also willing to purchase at a random premium offered relative to the non-GM product, *i.e.* "yes" to both bids.

Double-bounded logit models (Hanemann *et al.*, 1991) were used in this analysis. In this model, the initial bid (B_0) equals zero and implies no price difference between the GM product and the non-GM product. The second bid is contingent upon the response to the first bid. It will be a discount bid (B_D), if the respondents answer that they would not buy the GM product at the same price as the non-GM product. If they answer that they would buy the GM product at the same price as the non-GM product, it becomes a premium bid (B_P).

The sequence of questions isolated the range in which the respondents true WTP for GM products relative to non-GM products lay. The second bid, B_D or B_P, in conjunction with the response to the initial preference decision, allowed an upper bound and a lower bound to be placed on the respondent's unobservable true WTP for GM-food products.

Let WTP_i denote an individual's WTP (bid function) for a GM food. The following discrete outcomes of the bidding process are observable:

$$D_g = \begin{cases} 1 & WTP_i < B_D \\ 2 & B_D \leq WTP_i < B_0 \\ 3 & B_0 \leq WTP_i < B_P \\ 4 & B_P \leq WTP_i \end{cases}$$

Respondents who indicated they would require no discount and accepted the highest premium fell into the fourth group. Those indicating no discount and a premium less than B_P fell into the third group. Next, respondents who required a discount greater than or equal to B_D, fell into the second group. Finally, the first group contained respondents indicating the lowest WTP. Consumers in this group were not willing to purchase the GM product at the discount offered. The WTP function for GM-food products for individual i is

$$WTP_i = \alpha - \rho B_i + \lambda' z_i + \varepsilon_i \text{ for } i=1,....n$$

where
B_i is the ultimate bid individual i faces,
z_i is a column vector of observable characteristics of the individual, and
ε_i is a random variable accounting for random noise and possibly unobservable characteristics.

Unknown parameters to be estimated were α, ρ, and λ. Linearity in z and ε was assumed for all individuals. Furthermore, the distribution of the error term was assumed to follow the standard logistic distribution function with mean zero and standard deviation $\sigma = \pi / \sqrt{3}$. The bid information and other demographic information were used to estimate the magnitude of those factors that affect consumers' WTP for GM-food products and how much of a relative premium consumers will pay to purchase GM-food products.

RESULTS

Our results for Japan showed that variables representing food safety and environmental attitudes, self-reported knowledge about biotechnology, self-

reported risk perceptions toward GM foods, income, and education all significantly increased the discount that would be required for consumers to choose GM foods. Our results indicate that Seikyou members, on average, wanted a 60% discount on GM noodles compared to non-GM noodles. For GM tofu, a 64% discount compared to non-GM tofu was necessary.

With the Norwegian data, increasing self-reported risk perceptions toward GM foods and preferences for domestically produced food both significantly increased the discount required for Norwegian consumers to choose GM foods. Our results indicate that, on average, the Norwegian consumers in our sample wanted a 49.5% discount on GM bread compared to the conventional item. For GM-fed salmon, a 56% discount compared to non-GM salmon was necessary. The reason for the higher mean required discount for salmon may be that many people were more sensitive to genetic modification associated with animals than with plants.

Interestingly, our results for China presented a very different picture. A prevailing positive opinion regarding biotechnology significantly increased consumer confidence in GM foods. In fact, Chinese consumers were willing to pay a premium for GM foods. Our results indicated that, on average, they were willing to pay 38% more for GM rice over non-GM rice. (Age significantly decreased consumers' willingness to pay a premium.) They were willing to pay a 16% premium for GM soybean oil over non-GM soybean oil. This is not surprising given that 23% of the survey respondents were very positive about the role of biotechnology in foods, and 40% of the respondents were somewhat positive. It makes sense that consumers in China, who exhibited a low perception of risk associated with GM foods (82% felt these products present little or no risk) would be willing to pay a premium for GM products.

Consumer attitudes concerning biotechnology may reflect the Chinese government's strong support of such technologies. Thus far, the controversy in Europe and Japan is not evident in China, but new regulations regarding labeling and safety testing will likely lead to increased public awareness of the application of biotechnology to agricultural products.

Why were the Chinese results so different? One possible answer lies in historical differences. The European countries and Japan gradually developed modern capitalist societies while taking great concern and pride in preserving cultural traditions. For the Chinese, history took another turn. The Cultural Revolution from 1966 to 1976 systematically tore down historical and traditional structures in the society. The past was condemned as "feudal and superstitious" (Time, 2002). The resulting vacuum was, to some extent, replaced by the communist state. Now, with a highly desired and rapid transition to capitalism and with many traditions crushed by the Cultural Revolution, the Chinese are forward-looking. Technological novelties from the rest of the world are often considered much needed improvements and not reasons for concern.

Conclusions

The Japanese and Norwegian cultures both place a great deal of value on tradition. This worldview extends to the food they eat and give to their children. Therefore, it is not surprising that most Japanese and Norwegian consumers want to avoid GM foods. Based on the consumer responses in our studies, we would not recommend marketing GM foods to Japan and Europe. The vast majority of our Chinese respondents had a positive attitude, in general, toward science and toward the use of biotechnology in agriculture. The marketing outlook for GM foods in China is optimistic. Younger people were more willing to purchase GM-food products with product-enhancing attributes, which indicates that the Chinese market may be even more open to GM foods in the future. Additionally, government investment into biotechnology remains strong, as China works to fulfill its self-sufficiency food policies.

Acknowledgments

We thank, without implicating, Hiromi Ouchi, Maria Loureiro, Phil Wandschneider, and Kyrre Rickertsen for helpful comments, and gratefully acknowledge financial support from the IMPACT Center at Washington State University.

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Regulating Biotechnology: GM Food Labels

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Discussions of appropriate regulatory norms for foods derived through modern biotechnology date back to the early 1980s. Almost 20 years later, agreement among key trading countries on what such norms should be remains elusive. Some countries, including the United States and Canada, consider biotech or genetically modified (GM) foods substantially equivalent to conventional counterparts and regulate them similarly. Others, including the European Union (EU) and Japan, scrutinize and require mandatory labeling of GM foods.

Opponents of mandatory labeling have argued that it is unwarranted and costly. Proponents have argued that it is necessary to safeguard the informed consumer choice. Both such arguments have found acceptance in different parts of the world, raising questions about the optimal regulatory approach to GM-food labels and the factors that influence regulatory decisions. I address these questions in this paper.

Global Labeling Regulation of GM foods

Labeling regulations for GM foods around the world are highly fragmented—a patchwork of country-specific initiatives that continue to evolve. In 1986, the Organization for Economic Cooperation and Development (OECD) recommended that risks associated with organisms derived through modern biotechnology be regarded as the same as those from the conventional and could be assessed in similar ways. This concept of "substantial equivalence" has been mirrored in the United States and Canadian regulatory regimes where new food products derived through modern biotechnology are assessed for safety and nutritional fitness. Accordingly, mandatory labeling is not required unless the novel food products are substantially different from their conventional

counterparts.[1] At the same time, both countries have developed guidelines for use by producers, processors and merchants interested in voluntary labeling to indicate presence or absence of GM ingredients in their food products.[2]

Regulation in some other countries has focused on the process of biotechnology rather than on the product. In the EU, a process-specific regulatory framework was adopted early on and has evolved over time. Specifically, the European Commission decided to regulate biotechnology by newly installed institutions, starting with the deliberate release of genetically modified organisms (GMOs) in 1990. In 1997, the European Commission mandated labeling of GMOs and of food products derived from them. The presence of novel DNA or protein resulting from genetic modification was made the criterion for labeling. A standard was established in 1999 when the mandatory labeling threshold of the novel DNA or protein was set at 1%. Mandatory labeling was extended to food additives and flavorings in 2000.

In 2001, the European Commission adopted two new legislative proposals that sought to broaden mandatory labeling beyond foods and food ingredients. The proposals were adopted by the European Parliament and the Council of Ministers in July of 2003 and were expected to be enacted by year-end. When implemented, the new regulation will require labeling of animal feeds and feed additives as well as highly refined oils, sugars and starches and will affect a significantly increased portion of the market since a large share of GM commodities is used for the production of animal feed (Ballenger *et al.*, 2000; Kalaitzandonakes, 2000). Labeling will be mandatory also of products that are derived from GMOs but do not contain detectable levels of novel DNA or protein (*e.g.* highly refined oils). Under these circumstances, enforcement of mandatory labels can no longer rely on laboratory testing. Instead, the new regulation mandates the implementation of a traceability system that requires chain of custody and accountability for all GM commodities and food ingredients at each point of the European agrifood marketing chain.

Other countries have also mandated labeling of GM foods, but their regulatory regimes are more liberal than that of the EU. For instance, Japan and South Korea have introduced mandatory labeling for food products that contain over 5% and 2% of GM food ingredients, respectively. Mandatory labeling rules in both countries, however, have affected only a very small part of the market as they explicitly exclude animal feeds, highly processed foods and many oils. Similarly, Australia and New Zealand require mandatory labeling for whole foods, processed foods, fruits, and vegetables that contain more than 1% of GM

[1]If a GM food has significantly different nutritional properties from its conventional counterpart, its label must reflect the difference. Similarly, if the new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

[2]Formal guidelines for voluntary labeling of GM foods in Canada are expected in early 2004.

material. Highly refined foods, such as oils, sugars and starches are again excluded from mandatory labeling.

Labeling regulation levied on GM foods around the world could remain fragmented for some time, as countries continue to go their separate regulatory ways. But what factors drive governments in different parts of the world to intervene so variously in the functions of their markets? And what is an appropriate framework to examine the relevance and optimality of such regulatory interventions?

Why Do Governments Regulate And When Should They?

Since Adam Smith, market economists have argued that perfectly competitive markets yield optimal outcomes and that, given resources and technology, no rearrangement of goods and services can unambiguously improve the welfare of society. Government intervention in the functions of the market then has been justified, principally, on two grounds: (a) equity improvements through more desirable outcomes in the distribution of goods and services, and (b) efficiency improvements when markets fail.

Market failure can occur under a variety of circumstances that can generally be viewed as presence of: (a) market power (including natural monopolies), (b) asymmetries in market information and (c) externalities and public goods (Noll, 1989). Market failure is the predominant justification for regulatory intervention. Market failure, however, does not constitute a mandate for government regulation. It simply suggests that government regulation might be beneficial. The economic literature includes an array of alternatives that often turn out to be preferable to regulation for coping with market failures (*e.g.* relevant use of taxes and subsidies, use of incentives to influence private decisions, and, quite often, "doing nothing"). The standard criteria governments must then confront as they consider alternative regulatory policies are:

- Is there, indeed, a market failure?
- If so, would regulation be efficient? That is, would the social benefits secured through regulatory intervention exceed the costs?
- Would the regulation be cost-effective? In other words, would the regulatory policy of choice be the lowest cost option for achieving the policy goals?

Cost-effectiveness ensures that overall policy goals are achieved at minimum cost, eliminating unproductive alternatives. However, cost effectiveness does not ensure that the regulation is in the best interest of society. For that, the regulation must be shown to be efficient—*i.e.* that it generates more benefits to society than costs.

Clearly, much discussion about the optimality of regulation revolves around social benefits and costs. Clarifying the ways a particular regulation benefits and burdens a society then helps size up the expected net social welfare gains

(social benefits minus costs). In this context, a government's reasoning for intervening in the market is important.

Regulation of GM Foods: Mandatory Labeling

So, what is the reasoning of governments for intervening in their respective markets and mandating the labeling of GM foods? Proponents of mandatory labeling of GM foods have rationalized the need for regulatory intervention on two separate grounds: (a) possible existence of health risks from the consumption of GM foods and (b) presence of informational asymmetries (Hobbs and Plunkett, 2000).

Health Safety Concerns and GM-Food Labels

Two kinds of safety concerns have been raised about GM foods over the years (Hobbs and Plunkett, 2000): specific health concerns (*e.g.* the potential for transferring allergens across foods) and "unknown" long-run health concerns. The latter have been motivated by doubts that scientists can predict the impacts of cumulative GM food consumption over long periods of time. Lack of specific hypotheses and failure to articulate potential hazard mechanisms, however, have led some to dismiss this kind of concern as "fear of the unknown" [*e.g.* the US Food and Drug Administration (FDA)]. Specific health concerns have attracted more attention.

If specific health risks from consumption of GM foods could be substantiated, then market failure could materialize. Individuals with imperfect knowledge of relevant risks would be unable to make sound decisions leading to inefficient market outcomes and market failure. Under such circumstances, regulators could impose outright bans. Alternatively, regulators could choose to mandate labels to serve as hazard warnings. Hazard-warning labels have been used by regulators in cases when the risks are not great enough to warrant the ban of a product, but too troubling to ignore (Viscusi *et al.*, 1986).[3] With increased information through mandated labels, users with different susceptibilities to a particular health risk, different tolerances for risk, and different product needs and usage rates can select a bundle of product attributes—including risk—that corresponds to their preferences and needs. Within this context, mandatory labeling could yield social welfare gains.

In order to increase the market information about potential health risks associated with GM foods, governments around the world have used similar approaches. In the United States, the FDA has published guidelines on the questions that companies need to answer in assessing the safety of GM foods. Test results are submitted to the FDA for evaluation throughout a consultation

[3]Examples of hazard-warning labels in the United States can be found in the use of toxic chemicals, previously unregulated workplace carcinogens, use of consumer products as home insulation and wearing-apparel textiles, and consumption of alcoholic beverages and tobacco products.

process. While consultation with FDA is voluntary, all GM foods that have been approved for commercialization have undergone such a review.[4]

The European Commission requires all GM foods to undergo premarket risk assessment and approval. Each individual product must be subjected to a scientific review to ensure that it poses no risks to public health, animals, or to the environment. A new centralized agency—the European Food Safety Authority—was created and charged with all scientific safety assessments and communication with the public. Following scientific assessment, product-approval decisions rest with the Council of Ministers.

In the premarket risk assessment of GM foods, the European Union has advocated the use of the controversial "precautionary principle." In effect, the principle argues that, when in doubt about the potential environmental or health safety impacts of any GM product, one should err on the side of caution. Critics have countered that the principle advocates an impossible and impractical burden of proof in establishing "absence of harm" with no uncertainty. Irrespectively, the scientific assessment processes in the European Union, the United States, and also in Japan, Australia, and elsewhere, involve similar test regimens and have arrived at similar conclusions: the reviewed GM food products pose health risks similar to their conventional counterparts.

Informational Asymmetries and GM-Food Labels

Despite lack of evidence of any extra health risks from GM foods, consumer preferences towards marketed GM foods might range from complete aversion to indifference.[5] The technical rationality of consumer aversion is not material. Aversion might be associated with consumer values and beliefs, ethical and religious convictions, level of understanding of modern biotechnology, and other personal factors.

Under these circumstances, some consumers could derive differential utility levels from consumption of GM and conventional foods and, accordingly, exhibit differential demand for GM and conventional products. Consumers could encounter difficulties, however, in articulating their, potentially, differential demand for GM and conventional food products in the market-place. Genetically modified and conventional foods are indistinguishable through standard product-inspection practices, before or after consumption. These informational imperfections could lead markets to operate sub-optimally as consumer outlays could be misaligned with their underlying willingness to pay for GM and conventional food products. Supply of relevant information on the GM content of various foods could then provide market efficiencies by

[4]In 2001, the FDA proposed a rule that will make the current consultation process mandatory.

[5]Only first-generation GM food products are considered here, which are assumed to have no distinguishable consumer attributes from those of their conventional counterparts.

causing supply and demand for GM and conventional food products to more closely match.

Labels could be used to inform consumers about the presence or absence of GM ingredients in various food products (Caswell, 2000). Practical implementation of labeling, however, affects the entire agrifood marketing chain in requiring identity preservation (separation) of GM and conventional commodities, ingredients, and processed foods, from seed to the supermarket shelf. Labeling is, therefore, costly. In this market context, producers across the agrifood marketing chain could recognize differential consumer demand for various GM and conventional food products and, after accounting for incremental costs, they could decide to voluntarily label their products in order to differentiate them in the market place and increase their share and profits. Alternatively, informational asymmetries between producers and consumers could be such that supply and demand would not converge, raising the possibility of market failure and the potential need for government intervention.

Confronted with the possibility of market failure, governments could consider whether they should mandate GM labels as a remedy. In this context, mandatory labeling in a given market could be justified as a means of ensuring informed consumer choice and efficient market operation, notwithstanding scientific assurances that GM and conventional foods are equally safe. Of course, regulators must evaluate the merits and relevance of mandatory labeling policy against the standard criteria any regulation must confront: would there, indeed, be a market failure necessitating regulatory intervention? If so, would regulation be efficient and cost-effective?

Given that some governments have mandated labeling of GM foods, they apparently arrived at the conclusion that if markets were left on their own they would fail. They also concluded that specific mandatory labeling policies installed (*e.g.* types of foods to be labeled, thresholds at which requirements for labels are triggered, traceability requirements) are efficient and cost-effective. Six years after the commercial introduction of GM foods in the global market, is there sufficient evidence to support such judgments?

The Economics of GM Labels

Is Market Failure Apparent or Unavoidable?

Miller and Van Doren (2001) argued that market failure would be evident only if food markets were unable to segment despite differentiated consumer demand for GM and conventional products. Put differently, if markets responded to differential consumer demands achieving, so called, separating equilibria, then the case for market failure is undermined. Substantial voluntary "non-GM" and "GM-free" labeling activity as well as other forms of market segmentation for GM and conventional food products would then signal a diminishing prospect of market failure.

Assessment of whether market failure exists is rather difficult in some markets. For instance, in the European Union, mandatory labeling was implemented before any significant commercialization of GM foods and, hence, markets were effectively preempted. One must, therefore, evaluate the counterfactual of whether there would have been market failure (or how well markets would have segmented) in the absence of preemptive regulation. Empirically, this is a difficult assessment as it is difficult to anticipate all the possible ways firms might have attempted to differentiate their products in the marketplace in order to accommodate the preferences of various consumer segments. For instance, while some firms could have voluntarily labeled for GM content (*e.g.* making "non-GM" or "GM-free" claims), others could have used in-store information and could have leveraged their brand equity to assure consumers of product safety and quality.[6] Similarly, it is tricky to, *ex post*, measure what would have been the demand for GM and conventional foods in the absence of regulation. Upfront regulatory requirements for mandatory labeling could have signaled increased product risk for some consumers and could have influenced their preferences towards GM foods.

Despite these and other inherent empirical difficulties, there is evidence that firms have extensively used voluntary "GM-free" or "non-GM" labels to differentiate their products in markets around the world. Kalaitzandonakes and Bijman (2003) have reported significant and strategic voluntary labeling activity in European markets for products that are not covered by current mandatory labeling requirements. Major retail chains—Sainsbury, Tesco, and ASDA in the United Kingdom, Carrefour in France, Delhaize "Le Lion" in Belgium, Migros and Coop in Switzerland, *etc*.—have offered labeled products from animals reared on non-GM feed (*e.g.* meats, eggs, poultry, dairy and various related processed foods). Large food-service chains, like Burger King, have also opted for serving poultry products reared on non-GM feeds. While such chains do not offer both product lines in their stores, many of their competitors have not followed such strategies, thereby allowing market segmentation. A host of small and medium-size manufacturers and retailers in the European Union have also actively participated in the "non-GM" and "GM-free" markets, offering a wide variety of products, from cookies and meats to cotton wool.

In addition to market differentiation through "non-GM" and "GM-free" claims, further segmentation has been achieved in the European Union through broad offerings of products that are considered substitutes to GM commodities and foods. These include organics that explicitly preclude use of GMOs as well as commodities where GM varieties have not been marketed (*e.g.* wheat and sugar beet), thereby guaranteeing, though often implicitly, non-GM status. Organics alone amount to a $9 billion market in Europe with a full range of

[6]Noussair *et al.* (2002), for instance, have determined through experimental auctions that French consumers could readily substitute trust in specific food brands for explicit information on GM content.

products, from dairy, fresh and frozen meats, fruits and vegetables to a variety of drinks, including spirits, and prepared foods.

Active segmentation of GM and conventional commodity, ingredient, and processed food markets can be found in many other parts of the world. For instance, in the United States, the production of an estimated 2.5 million acres of corn and soybean have been identity-preserved and directed to the non-GM market segment every year since the late 1990s. Similarly, there has been active market segmentation and voluntary labeling of processed foods. A few large US manufacturers (*e.g.* Gerber, Heinz, and Frito-Lay) have announced non-GM status while some specialized food manufacturers (*e.g.* Hain Celestial, and Eden Foods) and retailers (*e.g.* Whole Foods, and Wild Oats) offer a wide range of products voluntarily labeled as "non-GM." In most cases, such voluntary labels also claim organic status indicating the close attribute overlap in the preferences of consumers targeted by these products. In recent years, "non-GM" claims in the United States have been increasingly subsumed into organic labels. Sloan (2002) explained that a large percentage of core consumers seek out organics specifically to avoid GM foods. Accordingly, in the United States, the "non-GM" and organic segments have been converging, representing a $6 billion market with extensive offerings in virtually every food-product category.

Probably the most direct case of voluntary labeling in the United States is the small but stable market of milk labeled as "free of rBST"—a bioengineered hormone that induces yield increases in dairy cattle; "rBST-free" milk has been sold side by side with unlabeled milk since 1995 and is currently estimated to represent about 1.5% of the total whole milk market in the United States.

There is also empirical evidence of active differentiation between GM and conventional food products in Japan, Korea, Taiwan, Thailand, and elsewhere. For instance, futures for non-GM soybeans have been actively traded in the Tokyo Grain Exchange since 2000. Similarly, voluntary "GM-free" or "non-GM" labels have been placed on a variety of processed foods in the Japanese market—from soy sauce and tofu to corn snacks and potato chips.

Clearly, the empirical evidence on voluntary market response for GM labels is sketchy. Furthermore, the existence of market failure can be fully examined only through joint analysis of supply and demand conditions. Still, the substantial voluntary labeling activity and product differentiation that exists today through various firm initiatives in markets around the world suggests that market failure is by no means obvious or demonstrated.

Is Mandatory GM-Labeling Regulation Efficient?

Even if economic analysis could demonstrate that markets would indeed fail and that efficiency gains were possible through regulatory intervention in the case of GM foods, only a necessary condition for regulation would have been established. Additional analysis would be needed to demonstrate that selected regulatory policies are both efficient and cost effective.

Cost-benefit analysis is necessary to confirm that these sufficient conditions for regulation hold. Appropriate value must be assigned to the benefits that society derives from mandatory GM-food labels and the relevant costs must be calculated. Giannakas and Fulton (2002) considered the problem and obtained the conditions of optimal labeling regimes for GM foods in markets with differentiated consumer demand. They showed that the relative optimality of mandatory labeling regimes depends chiefly on the level of consumer aversion to GM foods, the costs associated with mandatory labeling, and the extent of mislabeling. Naturally, the desirability of mandatory labeling increases as a society's aversion to GM foods grows, labeling costs decline, and the probability of mislabeling in the specific market is reduced.

The level of aversion to GM foods exhibited by society is determined both by the degree of aversion and by the distribution of aversion among consumers. In a market with widespread and intense aversion towards GM foods, benefits from mandatory labeling would be expected to be substantial. Society's differential willingness to pay for GM and conventional foods provides a proper measure of societal benefits from mandatory labeling. Estimates of willingness to pay may be derived through consumer interviews. But as Viscusi and Gayer (2002) explained, due to their hypothetical nature, such estimates often turn out to be misleading. Instead, economists prefer to turn to actual market behavior for insights.

The Benefits of GM Labeling

What do we know about the degree of aversion of various consumer groups towards GM foods, their differential willingness to pay for GM and conventional foods and relevant interest in GM food labels? We know less than is typically presumed. Despite regular references by the European Commission, for example, to the strong interest of European consumers in GM-food labels and their aversion to GM foods, market evidence for such behaviors is almost non-existent. Indeed, much of what is known today about consumer purchasing intentions towards GM foods and about interest in GM labels in Europe (and elsewhere) is inferred from attitude surveys, such as the Eurobarometer (European Commission, 2003). Indeed, such surveys have long indicated widespread public skepticism towards GM foods and interest in mandatory GM labels. Attitude surveys can capture public sentiment towards GM foods and biotechnologies, but are constrained by their hypothetical structure, especially since they do not account for price and income effects on consumer-stated preferences. Attitude surveys may also engage their subjects as citizens rather than strictly as consumers. Importantly, as Sterngold *et al.* (1994) explained, attitude surveys are subject to significant biases. How questions are framed, the order in which information is presented, and the degree of knowledge and understanding of the respondent are just some of the potential sources of bias and error. Accordingly, attitude surveys may, or may not, provide effective

proxies of consumer-market behavior and willingness to pay for GM and conventional products or relevant GM labels.

While the bulk of existing research has focused on attitudinal surveys, a handful of researchers have utilized willingness-to-pay surveys and experimental auction-market techniques to capture how consumers might respond to GM foods if faced with realistic food choices (*e.g.* Huffman *et al.* 2003; Lusk *et al.*, 2001; Moon and Balasubramanian, 2001; Noussair *et al.* 2002). Some of these studies have arrived at conclusions that are qualitatively different from those obtained through attitude surveys. For instance, Noussair *et al.* (2002) studied the response of a representative sample of ninety-seven consumers to "GM" versus "non-GM" labeled and organic foods in an experimental laboratory setting in Grenoble, France. The authors concluded that 35% of consumers boycotted GM-labeled foods, but the rest were willing to purchase products containing GM ingredients at some prices or were indifferent and would purchase them regardless—a conclusion different from those drawn from attitude surveys in France. Of course, experimental auction market analyses and survey-based willingness to pay studies are still hypothetical in nature. Accordingly, elicited consumer-stated preferences can be different from normal purchasing behavior exhibited by the market.

In the literature on consumer behavior towards GM foods, only a handful of studies have focused on revealed rather than stated preferences (James *et al.*, 2002; Kiesel *et al.*, 2003; Marks *et al.* 2003). Of these three studies, only one has examined consumer response to positively labeled GM products (*e.g.* "this contains GM ingredients") in a market with presumed consumer hostility.[7] Specifically, Marks *et al.* (2003) examined how consumers actually behaved when they could choose between positively labeled GM foods and unlabeled conventional food products in supermarkets across the Netherlands over a 3-year period. Empirical results indicate that, on aggregate, Dutch consumers did not change their purchasing behavior towards processed foods after labels indicating the presence of GM ingredients were placed on them. Hence, consumer avoidance of GM foods was not confirmed.

Divergence between stated preferences and actual purchasing behavior in the case of GM foods has been observed in the past. Aldrich and Blisard (1998) summarized studies on consumer attitudes carried out as rBST was being introduced in the United Staes in 1995. Such surveys indicated that three out of four consumers expressed interest in avoiding milk from rBST-treated cows

[7] James *et al.* (2002) set up a limited market experiment and observed consumers' purchasing patterns towards GM and non-GM sweet corn placed in a few grocery stores in a single US location. Kiesel *et al.* (2003) examined a national dataset of actual consumer purchases of fluid milk produced with rBST and rBST-free milk in the United States. Thus, they examined consumer response to negative ("does not contain") labels. Their results indicated that a small segment of consumers respond positively to such labels.

and in relevant labels that could facilitate choice. Hindsight being 20-20, we now know that such attitudes did not translate into significant changes in purchasing behavior—or avoidance—on the part of US consumers. The vast majority of US consumers purchased milk from rBST-treated cattle even when "non-rBST" milk was offered side-by-side at minimal premiums.

The important point here is that current knowledge on the distribution and intensity of consumer aversion towards GM foods is limited. Accordingly, little is known about the size of the social benefits derived through mandatory labels of GM foods in various markets.

The Costs of GM Labeling

As in the case of social benefits, comprehensive estimates of the regulatory costs associated with GM-food labeling are scarce. A small number of studies, mostly from North America, have measured some of the costs associated with GM labeling. Most such studies have focused exclusively on the compliance costs of the regulation—the incremental costs associated with physically separating as well as preserving, testing, and assuring the identity of various GM or conventional foods across the agrifood marketing chain. Compliance costs are certainly worth close scrutiny as they can be substantial, especially in the case of commodities used in thousands of processed foods, like corn and soybeans. Nevertheless, most existing studies are limited in scope, as they have focused on a small subset of products and limited portions of the agrifood marketing chain. Only a handful of studies have investigated compliance costs across large portions of the agrifood marketing chain. Most such studies indicate that compliance costs can be quite meaningful (KPMG, 2001; National Economic Research Associates, 2001).

While estimates of compliance costs are incomplete, other possible costs from GM-labeling regulation remain entirely unarticulated. Chief among them are bureaucratic monitoring and enforcement costs, costs from loss of trade, and costs associated with potential structural impacts from regulation and potential inefficiencies in implied market structures.

Credibility of GM Labeling

Beyond benefits and costs, the relevance and optimality of mandatory GM labeling are also influenced by the credibility of the system or the probability of mislabeling. Mislabeling refers to cases where producers (by accident or intention) falsely label food products as "non-GM" or fail to label products as "GM" when required. As the incidence of mislabeling increases and consumer trust is eroded, the social benefits from labeling are reduced and its desirability is diminished.

The possibility of mislabeling foods for GM content is not remote. Under most current mandatory labeling regimes, presence or absence of GM ingredients can be assured through laboratory analysis. Given that analytical

testing is based on statistical methods, some testing error (*e.g.* sampling error, array systemic error) must be assumed and accepted. Lack of standardization of sampling and testing protocols, validation procedures or performance criteria in laboratory tests of GM foods amplifies the probability of testing errors, the existence of which has been verified by a number of laboratory ring trials around the world. A recent report published by the Australian Government Analytical Laboratories (2002) is one of several that have documented such errors. Similarly, mislabeling has been confirmed. Most recently, the Irish Food Safety Authority through its 2002 market survey determined that 32% of the surveyed "GM-free" products were mislabeled. The degree of understanding among consumers of mislabeling possibilities and relevant impacts on their purchasing decisions is unclear.

Is Mandatory GM Labeling Cost-Effective?

Even if net welfare gains from GM labeling in any given market could be positive, some attention to the cost-effectiveness of specific mandatory labeling policies would still be warranted. Effectiveness considerations require that alternative policies that could achieve the overall policy goals at lower regulatory costs be explicitly investigated. Alternative policies to mandatory GM labeling, for instance, might include incentives for voluntary labeling and establishment of third-party certification bodies in order to reduce the costs for verification of "non-GM" and "GM-free" claims.

Attention to the standards of mandatory labeling policies is similarly necessary as they affect the efficiency and cost-effectiveness of the policies in question. To clarify, consider the evolution of GM-labeling standards in the European Union and corresponding changes in social welfare. Since the inception of the mandatory labeling policy, the European Commission has incrementally stretched its GM-labeling regulation by continuously broadening the definition of what constitutes a "GM food" and, more recently, by requiring full traceability across the agrifood supply chain. In 2001, a study commissioned by the UK Food Standards Agency included comparative institutional analysis for these alternative GM-labeling policies. The study estimated that compliance costs would increase eight-fold in the United Kingdom—from $140 million to over $1 billion—when the mandatory labeling regime expands from food ingredients to include feeds and oils. This result prompted the authors of the study to conclude that "the extra costs of moving towards the more stringent GM-labeling standards outweigh the extra benefits that can be achieved."

The credibility of the progressively rigid GM-labeling regime in Europe was also called into question. For the bulk of the market, enforcement will no longer rely on analytical laboratory testing but on chain-of-custody certificates and traceability systems, both inside the European Union and in exporting countries. Practical implementation of such systems implies increased

possibilities of fraud and problems with enforcement. These issues prompted the UK Food Standards Agency to conclude that "the (pending regulation) is not practical, proportionate, or enforceable."

While broadening the scope of mandatory GM labeling, the EU government has also sought to tighten the standards (tolerances) in defining GM and conventional foods. Kalaitzandonakes *et al*. (2001) have explained that compliance costs increase non-linearly as tolerances diminish beyond certain low thresholds, like those awaiting implementation in the European Union.

The key point here is that implementation standards matter in determining the efficiency and cost-effectiveness of a given labeling policy. And, based on scant empirical data, the efficiency and effectiveness of certain mandatory labeling policies could prove questionable.

Concluding Comments

Market failure is the predominant justification for regulatory interventions of all kinds. Potential market failure has also been the basic argument behind calls for mandatory labeling of GM foods. This argument is, indeed, theoretically well founded.

As I have argued here, however, there is little empirical evidence to suggest that any of the necessary and sufficient conditions for mandatory labeling of GM foods is satisfied. Indeed, it is possible that mandatory GM-food labeling policies installed in some countries could fail all three standard criteria used to justify regulatory intervention:

- A case has not been made that a market failure actually exists or should be expected. Despite evidence that voluntary labeling and other market-driven solutions emerge to satisfy various consumer segments with differential demands, governments around the world have anticipated market failure, often ahead of any commercial introduction of GM foods in the market, and have pursued mandatory labeling.
- The efficiency of various mandatory labeling regimes has not been sufficiently appraised. Proper methods for measuring consumer behavior and relevant social benefits from mandatory labeling have been ignored. The costs of mandatory labeling policies have been under-scrutinized or brushed aside. And, key uncertainties that undermine the credibility of current and pending mandatory labeling policies continue to be over-looked.
- The cost-effectiveness of current and pending mandatory labeling policies has not been evaluated. Gradual tightening of regulatory standards in some countries promises to further cloud a murky picture of regulatory efficiency by drastically increasing the costs of regulatory restrictions while diminishing their enforceability in return for unspecified consumer benefits.

A positive step out of the current international gridlock on GM-food labeling could involve regulators in various countries articulating what market failures they hope to improve upon and through what regulatory instruments. Such articulation, along with the use of proper methods for the measurement of relevant social costs and benefits, could lead to the clarification of the welfare impacts of various GM-food labeling regimes and improved decision-making. Of course, cost-benefit analysis is neither necessary nor sufficient for designing sensible regulation (Arrow *et al.*). Yet, economic analyses of that kind could: quantify the relevance of regulatory policies; identify incremental benefits and costs associated with different regulatory policies; organize tradeoffs inherent in regulatory policies; illustrate the distributional implications of regulatory policies; increase transparency.

A final comment is necessary on the argument that mandatory labeling is warranted in order to protect the "consumer right to know." This argument often appears self-evident, seemingly detached from more mundane cost-benefit considerations. Yet, the closest that "consumer right to know" has come to a formal legal basis, appears to be in the European Union through an explicit reference in the 1997 Amsterdam Treaty to the "consumer right to information" (Kalaitzandonakes, 2003). Yet the very same article that obligates the European Commission to promote the consumer right to information also obligates it to protect the "economic interests of consumers." Accordingly, considerations on costs and benefits associated with various mandatory labeling policies are relevant even within this context.

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Traceability and Trade of Genetically Modified Food

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Increasingly variable consumer preferences, rising concerns about food safety, technological advances and diverging national regulatory systems are forcing the global agri-food industry to test a variety of new product-differentiation systems. Consumers, both through their individual purchases and through their representative governments, are demanding more specific and often new product attributes—sometimes related to food safety and at other times related to production and processing methods or non-safety related traits. Meanwhile, biotechnology, in particular, is offering new options for farmers and consumers, as well as putting pressure on existing public and private regulatory systems. Finally, even though primary agriculture was brought under the aegis of the World Trade Organization Agreement in 1995, many governments are slowly, but surely, establishing divergent regulatory hurdles for trade in many of these markets. In a search to sustain or improve operating margins, processors and producers are seeking new ways to differentiate their products to satisfy those diverging demands. It is unclear, so far, whether this effort is coming at a cost that is less than or exceeds the related benefits of satisfying differentiated consumer demand and new technologies.

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In this paper I will:

- discuss the driving forces behind this movement,
- examine how regulatory systems are addressing the challenge,
- outline the extent to which the challenge offers a typology of product-differentiation systems, and
- examine the limited evidence on the costs and benefits of those systems.

Driving Forces For Product Differentiation

The provision of adequate supply and variety of relatively safe, affordable, and nutritious foods to feed a rapidly growing world population and increasingly affluent consumers was one of the key accomplishments of the twentieth century. However, in response to rising standards of living, consumers have increasingly demanded more specific assurances of the safety, provenance, and quality of the foods they consume. This trend became evident shortly after the Second World War and accelerated during the 1990s in response to a series of food-safety failures and introduction of new technologies, especially genetically modified (GM) foodstuffs (particularly corn, soybean, and canola).

Meanwhile, biotechnology is expanding the number of possible types, qualities, and features in our foods. Between 1986 and 1997, biotechnology was used to genetically modify sixty crops for ten different classes of traits. During that period, in excess of 25,000 field trials were conducted in more than forty-five countries (James, 1997). As of 2002, sixteen crops modified for one or more of forty-seven phenotypic traits were commercialized, most with attributes related to input and yield performance. Insect resistance (*e.g. Bt* cotton and corn) and herbicide tolerance (*e.g.* Roundup Ready® soybean, corn and canola), as single or stacked constructs, accounted for 99% of the GM world acreage in 2002. Plants have also been engineered to resist viruses (*e.g.* NewLeaf™ potato) and to be sterile (*e.g.* the InVigor® hybrid system for canola). Over the first eight years of commercial cultivation, those fifteen crops were planted on an estimated 240 million hectares. There also has been an effort to develop and commercialize output trait crops, including delayed ripening tomatoes (*i.e.* FlavrSavr™), new or modified oils (*e.g.* Laurical® canola) and blue carnations. Industry reports that many more are expected in the near future. Finally, there is a push to use the global agri-food system as the base for bioengineered industrial products (such as producing industrial enzymes and oils) and to produce pharmaceutical proteins in plants; between 1990 and 2003, the United States authorized sixty-two field trials for plant pharmaceuticals while Canada approved fifty-two.

Meanwhile, the trade imperative has been rising. While sixteen countries have produced one or more transgenic crops, the United States, Argentina, Canada, and China accounted for 99% of the acreage over the first eight years of production (James, 2002). With GM production concentrated in those key exporting countries, a wide range of markets are now affected. Table 1 shows

TABLE 1. DISTRIBUTION OF PRODUCTION AND TRADE IN GENETICALLY MODIFIED FOOD CROPS, 2002.

[adapted and updated from Phillips (2002) using James (various) and FAO (2000)]

	Total world production (2002)		Production in countries producing approved GM varieties (2002)		Exports (2001)	Imports (2001)
Commodity	# Countries	Volume (Mt)	Country	% total	% total world exports originating in countries with GM prod'n	Total # countries importing commodities
Canola	53	33.1	Canada, USA	13%	45%	70
Cotton	85	33.2	Argentina, Australia, China, Honduras, India, Mexico, South Africa, USA	59%	67%	57
Maize	160	603	Argentina, Canada, France, Portugal, Philippines, Spain, South Africa, USA	48%	85%	181
Melon	13	0.6	USA	0%	0%	10
Papaya	51	5.9	USA	<1%	<1%	77
Potato	154	307	Canada, Ukraine, USA	14%	9%	190
Rice	114	576	USA	2%	10%	195
Soybean	84	180	Argentina, Canada, Romania, USA	59%	65%	128
Squash	88	16.9	USA	4%	0%	38
Sugar beet	52	247	USA	10%	3%	34
Tobacco	129	6.3	China, USA	44%	16%	195
Tomato	162	109	USA*	11%	5%	148

NOTES: GM flax was approved in Canada and the United States, but never commercialized. *Records are inadequate to determine whether GM tomatoes are being grown in four other countries. Other minor crops approved in the United States include chicory, cantaloupe and radish.

that 85% of trade in some products comes from GM producers (although GM produce does not represent 100% of their sales) and as many as 195 countries could be importing GMOs.

DOMESTIC AND INTERNATIONAL REGULATION OF FOOD SAFETY

In the past, new food products that were reviewed and approved in the country of production were generally granted unrestricted access to global markets. Rising consumer concerns about food safety and widely varying citizen concerns about environmental, social, economic, and ethical aspects of GM

foods have led many countries to change their practices and require a domestic review of food products before they can be imported or sold to local consumers. Governments in most exporting and importing countries acknowledge that these national reviews could adversely affect the free flow of trade in food products. As a result, there has been renewed international effort to find a means of redesigning the multilateral trade system to more comprehensively assess and manage food-safety risks. In effect, each of the institutions is attempting to create greater consensus about how to manage such risks.

National governments have responded to these pressures in a variety of ways. While many of the individual government measures (such as reviews of efficacy and safety of GM products and differential labeling rules) may have been implemented for legitimate objectives, the result has been diverging regulatory hurdles for trade in many of these markets. Different countries now require different levels of assurance that the products they are importing do not involve certain production processes, such as GM traits. These new hurdles are not only higher, but differ between markets, requiring greater specificity in shipments to international markets.

The main visible manifestation of these different views is the diverging rules related to labeling GM foods. The ultimate challenge is to provide a credible, transparent, and accountable system that provides effective choice to consumers between GM and non-GM foods. While the principle is simple, and most governments agree with it, many difficulties are involved in delivery. Given the credence nature of these markets—*i.e.* claims are not testable by consumers directly—most companies have been unwilling to voluntarily label their products. Thus, the debate has moved to the regulatory systems around the world. As of 2002, more than twenty-six countries had either adopted provisions or announced plans for rules to assist the market to develop and deliver labeled products. At one extreme, regulators in the United States, Canada, Argentina, and Hong Kong have concluded that mandatory labels will be required only to signal known public-health and safety aspects, such as nutritional and compositional changes or new allergens. Food processors may use voluntary labels in those markets to signal that their product includes either GM traits or that it is free of GM traits, provided the claims are credible and verifiable. At the other extreme, twenty-two countries, plus the European Union (EU), have adopted or announced plans to implement mandatory labeling systems, with a range of thresholds for co-mingling(*e.g.* 1%, 3%, 4%, or 5% by volume of ingredient). While mandatory labels seem to address consumers' concerns, they are far from a perfect solution. A variety of studies suggests that labeling systems could impose a one-time set-up cost of 1 to 6% of annual food expenditures and an on-going cost of 0.5 to 3%. Given that there is no strong public-health rationale, and that only a minority of consumers state, or show in experiments, that they would pay for GM-free or proactively-labeled GM products, there is some question about whether mandatory labels are

TABLE 2. THE CURRENT ARRAY OF INSTITUTIONS REGULATING INTERNATIONAL TRADE IN GM CROPS.

(adapted from Phillips, 2002)

Institution	Date	Coverage	Member states	DSM*	Orientation
International Office of Epizootics (OIE)	1924	Infectious animal diseases	155	Non-binding; sets WTO standards via SPS S.3.4	Harmonize import and export regulations for animals and animal products through International Animal Health Code
Food and Agriculture Organization	1945	Food security	184	None	Establish policy statements and convene expert groups
International Plant Protection Convention (IPPC)	1952	Pests and pathogens of plants and plant products	107	Non-binding; sets WTO standards via SPS S.3.4	International Standard for Plant Measures (ISPMs) involving quarantines
World Health Organization	1954	World health	192	None	Establish policy statements and convene expert groups
The Codex Alimentarius Commission (Codex)	1962	Food labeling and safety standards	165	Non-binding; sets WTO standards via SPS S.3.4	international standards to provide guidance to the food industry and protection to consumer health
OECD	1969	Harmonization of international regulatory requirements, standards and policies	29	None	Consensus documents
Regional initiatives	1990s	Harmonization of the science of regulation	Various	None	Regional side agreements, MOU, MRA, formal dialogues, and joint research projects
WTO	1995	Trade in all goods and most services	138	Binding	Establish rules for transparency and dispute settlement through TBT and SPS agreements
BioSafety Protocol (BSP)	2000?	Transboundary movements of living modified organisms	63 signed	None	Will require advanced informed agreement for first shipments of LMOs intended for deliberate release; commodity shipments to be notified

*Dispute-settlement mechanism.

efficient. A recent development is the plans by the EU to replace its system of labeling only for detectable proteins with one that requires full labeling of all foods produced using transgenic technologies, which will require a full traceback system to operate, both in the EU and in exporting markets (European Union, 2001).

The recent trade challenge to the EU has signaled a new phase in the debate about regulation of GM foods. On May 13, 2003, the governments of the United States, Canada, Argentina, and Egypt announced that they would be filing a complaint with the World Trade Organization on the grounds that a *de facto* EU moratorium on new GM foods violates international trade law. Their position is that the moratorium on the approval of GMOs is inconsistent with WTO rules and that the moratorium is not based on scientific risk assessments and, therefore, creates an unjustified barrier to trade. Other countries that have since expressed support for the filing of this case include Australia, Chile, Colombia, El Salvador, Honduras, Mexico, New Zealand, Peru, and Uruguay. Nine international bodies have been working to coordinate and regulate different aspects of food safety (Table 2). Conceptually they represent a progression from institutions that are largely science-based (IPPC, OIE, Codex, WHO), one trade-based (WTO) and others that have broader objectives, such as environmental protection and other social and political goals (OECD, FAO, regional initiatives and BSP). A more detailed analysis of these institutions and their roles is available in Phillips (2002).

Suffice it to say that these nine institutions are working to develop rules to ensure health and environmental sustainability while, at the same time, supporting international trade. To that end, they are individually (and occasionally collectively) undertaking efforts to develop standards for safety and evaluation, to develop scientifically defensible testing procedures and to develop rules to ensure consistency where possible. They also offer dispute-settlement processes or mechanisms to handle any disagreements.

The difficulty with the evolution of the combined national-international regulatory systems is that while some progress is being made in some areas on technical matters, none of the international effort is designed to deal with many of the challenges posed by new technologies. Consumer concerns, ethical considerations, and various socio-economic factors do not fit within any of the institutions. In absence of any consensus on those and other issues, national regulatory systems will continue to diverge. As a result, the GM agri-food community will continue to face a "patchwork" of regulations, with national systems providing basic, but different, standards and international bodies setting minimum, but potentially unenforceable, standards for different aspects of the regulation of products of biotechnology. At root, national governments do not have enough confidence in each other to accept a trading partner's system. For the time being, the agri-food market will continue to face that uncertainty.

The structure of the global commodity production and marketing system

A compounding problem for consumers, industry and the regulators is that the global agri-food system is highly integrated, with more than 340 million tonnes of bulk cereals and oilseeds traded in 2001. The global commodity trade system—the current target for GM varieties—is fundamentally designed to deliver consistent quality at competitive costs and prices, which has led to extensive standardization, blending, and pooling to either create uniform quality or to lower transportation and handling costs. I will use Canada's system to illustrate this point.

In Canada, the research community, both indigenous and foreign-controlled, annually produces, on average, thirty new canola varieties, fifteen wheat and durum varieties, ten barley cultivars, and five pea varieties. Once approved for release, seeds of these cultivars are multiplied for sale. Farmers purchase different shares of their seeds for different crops. Canola producers buy, on average, 90% of the seed they need annually, while wheat, durum, barley, and pea farmers buy only about 40%. This seed is produced by more than 3,000 registered and certified seed growers in Canada. Annually, approximately 250,000 Western Canadian farmers plant 50 million acres of these five crops, generally in 80- to 160-acre fields, each of which yields between 2,400 and 8,200 bushels, depending on the crop and area harvested. Producers harvest the seed usually within a 1-month period in the fall, using mostly owned or leased equipment and family or hired labour, and then store their grain on-farm in bins that range in size from 1,500 to 4,200 bushels.

Grains or oilseeds for export are called forward through quotas by the Canadian Wheat Board (for wheat, durum, and malt barley) or under contracted conditions or spot market offers by the private grain trade (for canola and peas). Farmers deliver about half their grain themselves in trucks that haul 300 to 350 bushels, while about half the crop is moved in commercial trucks that hold between 25 and 42 tonnes, equal to 900 to 2,000 bushels. More than 80% of the delivered grain is elevated either in a primary elevator (on average with forty-four bins each holding between 45 and 120 tonnes, equal to one to five commercial truck loads or fifteen farm-grain trucks) or in an inland terminal (each with bins holding between 160 and 700 tonnes, the smallest of which could hold twenty farm-truck deliveries or four to six loads from commercial trucks). The bulk of that grain is then transported to port on rail hopper cars of 90 tonnes capacity (equal to one to two bins from an average country elevator or a fraction of a bin in an inland terminal), usually in 125-car unit trains . At port, the grain is offloaded, sorted into large terminal bins and, finally, loaded onto ships with holds averaging 5,000 to 6,000 tonnes, destined for one of 120 foreign markets.

Clearly, the system goes from the smallest and most discrete scale at the seed-development stage to a highly aggregated and blended system when exported.

This blending is done both to ensure the most consistent quality within and between shipments and to drive marketing and distribution to the lowest unit cost. One difficulty is that the large number of physical transfers and the high amount of blending increases the risk that crops will be co-mingled with other elements that could lower the quality. Historically, this has been handled by rigorous regulations, based on visual identification, that have limited the potential for unintended or deliberate co-mingling. This has been matched by extensive quality assurance by the private grain trade. With the introduction of GM varieties, however, visual identification is no longer easy. The regulatory and marketing systems are going to be forced to adjust.

A Typology of Product Differentiation

Firms facing the combination of consumer demands for differentiation, increasingly specialized technologies and products, and diverging regulatory systems have resorted to seeking new ways to differentiate their products in the market. The definition of product differentiation can have several nuances, depending on the justification for the differentiation. Frequently the terms "identity-preserved production and marketing," "segregation," and "traceability" are used interchangeably in the supply-chain literature. This is creating misconceptions about the distinct role that each of these product-differentiation systems has in the supply of food products. The purpose of this section is to delineate the three systems, identify the features that are both unique and common and to identify the relative costs and benefits of each system (Table 3)[2].

Identity Preservation

The first system involves identity-preserved production and marketing (IPPM), which is initiated by private firms in the food industry to extract premiums from a marketplace that has expressed a willingness to pay for an identifiable and marketable product trait or feature. An IPPM system is a "closed loop" channel that facilitates the production and delivery of an assured quality by allowing identification of a commodity from the germplasm or breeding stock to the processed product on a retail shelf (Buckwell *et al.*, 1999; Lin, 2002).

The objective of an IPPM system is revenue-management. Premiums need to be available to attract participants and the efforts of participants will be directed towards capturing a share of the premium. Participation in these systems is voluntary. The lead stakeholders in IPPM systems are private firms seeking to capture the increased value of special traits. The role of the regulatory body is to ensure that industry standards are handled in such a way as to prevent consumer fraud. The information may be asymmetric, as only the product seller

[2]See Smyth and Phillips (2003) for more discussion of this typology.

TABLE 3. COMPARING IDENTITY PRESERVATION, SEGREGATION AND TRACEABILITY.

(adapted from Smyth and Phillips, 2003)

Component	IPPM	Segregation	Traceability
Overall management			
Objective	Revenue management	Product safety	Liability management
Status	Voluntary	Mandatory	Voluntary or mandatory
Lead stakeholder	Private company	Regulator	Commodity group, standards organization or regulator
Information flow	One or two way	One-way	Two-way
Supply chain focus	Downstream	Downstream	Upstream
Testing/auditing	2nd party/brand owner	1st party/regulator	3rd party/standards organization
Production-stage features			
Production arrangements	Formal production contracts	Regulation and contracts	Membership in quality standard
Production controls	In-season agronomic rules vary with product	Formal buffer zones; post production land use controls	Process standards adopted and record keeping
Processing-stage features			
Enforcement	Private	Public	Collective
Quality criteria based on	Product standards	Regs or HACCP	Processes (*e.g.* ISO)
Tolerance levels	Variable	Set in law	Performance based
Testing/auditing	2nd party	1st party	3rd party
Retail-stage features			
Provides access to	Branded product market	Markets	Product categories
Information provided to	Consumer	Regulator	Regulator, retailer or processor
Penalties for failure in product market	Consumer fraud charges; lost brand value	Criminal prosecution; mandated product recalls	Consumer fraud charges; exclusion from product category
Price premium	Yes	None	None
Labeling	Private brands	None	Quality standard

can know with certainty what level, if any, of cheating has occurred in the delivery of the product. Moral hazard may be present due to the presence of premiums. Effective IPPM systems that span entire supply chains must have accurate two-way flows of information. This means that information about purity and quality of the product flows downstream and information coming from consumers must flow upstream. While the information flow in IPPM systems is two-way, the focus of the system is downstream. Each participant in the system wants to ensure they extract a portion of the value of the special trait, whether from production, processing or retailing the product. This means that each participant will focus on the needs of the next participant in the supply chain. Market failure can result in fraud charges for improper labeling and create awareness among consumers that certain brand names cannot be trusted. Second parties acting on behalf of the brand owner or developer of the special trait will usually do the testing and auditing.

Numerous IPPM systems are operating around the world. Some involve only the breeders and the wholesale market or processor, while others extend to the retailer. Their structure depends on the attribute they are trying to preserve. Some novel oils, such as low linolenic oils that are more stable in fryers, have value only at the processing level while others, such as high oleic oils, have health attributes that can be marketed to consumers. Identity-preserved production and marketing systems are important for providing information to consumers about the provenance of a product, as those attributes are not visible or detectable in the product itself. A number of IPPM systems operate in North America. While organic products are perhaps the most noticeable IPPM products, Cargill has an IPPM system in place to export canola to Japan (the variety gives off virtually no odor when used to fry food), General Mills operates an IPPM system for a select variety of white wheat that possesses a special trait for "flake curling" when processed into breakfast cereal, and Dow AgroSciences uses an IPPM system to export the Nexera canola variety to Japan where it is sold into the specialty gift oil market. In each of these systems, there are a range of costs and benefits. Essentially, the systems must generate adequate premiums in the intermediate or final markets to justify the added costs. The market actually determines the value of the systems, by revealing what tolerance for off-types it will allow (which sets the benchmark for costs) and then revealing the incremental premium for the differentiated trait. A number of systems studied have been calculated to have incremental costs (over the commodity system) of US$20 to 35/tonne, and by assumption their continued operation implies that the premiums must exceed those levels.

Segregation

The second product-differentiation system is segregation, which Lin (2002) defined as the requirement "that crops be kept separate to avoid co-mingling during planting, harvesting, loading and unloading, storage, and transport."

Segregation systems are used when potential food-safety concerns exist over the co-mingling of the segregated product and all other like products. In short, IPPM systems are used to capture premiums and segregation is used to ensure food safety. Participation is not optional—any producer or firm involved with segregated products will have to comply with standards that have been approved by the regulatory agency. The private firm will have the responsibility of developing the actual system, but the regulatory agency will be the final arbiter on approving the system for field use. The focus of product delivery within a segregation supply chain will be downstream. Segregated commodities commonly have industrial value, so these products will be supplied to meet the criteria of the processor. Product failure would most definitely see a complete recall of any products suspected of being affected and could result in criminal prosecution in the most severe instances. Testing and auditing will be vital features of segregation systems and will be conducted by agents of, or acting on behalf of, the regulator. This process will also reinforce the level of trust with foreign export markets.

Very few open-field crop-segregation systems presently operate in the global agri-food system. All industrial and pharmaceutical crops would require segregation. The best-known segregation system in Canada is for high erucic acid rapeseed (HEAR), which has industrial value due to the high acid content—eleven HEAR varieties are currently under cultivation in Canada. Two varieties of transgenic, novel oil canola (Calgene's Laurical® varieties) were contract registered and produced between 1996 and 1999, and a small amount of *Brassica juncea* was segregated for the first time in 2002. All plant-made pharmaceutical trials require full segregation. As one would expect with these types of systems, there is no tolerance for co-mingling. As such, the costs have tended to be higher, and by implication, the premiums must be higher. High erucic acid rapeseed earns, on average, a $60/tonne premium in Canada and unsubstantiated reports peg premiums at well over $100/tonne for other specialty industrial and pharmaceutical crops.

Traceability

The third product-differentiation system is traceability. The International Organization for Standardization (ISO) has defined traceability as the "ability to trace the history, application or location of an entity by means of recorded identifications," and the Codex Alimentarius Commission has adopted this as their working definition for all Codex standards (Codex, 2001). Traceability systems are designed to ensure that products available for consumption are as safe as possible. Participation in a traceability system can be voluntary, depending on where in the supply chain the participant is located. The closer the participant is to the start of the supply chain, the more likely it will be that participation is voluntary. The lead stakeholder may be a commodity group demanding greater clarity in, or selection of, food products, a standards council

that comprises industry representatives from all sectors of the supply chain or the regulator seeking to ensure consumer protection. Traceability systems have information flowing two ways, as these systems are designed to react quickly to food-safety concerns. If a product is discovered to exceed any defined tolerance level at any point in the supply chain, traceability will be used to identify the source of the problem and to locate any and all retail products that may be affected. Information on food safety flows upstream while information on specific products flows downstream. This results in the focus of traceability systems being upstream. Market failures can also result in consumer fraud charges in addition to permanent exclusion from selling into that supply chain. Testing and auditing will be conducted according to standards developed by third-party organizations.

Increasing numbers of traceability systems are operating. Perhaps the oldest and most-developed is the manufacturer's lot number system that traces processed foods from plants to consumers. Those were implemented largely to handle liability of contaminated foods. More recently, retail chains in the United Kingdom adopted extensive traceability systems (from retailer to farmer), initially for beef but now for a growing list of products, in order to manage liabilities flowing from the UK Food Safety Act, 1990. More recently, the livestock industries in twenty-five countries have either introduced or announced plans to introduce partial traceback systems (from slaughter house to birth), and there has been significant discussion about if and how a traceback system can be developed for commodity grains and oilseeds. While these systems, which add between 1 to 5% to the cost of a product, do not add any directly identifiable premium to the product, they do act as a form of insurance against a food contamination that could cause the recall of an entire product category. The recent detection of bovine spongiform encephalopathy in a Canadian cattle herd is estimated to have cost the industry $11 million/day. The incomplete traceback system operated by the Canadian Cattle Identification Agency will have paid for itself if it can reduce the trade embargo by even a few days. Even though no traceback provisions exist for GM foods yet, the EU has proposed in its latest set of rules that its modified labeling rules would need to be backed up by a traceback system both within the EU and in the exporting countries, in order to validate claims of GM or GM-free status in products without detectable recombinant DNA (EU, 2001). This would be a novel use of traceback, as no other systems operating are imposed by the state—all of the others are economic choices adopted by potentially liable firms seeking to limit their exposure to losses.

Conclusions and Observations on the Way Ahead

Global agri-food markets, and especially markets for GM foods, are at a crossroads. It is probably fair to assume that consumers will not be any less demanding in the coming years, or that technology will stop advancing. The

real uncertainties relate to how regulators and industry will manage the two trends. There would appear to be three possible futures.

The pessimistic future might be that technologies swamp the capacities of consumers and regulators to assess, test, and adopt new products. In that case, everyone will be playing catch-up, which would create the conditions for individual national governments to attempt to handle their own problems by erecting even higher or more impermeable barriers to trade. This would be disastrous, as the global agri-food system depends critically on trade, and many nations around the world require trade to assure the appropriate quantities or varieties of food to meet their domestic needs.

The alternative, optimistic outcome might be for regulators to come together, either through negotiation or litigation, and adopt common standards, testing protocols, and regulatory processes that can effectively and efficiently deliver consistent and timely decisions in all key markets. This would not be impossible to achieve, but is unlikely given current government trajectories.

Finally, the most likely outcome would involve us muddling through, with industrial organizational reforms just about keeping ahead of the pressures for product differentiation coming from consumers, the technology, and regulators. To some extent, this would be like moving along the hogback of a steep hill—one small deviation either side would tip the sector into a new direction.

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Module III Panel Discussion and Q&A Session

Moderated by Thomas Wahl
Washington State University IMPACT Center
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Panel Discussion

Gregory Jaffe (Center for Science in the Public Interest, Washington, DC): [audio lost, question for Nicholas Kalaitzandonakes] Éthe surveys have lots of faults in them, but I don't see the market voluntarily addressing the ethical or social concerns that people have with genetic engineering technology.

Nicholas Kalaitzandonakes: But on the basis of what evidence can you make such an assertion? I understand that it is not exactly standard practice for the person who is receiving the question to turn it around, but, my response is that part of the problem is that we often make statements that we believe to be true, but we have very little evidence to suggest that they are, in fact, true. We do not know that markets are "failing" us and that they are not putting on the shelf the products that consumers really demand. Indeed, we don't have any evidence to argue either way. The European Union very recently said that mandatory labeling was necessary because grain traders refused to segregate GM from non-GM in response to European regulators' demands. But that's not how markets work. Markets do not respond to regulators, but to consumer demands. Limited non-GM product offerings could indicate unresponsive suppliers, but could also mean uninterested consumers. But the point is, we do not know. Let me make one point very briefly: consumers buy a variety of products every day

with more than price in mind. They take into account all kinds of factors including, convenience, quality, and socio-economic aspects. A whole host of products being offered today have explicit socioeconomic dimensions, from shade-grown Starbucks coffee to dolphin-safe tuna to non-child-labor Levi's jeans. Non-GM food is not the first product category for which we would like to see consumer preferences taken into account; but it is a big leap from wanting consumer preferences taken into account—including socio-economic preferences—to arguing for mandatory labeling. Also, it's a costly leap and it doesn't add up from a regulatory optimality perspective.

Cathleen Kneen (The Ram's Horn, Sorrento, BC): It is difficult to frame questions for these speakers. They did an excellent job. Peter, yours was the most complete and competent discussion of the issues that I have ever heard. But, I'm feeling a huge amount of frustration and maybe many of you are also feeling some frustration, and I would like to characterize that frustration as follows. Those of you who are involved in the science of biotechnology are completely convinced that what you are doing is, first of all, immensely exciting, I've heard you say that over and over again, and secondly, absolutely wonderful. And those of us out in consumer-land are just being obtuse. Where is this resistance coming from? Why do consumers insist on being so suspicious, so fearful? Following on from what Fred Kirschenmann said this morning about different models and different ways people look at the world—Peter just alluded to it as well—one of the reasons for the resistance is that people want something other than what is being presented by the dominant food system. The growth of organics and a number of other fair-trade products, and so on, are an example of that. It's important to understand that, as the food industry insists on imposing a more and more technological model, people are getting angrier and angrier. That is a message that has to be heard. So if I had a question it would be, do you recognize that anger and how do you propose to address it?

Jill McCluskey: I'm sure some segments of consumers are angry. I was discussing at lunch with someone that, at our level of societal development, it seems like we have less and less control over our lives. On the other hand, food is an area that we can take control over, and consumers are taking an increasing interest in controlling the food they eat and give their children. They are also making a political statement by purchasing food that is produced in a socially responsible manner. The media have focused on this in terms not only of food safety issues but also on social issues including fair trade. There has been a lot of coverage of Starbucks fair-trade coffee, for example. Your question was why are consumers angry and how are we addressing that anger?

Kneen: More the second than the first. I think we know the first.

McCluskey: Voluntary labeling and marketing are addressing that anger. All sorts of products have specialty labels, including aspects of social responsibility and organic methods of production. Big business is starting to realize the potential in the organic market. You'll see more and more large corporations selling side-by-side organic versions of their products. That market is going to grow as corporate America sees it as a way to make money by addressing the needs of consumers with those preferences.

William Aal (Tools for Change Institute, Seattle, WA): The issue at stake here isn't market acceptance. It's the power to determine the future—whose information are we looking for? Jill, when you chose the people to talk to in China, Japan and Norway, they were above average by your own definition. When you look at China and the impact of globalization on farmers there, you would probably get different answers to questions in comparison with high-school or college educated people in the city. If you expanded your survey to a deeper segment of the Chinese population for example, what kinds of results do you think you would have gotten?

McCluskey: We conducted the study in greater Beijing. Therefore, if we went into the countryside we would get people who were less educated and have lower incomes and probably would have a lower level of self-reported knowledge about genetically modified foods. I'm not really sure if they'd be more suspicious, more skeptical, or not. Tom, what do you think? You've traveled extensively in China. How would people in the countryside have reacted compared to the people in greater Beijing?

Wahl: Indeed the knowledge of consumers in rural areas would have been much less and I would guess the results would have shown much less premium than what we found in the city. The same trust in science would have been there. So it would have been the same direction, but probably less.

Aal: Jill, you suggested that people in Norway and Japan are perhaps closer to agricultural history and heritage. You didn't quite say it that way and that's why I was asking about China because the folks whom you didn't talk to are more closely connected to the land. We know from consumer surveys in the European Union that one of the big concerns is maintenance of family farms. Did you ask people what they think about farming, connection to the land and preservation of farms? Or did you simply ask health and safety questions?

McCluskey: We did not ask those questions. We had to get permission to conduct these surveys in grocery stores and time spent with each respondent was limited. In Norway, the survey was made in the Oslo region, so I didn't mean to imply that they were closely connected to the land or agriculture, I just

meant in general. From what I've read in the literature, Europeans are more traditional and they perceive food as high quality if it is cooked and produced in the same way as did their grandparents. In Japan, the survey was conducted in the city of Matsumoto, where relatively more people are involved in agriculture than the general population. It's a more agricultural city although not greatly so. There was a limited number of questions that we could ask, so I'm not sure how that would affect it.

Jaffe: I don't know a lot about the consumers in Norway, Japan or China, but I know that, in the United States, the food companies treat their brands as golden. Consumers buy based on brand name, be it Coca-Cola, Kellogg's corn flakes, or Kirin beer in Japan. People pay premiums for brands that they like. I haven't seen any surveys of biotech products that take brand name into account. If Coca-Cola contained genetically engineered corn syrup and was labeled accordingly, how many people would no longer buy it and switch to Pepsi-Cola or a generic alternative. I wonder how that would affect your survey results. Are you aware of surveys that take brand into account? My gut feeling is that a lot of people in the United States would continue to purchase their brand even if it was labeled that it contained genetically engineered ingredients, but I haven't seen surveys that address that. It seems to me that that is something that needs to be addressed.

McCluskey: That's an interesting point. Kirin beer for example, has refused genetically modified ingredients in order to maintain their brand reputation. And McDonalds refused to accept *Bt* potatoes. So I know that is important, and that they are trying to maintain their reputation. A branded product is a differentiated product with which the producers try to separate themselves. If it were to contain a genetically modified ingredient, it might compromise their value.

Kalaitzandonakes: Two issues: one is recognizing that branded product manufacturers and retailers have strategically responded to GMOs quite often with bans. I published on this in the April 2003 issuse of *Nature Biotechnology*, so I won't go into detail here, but I will answer your question. A study done in Montpellier, France, by French researchers, takes into account the potential substitution of brands for non-GM labels. Through an experimental auction, French consumers were asked for their willingness to pay for non-GM and organic foods, unbranded and branded. When the brand was presented to the consumers, their willingness to pay for a non-GM product decreased because, in essence, the brand acted, through trust, as a substitute for the non-GM label. In the presence of the brand, consumer anxiety was reduced, in which case the premium associated with non-GM products was also reduced.

Kneen: A question for Peter. Nick commented that we've had 6 years of genetically engineered foods and not a cough or a sniffle. There is absolutely no way of knowing what the effects of GM foods on the population may be if there is no traceability because there is no labeling. You spoke very eloquently about traceability, Peter. I'd like you to comment on that.

Kalaitzandonakes: Before Peter comments on this, let me clarify what I said. I said that these are the typical pro and con arguments on labeling. I did not make any judgments on how accurate or relevant they are.

Kneen: It was in quotes.

Kalaitzandonakes: No, no—my point was that I had nothing to do with the arguments other than presenting the two sides. I don't want you to attribute that to me. I have no evidence of one cough either way.

Peter Phillips: He doth protest too much. This issue of traceability and labeling is an interesting one, and I've been engaged in it in Canada in a substantive way. The argument goes: if you don't label it, you can't detect whether it is causing a difficulty in the food system, and at one level that makes good sense. If somebody has a problem, they identify they have a problem and they say, "Oh by the way, I ate X and X must be the cause." The reality is that the epidemiological studies that look for trace-back of food-borne risk never rely on customer reported consumption as the sole determinant of causality. The labeling structure that Europe has, that we have in a voluntary way in North America, that Japan has, is almost useless for determining whether there is a risk that flows into the food chain. Let's take *Bt* crops, for example. How many *Bt* constructs do we have? Okay, we have a lot of constructs. One of them may be risky, the others may not. You need to know the exact formulations. You need to know the percentages. You need to know the provenance, which means you need the lot numbers. So, yes, you need traceability, but traceability does not need labels. In fact, labeling actually lead to red herrings, because people self-identify because of their prior views about the efficacy of the product.

Q&A

Craig Winters (Campaign to Label Genetically Engineered Foods, Shoreline, WA): My question is for Nick on labeling. It took thousands of years to 1800 to put a billion people on the planet. A hundred years, from 1800 to 1900, to put 2 billion, 1900 to 1950, 3 billion, 25 years to put 4 billion. Now we're putting a billion people on the planet every 13 years. So, population is the number-one environmental problem. There's the argument that genetically engineered foods are going to feed the planet, but people are realizing that the American culture

of increasing the consumption of meat is really a big problem. Seventy to 80% of the grains that we produce go to feed animals, and companies like McDonalds are opening up these restaurants all over the world. So there's a perception that American corporations are destroying the planet. Although we only have 5% of the population, our influence is commensurately much greater. The issue of genetically engineered foods has become a lightning rod, and for the biotech industry to say, "Sorry, you guys don't have the right to know if your food has been genetically engineered," is angering people all around the world. All these countries are adopting labeling and we in the United States are fighting it. Nick, if I was going to hire you as my consultant, as someone who understands the biotech industry, what can I do as the executive director of the Campaign to Label Genetically Engineered Foods to get the biotech industry to wake up to how deep the feelings are here. What can we do to get these labeling laws implemented?

Kalaitzandonakes: In order to get new mandatory labeling laws implemented, one must begin with the question whether the legal system has already addressed the issue. At the end of the day, you are asking, "Might we be able to label products because of consumer right-to-know?" The answer has to be viewed in the context of prior legal decisions. About 3 years ago, the FDA reviewed its GM regulatory procedures and decided that mandatory labeling—for anything other than food-safety risks—is beyond its regulatory prerogative. The courts have upheld this FDA view as appropriate. An appellate court has already decided on that in the context of a lawsuit against FDA. We also have the decision in the case of Vermont where a state installed a mandatory labeling regime, which was deemed unconstitutional because, fundamentally, there is no constitutional protection for a consumer right-to-know. So, if I'm a consultant, and since I'm not a lawyer—I'm an economist—I would go to Greg and try to get his advice as to how one might go about establishing such a legal right, fundamentally a political process. We live in a democracy. If a social group wants to pursue the establishment of a new right—one that guarantees the right-to-know—one would have to go through the political process of convincing the electorate that it represents a true issue for more than the 1% or 2% of the population who buy organic foods. Back to my original argument: how many of us feel that this really matters? Because, at the end of the day, regulation is a costly process, and whether you go through FDA or through a local government or your state government or your elections in Oregon or whatever the political platform of choice is, you have to demonstrate that it is a real issue that an interested majority cares about. Today, I don't think we have met that threshold.

Lawrence Busch (Michigan State University, East Lansing, MI): Nick, I'm a little puzzled at your argument. I thought your argument made sense providing that

you accepted what appeared to be a positive assumption at the beginning, but which was, in fact, a normative assumption. That is, you told us that governments regulate when markets fail or when it's necessary to produce equity, but of course we also know that governments do things like pass Farm Bills which pass lots of money out to people and that's a form of regulation. We just passed the Country of Origin labeling legislation, which has absolutely nothing to do with any of the issues we've been talking about here except that, indeed, it is now a new set of regulatory requirements about the labeling of food that somebody is going to pay for. It seems to me that what you've been arguing—that we have to show that regulation is efficient—and that that might be a nice normative argument, that is to say an ethical argument that an economist might want to put forth, but one could just as easily make a different normative argument and say that the costs be damned, we should label it anyway.

Kalaitzandonakes: Is cost-benefit analysis—which is what we are talking about here—a necessary and/or sufficient condition for regulation? The answer to that is: it is not. Indeed, there are laws in this country that explicitly prevent cost considerations in certain regulations. But, it is my opinion that cost-benefit analysis would serve us very well as a society when we consider alternative regulatory regimes. There is a substantial body of literature that refers to the political economy of regulation, which deals with the issue of minorities that can hijack the process for their own purposes. So, without consideration of demonstrable benefits *vs*. regulatory costs, if we don't deal with that criterion, whether it's positive or normative, we could be failing society at the end of the day.

Phillips: Let me add one other thing that you have to keep in mind. This debate isn't happening in a vacuum. All of our nations are members of various international organizations that have rules of engagement. One of them is that you can deviate from the norms established under the WTO, for example, but you A) must have a legitimate objective, B) the objective you are trying to meet actually must be relevant to the measure you adopt, and C) it must be done in the least trade-distorting way. So precedents are set that are in all of our best interests to ensure that we go through the motions, even if we are going to choose to not accept the results, but so we know how far we are deviating from norms that we've established for international governments.

John Browne (Judd Creek Nursery, Burton, WA): I have a simple question for Peter on your note about 3,000 Canadian oil-seed growers for 250,000 farmers. Can you put that in a historical context?

Phillips: I'm talking about the certified seed growers that are the registered and licensed agents to multiply the foundation and certified seed for the commercial

trade. They are a small group. They already practice identity-preservation to ensure quality standards of product entry in the market. If you are talking about the aggregate industry, about 20% of the people we used to have farming are still farming, and farms have tended to become much more sophisticated and specialized in terms of what they produce. There is a much narrower range of products, and we've moved into the higher value-added quasi-differentiated commodity markets.

Browne: So the differentiation then is a self-regulating thing as opposed to the old model where the farmer who produced kept his own seed.

Phillips: Yes, we have a variety of different differentiation models. Some are publicly regulated. We still have the Canadian Wheat Board which does a fair bit of the product differentiation. We have commodity groups like the Canola Council, which owns the standard. A variety of mechanisms are being used.

Robert Wager (Malaspina University College, Nanaimo, BC): This question is for Nick mainly, but Peter may have some answer to it. When you were discussing the four areas of cost-benefit considerations, you said that you wouldn't talk about the integrity of the labeling system and you passed over the high integrity. I think we all appreciate the trust we put in the validity of labels right now, knowing that about 70% of our foods have at least one GM ingredient, although in many cases the levels are too low or they are too highly processed to be detected. What will it do to the high level of integrity of the labeling system if food is labeled as "GM" when the GM component cannot be detected?

Kalaitzandonakes: The work that I quoted considers the issue of the integrity of the labeling system as one of the factors that determines the benefits of any such system. If consumers do not believe in what labels say, then, obviously, the benefit or the utility to the consumer from such labels decreases. If the integrity of the labeling system is compromised, then mandatory labeling implies fewer social benefits. If we look at the system we are putting in place today—including testing procedures through non-standardized methods, thresholds that cannot be accurately measured or assessed and so on—problems are likely to emerge. Adding the issue of traceability, when one cannot analytically assess the presence or absence of GM ingredients in certain products like feed, oils and highly processed foods, then it's anybody's guess how that system will work. Obviously, if the integrity of the labeling system is affected, the benefits for mandatory labeling are compromised, which, in turn, argues against mandatory labeling regulation.

Wahl: Peter, did you have anything to add?

Phillips: People care about the provenance of certain products, but it may be impossible to determine whether a declaration is honest or not. Sometimes those are branded products. Sometimes those are collectively-managed-standards products, as in the organic industry. Sometimes they are managed by outside authorities—halal and kosher foods are good examples. There is a tendency in the debate around GM foods to iterate towards a single consistent unified standard for labeling and declaration of content, and at times I've thought that's not a bad idea. Increasingly I am questioning that view. There isn't one reason we want the stuff labeled; there are multiple reasons and what people want labels for should perhaps determine why they are there. Let me give you an example from some research we are doing. Not being Jewish, I assumed that kosher is kosher. In fact, within North America there is a number of rabbinical councils and something like 3,000 differentiable kosher standards that vary marginally based on the community and the rabbi who is the authority. Would anybody argue that that's a market that is not functioning? This is an illustrative example of where we need to start thinking about how we actually mediate the exchange between the production system and consumers. Different parts of this state, this country, this continent and this world, want products labeled for different reasons and the labels almost by definition have to be different. The desire to go for a standard that is consistent may be counter-productive in the long run. It will generate a lot of legal activity, but not necessarily much consumer acceptance.

McCluskey: I've done research in this area on credence goods, which, as Nick discussed, are those for which, even after being consumed, quality is not verifiable. So the ability to support an equilibrium where high-quality credence goods are available depends on the probability of getting caught, because there is economic incentive to cheat if there is a premium for, let's say, a GM-free product or if the GM item is less costly to produce. It also depends on possible effects on product reputation. For example, the presence of StarLink[a] corn in their taco shells must have hurt Taco Bell's product reputation. Adverse effects on product reputation and price may be long term, and it depends on discount rate and on how much future profits are valued, which depend on the degree of damage. So, if there is a sufficiently high probability of getting caught and they care about the future, then we could have true labeling.

Module IV

Biotechnology: Applications for Agriculture in Developing Countries

Insect Resistant Maize for Africa: Lab to Field and Challenges along the Way

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Christopher Ngichabe

I will provide some background on the challenges facing Africans and African researchers—with emphasis on the Kenyan experience—and the prospects for using science in general and biotechnology in particular to address some of our major problems.

Agriculture in Sub-Saharan Africa

In Kenya, as in sub-Saharan Africa as a whole, most people's livelihoods are tied to agriculture. Although we have large well managed farms that resemble those in the United States, the vast majority are smallholder operations, typically of 1 to 2 ha, that feed extended families of twenty or more people. On these small plots, crops are grown mainly for direct consumption, with the little left over being sold to cover school fees or saved to eventually purchase an ox. Some farmers can pay to have their land tilled by a tractor or ox-driven plow, but, as often as not, tilling is accomplished by women working for days with hand-hoes. Hybrid seeds, like fertilizer, are available, but considered a significant investment, and insecticides and herbicides even more so. Sometimes these chemicals are fake and do not work, and farmers may apply them incorrectly or at the wrong time. But, like farmers everywhere, they weigh the risks and

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benefits and invest their meager resources if they see a good chance of a return. The difficult situation at the ground level is reflected in the situation at the national and regional levels. Although two-thirds of sub-Saharan Africa's people live on small-scale farms and produce their own food, nearly a third of them are undernourished (FAO, 2001). The region simply does not produce enough food to adequately feed its population, and food production per capita is declining. Although land is relatively plentiful in comparison to other parts of the world, soil fertility, a key factor in productivity, is declining, leading to devastating infestations of the parasitic weed, *Striga*. Drought and its partner, crop failure, are regular visitors in sub-Saharan Africa. In the past, with all these constraints facing farmers, the one thing they could rely on was family labor. But with AIDS and the migration of the younger generation to urban areas, even this is no longer assured.

Times are tough for smallholders in Africa, and they were tough also for the farmers of South Asia before the Green Revolution—a revolution in agricultural production that bypassed Africa. Today, we in Africa are looking for our own Green Revolution to bring us to a new era of food security. But our Green Revolution will probably entail a range of agricultural advances on a number of fronts rather than the introduction of a new plant variety supported by a specific technology package (short-statured wheat and rice and intensified planting). One thing is clear: biotechnology will play a central role in Africa's agricultural revolution (Conway and Toenniessen, 2003; Toenniessen *et al.*, 2003).

Critical Role of Biotechnology

Why will biotechnology play such a critical role?

- Traits incorporated into a host plant (such as insect resistance or drought tolerance) do not require extensive training regimes for adoption by farmers. In Africa, where national budgets are called upon to meet pressing needs in education and health, agricultural extension services are usually under-funded. Reaching poor farmers, many of whom do not even have a radio, is a daunting task. Therefore, providing technologies that are literally carried within the seed itself is one of the most efficient ways to bring enhanced productivity to the field.
- Progress in solving many of our agricultural problems using conventional breeding has been very limited. Notable needs include drought and low-nitrogen tolerance, *Striga* resistance, and insect resistance. Although agronomic and crop-management measures can be taken, they are often beyond the means of our resource-poor farmers. By extending our plant-improvement horizons to include genes from other species, we dramatically increase our chances of producing plants that are relatively unaffected by environmental stresses and produce higher yields.

- We in Africa simply do not have the time to follow the timeworn footsteps of industrialized countries in developing our agriculture. We must leapfrog to new approaches and new technologies to meet our needs. A case in point, outside of the agricultural sector, is telecommunications. Land phone lines in my country are unreliable, expensive, and not plentiful. But within a short 5-year period, cell phones have become ubiquitous and people can, for the first time, communicate easily and reliably over long distances. I believe that similar leaps forward are possible in the realm of agriculture.
- Some of the traits that are available or are waiting in the wings will meet pressing needs at the grassroots level. Crops with higher levels of vitamin-A precursors and other critical micronutrients could significantly improve the health of my rural countrymen. Herbicide-resistant plants would significantly decrease the labor needed to manage field plots, thereby helping to meet the challenge posed by AIDS and urbanization. While, admittedly, there are costs to herbicides, if farmers see increased income, I can assure you they will find ways to purchase them. These same genetically modified (GM) plants could also allow our farmers to practice zero-till agriculture, thereby helping to conserve our soil resources.

Although the picture I have painted may in some ways sound bleak, we Kenyans are optimistic. We have a sound foundation of scientific researchers, we have established effective partnerships, we have a new government that welcomes innovation, and we are willing to embrace fresh approaches and technologies methodically and safely for the benefit of our countrymen and Africans in general.

DAVID HOISINGTON

It is said in Kenya: "Without maize, there is no food." This reflects reality far too often, especially for smallholder, subsistence farmers. And, as Chris pointed out, a host of abiotic and biotic factors threaten the harvest of these farmers, prominent among which are attacks from stem borers capable of destroying entire maize fields. These widespread pests eliminate approximately 15% of Kenya's maize crop annually, valued at US$72 million. Current controls for stem borers vary in efficacy, cost, and importantly, potential environmental and health impacts. Clearly, solutions must be tailored to the farmers' needs and capabilities and to local conditions in the various maize-growing areas. This is exactly the aim of the Insect Resistant Maize in Africa (IRMA) project.

IRMA Project

Launched in 1999, the IRMA project is a collaborative effort of the Kenya Agricultural Research Institute (KARI), the International Maize and Wheat Improvement Center (CIMMYT) and the primary donor, the Syngenta

Foundation for Sustainable Agriculture (http://www. cimmyt.cgiar.org/ABC/InvestIn-InsectResist/htm/InvestIn-InsectResist.htm). From the beginning, the goal was clear: *to deliver insect resistance for maize in a form familiar to farmers—the seed they plant*. Four guiding principles were established: IRMA should:

- be a model of good practice (including biosafety aspects), from which other countries can learn,
- serve as a pilot project for public-private partnerships and cooperation,
- employ state-of-the-art technology and methodology, and
- be transparent and open, with ongoing stakeholder dialogue.

Under IRMA I, which will be concluded at the end of 2003, there have been two broad approaches, both based on host-plant resistance: development of maize with conventional resistance (*e.g.*, tougher leaves and stalks), and development of transgenic varieties with *Bt* genes proven effective against the Kenyan stem borers.

Traditional breeding and screening procedures have produced promising maize lines with conventional resistance, which are presently moving toward delivery to farmers. On the transgenics front, source lines of the key *Bt* genes *cry1Ab* and *cry1Ba* have been developed and tested against the target pests *Busseola fusca, Chilo partellus, C. orichalcocillielus, Sesamia calamistis, and Eldana saccharina*. These lines are the basis for transferring the genes to germplasm adapted to Kenyan conditions.

A number of technical and philosophical aspects distinguish IRMA from biotech efforts elsewhere in the world, both in developed and developing countries.

- This project may be the only one attempting to use only publicly derived *Bt* genes. As such, we are not constrained by private-sector intellectual property strictures and, based on reports from our legal counsel, eventual deployment to farmers will likewise not be constrained. Incidentally, this frees us also from charges that we are being driven solely by agri-business profits or by a desire to control the seeds that farmers plant.
- Also, we have gone to great lengths to produce plants that are free of the antibiotic-resistance and herbicide-tolerance markers that are frequently used in the transformation process. Although this has added time and expense to our work, it directly addresses the concerns of some regarding the effects of these markers on the environment or human health. Along with most scientists, I do not think the risks posed by these markers are significant, but recognize that the scientific and public-awareness environments within which we work in that part of the world differs from those in the United States. We see the use of these "clean events," as a way to move the product to the farmers more quickly in the long term.

- A tremendous amount of work has gone into collecting baseline data on insect ecologies in the five major agroecosystems for maize in Kenya. This will allow us to thoroughly investigate what, if any, impact the *Bt* maize will have on nontarget species, particularly the natural predators and parasites of the stem borers. Although the *Bt* maize/monarch-butterfly controversy turned out to be a false alarm (Conner *et al.*, 2003), we are looking to be proactive with regard to all such concerns—be they false or valid. This work also complements the development of an overall integrated pest management (IPM)-based strategy for insect control.
- Insect-resistance management is a critical component of the *Bt* technology. In industrialized countries, refugias of non-*Bt* maize are used to prolong the efficacy of the technology. But for smallholder farmers, such refugias may not be feasible or enforceable. To meet this challenge, the project investigated the effectiveness and incidence of alternative host plants to serve as refugias. Some of these were found to occur naturally, while others would need to produce good economic returns to induce farmers to use them. A map of the country was produced that showed which areas would require farmers to have managed refugias and which areas would require no special management. Analysis showed that many of the areas with the smallest farms and poorest farmers had sufficient natural refugias such that no extraordinary measures would be required. Areas with large-scale, highly productive farms showed inadequate natural refugias, but these farmers would be the most likely group to successfully implement conventional refugias. All this information will be used by the project and extension providers as they plan how to best deploy the *Bt* maize.
- Because of the sometimes controversial nature of *Bt* maize, emphasis has been put on communication and education since the initiation of the project. Participatory rural appraisals were conducted with farmers throughout the country to document their practices and assess their needs, preferences, and production constraints related to maize. Communication efforts were directed particularly toward the news media, with a focus on achieving balanced coverage of GM-crop issues through workshops and rapport-building practices. Extension services and like-minded organizations have also been engaged to help familiarize these key audiences with the technology in anticipation of its expected deployment. Educational materials such as fact sheets and posters for agricultural shows are under development to enhance the acceptance of *Bt* varieties by a wide range of stakeholders. Of note, meetings have been held annually to update a broad range of stakeholders, including government agencies and the press, on progress and to provide an opportunity for them to shape the future direction of the project.

- Capacity building has progressed on a number of levels. A biosafety greenhouse and laboratory will be completed in early 2004, perhaps the first in sub-Saharan Africa outside of South Africa. An open quarantine site has been built and tested and will hopefully be host to the first GM-maize field experiments in East Africa. Kenyan scientists and technicians have been trained to operate these facilities, and their skills, related to running the requisite experiments and analyzing the data, have been enhanced. Furthermore, high-level delegations representing various Kenyan regulatory agencies have been taken on fact-finding trips to the United States and Mexico to familiarize them with biosafety, intellectual property issues, food, and environmental regimes in these countries.

Technology Transfer—Doing it Right

A GM-crop project run in the developing world, if done in earnest, is far more involved than simple technology transfer or corporate marketing. But "doing it right" is critical if such technologies are to be used for the benefit of resource-poor farmers in these countries. In the words of Per Pinstrup Anderson, winner of the 2001 World Food Prize and former director general of IFPRI: "The prediction so often heard that the poor in developing countries are unlikely to benefit from modern biotechnology in the future could well come true—not because the technology has so little to offer, but because it will not be given a chance."

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Q&A

Mary Robinson (Tilth Producers of Washington, Vashon Island, WA): Are you planning to enlarge the 400-meter isolation margin around your maize fields?

Hoisington: That's the minimum distance. Actually some of the first field trials may not even go to male maturity, so there would be no pollen. We can go to well over a kilometer I believe, in that area.

Robinson: So, currently what does industry feel is adequate isolation?

Hoisington: I would have to ask somebody in industry about that. Our understanding in Kenya, based on the requirements for a quarantine site for seed production, is 400 meters. So, we've used that.

Robinson: But, since pollen can travel 6 or more miles how does that work?

Hoisington: Like I said, that's the limits that we are using currently.

Robinson: But don't you feel that would be inadequate if pollen goes 6 miles?

Audience Member: Pollen will go 6 miles, but it's not viable.

Robinson: Really? Then why is maize contaminated in the United States now? Hmm, curious. Are you planning to give the seeds away, and what are the rules about saving the seeds?

Hoisington: All the products that we will make are freely available to the farmers who will be allowed to save their seed. That's why we actually want it to be in their variety.

Robinson: Okay. I would suggest that some of you grow corn the way I do, and maybe you will find out that the pollen is viable quite far away.

Tanya Barnett (WA Sustainable Food and Farming Network, Seattle, WA): Thank you for confronting food-security issues, and for your compassion. Related to the question about seed saving, I was an agro-forestry extension agent in Niger, West Africa—one of the countries high on the hunger list—and I began to see the displacement of native seed stocks, the genetic material that has been handed down through millennia. You are encouraging farmers to save their seeds. Can you talk a bit about what they can expect in terms of yields if they plant GM seeds the following year? My main issue is promotion of food security, so I am interested in what you have to say in terms of that potential insecurity. Thank you.

Hoisington: As I tried to indicate, that's one of the distinct advantages of some of the biotech options that we have. We don't want to introduce new varieties. We want to take the varieties that they are growing, and give them options to enhance insect resistance and other traits through biotech. So the variety is the same. It has one or two additional genes. They can still save the seed. They can plant the same diversity of crops. That is an extremely important option for them.

Anne Schwartz (Blue Heron Farm, Rockport, WA): I want to repeat Tanya's comments about your compassion. I've been involved with sustainable agriculture issues here for a couple of decades, and I want to assure several of the scientists here that the sustainable ag community in the United States talks about food security in developing nations, especially Africa. It is one of the issues that we see as critical for the planet. And like Tanya I do want to commend the work, especially as it is in the public domain. Those of us in sustainable agriculture realize that the cropping patterns that have evolved in the United States have led to many of our problems. As organic farmers, we rely on crop rotations to deal with endemic pests, and I totally appreciate the difference between a climate with a winter and one without. With all the effort put into educating locals about new high-technology crops, it would seem to me at least appropriate to also focus on the types of rotations and differential cropping systems that can help maintain insect control and pest control. I appreciate your description of current activities, but it does seem that there are other systems approaches.

Hoisington: Thank you. It may sound strange coming from a person supposed to be in charge of biotechnology, but I fully agree. Farmers need a lot of options and we are trying to determine if the biotech option has a role to play in those farming systems. Because, yes, there are crop rotations, and they are growing alternative crops. I love to see that. And that actually can work in our favor. We're actually then trying to improve one component of that farming system. If we can incorporate insect resistance into the maize that they are growing, then I think we can actually help the farmer.

Karen Ganey (Western Washington University, Bellingham, WA): Among the challenges that you had in bringing *Bt* maize to Africa you didn't mention the strong resistance that Africa is presenting. Why is the *Bt* approach not valued and where is that recalcitrance coming from?

Hoisington: Are you specifically speaking to resistance to technologies in Africa?

Ganey: Yes.

Hoisington: I'll let Chris answer that because he's more up to date on some of those issues.

Ngichabe: Drawing from yesterday's presentation about the NewLeaf™ potato, it's all about awareness creation. The resistance we have experienced in the southern part of Africa was certainly because of awareness creation and also a top-down directive that we feel did not go properly through the consultation process with scientists at that time. Also, there was a visit to the United States

quite recently of a team from that direction and they met with various regulatory agencies and they now understand that a number of measures could be taken to avoid the kind of situation that occurred in South Africa. Now they agree that GM crops, or the GM-food aid should enter the countries, maybe after milling for example, so that the flour can go across the countries. We are now very actively involved in developing a policy, a transit policy, so that a similar situation does not occur again. So one, it was a learning process, and two, it simply underscores the importance of awareness creation in this particular area.

Cathleen Kneen (The Ram's Horn, Sorrento, BC): Just a very quick comment and maybe a caution: my experience with working with community organizations and with the public is that the more people know about genetic technology the more skeptical they are of it, not the less.

Ngichabe: Well, it appears to be the opposite in Africa, but we all are free to have our opinions on this.

Module V

Caution at the Crossroad: Evaluating Paths to Assure Sustainability in Agriculture

Moderator: Charles Benbrook

Module V: Preliminary Remarks

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This last session of the conference is an opportunity for all of us to pursue issues that we'd like to have more discussion on, particularly to try to understand how to take steps in moving ahead with our collective reflection on the underlying technology. The 1991 NABC meeting was titled *Agricultural Biotechnology at the Crossroads*, and as I've listened to the presentations over the last couple of days I've reflected upon whether we've come back to the same crossroads or are we at a new one. How have things changed in the last 10 or 12 years as we have pushed to develop this technology, tried to understand its biological, human health, and environmental impacts, dealt with market and consumer acceptance issues, and tried to wrestle with the public policies that have come into play? I think it's fair to say that not all is well in the house of agbiotech. I think that there is a depth of concern about it in a variety of communities and constituencies in the United States and around the world, in NGOs and civil societies that is, simply, unprecedented.

Ralph Hardy and Jim Cook will remember, back in the mid-80s, when I worked with them on the National Research Council Board on Agriculture, that we'd lament the fact that the public wasn't terribly interested in the problems of agriculture from supporting research and technology development to preserving and characterizing germplasm to investing in soil conservation systems and water quality to trying to promote ecologically based pest management and more-healthful nutritional products. Almost every project committee spent at least a few hours thinking what could be done in that project, or what could the National Academy of Sciences do, to capture the interest of the public and get them to understand the importance of the issues that we were dealing with.

This notion, of course, reflected the assumption that if the public became engaged with the issues there would be more support for changes in R&D priorities and funding for research and new policy initiatives. Little did any of us know then that it would be agricultural biotechnology and concerns and questions about it that would, in fact, engage the general public on the broad issues of what kind of food we have, how we produce it, the economic social justice issues in our food and fiber system, and not just in the United States but now in an increasingly globalized world where a small number of companies have such large market shares in many industries. These issues are now clearly being addressed and struggled with on an international level.

So, agricultural biotechnology has accomplished getting the public engaged. Nevertheless, I fear that the technical and scientific communities still have not found a voice in dealing with some of these issues with the public. After we faced that crossroads in 1991, perhaps some of the paths that people rushed down were not thought about as fully as possible. We have among our presenters three individuals who are uniquely qualified and experienced and have been extremely successful in engaging a broad range of publics in the discussion of agricultural science and technology. They will share a number of insights.

When each has made a presentation they will join me on the podium and we'll have a good discussion. Our first speaker is Carolyn Raffensperger.

The Precautionary Principle: Making Wise Decisions in an Uncertain World

Carolyn Raffensperger
Science and Environmental Health Network
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The Sunday *New York Times*, in May 2003, quoted John Graham of the Office of Information and Regulatory Affairs in the Bush administration, in a speech to European Union regulators, as follows:

> *The precautionary principle is an unjustified constraint on business and [the administration] does not even recognize the existence of the doctrine. We consider [the precautionary principle] to be a mythical concept, perhaps like a unicorn.*

Many think that the precautionary principle is used only to address biotechnology and agriculture. That's not the case. I will describe the history of the principle, focusing on scientific uncertainty—one of its elements—and describe some of the recent debates, especially with respect to trade.

Global Changes

We have caused major global change, some of which has serious implications, *e.g.*, the hole in the ozone layer and climate change as mentioned in some of the other presentations. Marine fisheries are collapsing and endocrine disruptors are present in wildlife and humans. I submit to you that the magnitude of human-induced global changes is unprecedented.

In a 1997 *Science*-magazine article, Peter Vitousek said that we've transformed the land and the sea and we've done it in myriad ways. We've altered the major biogeochemical cycles, *e.g.*, carbon, nitrogen, water. We've introduced synthetic chemicals across the globe—some of which may be found in the farthest corner of the Arctic. Also, we've added and removed species and genetically distinct populations via habitat alteration and loss, hunting, fishing and species invasion.

Consider the magnitude of these changes. Data from 1997 indicate that between a third and a half of the land surface has been transformed by human activity. Carbon dioxide concentration in the atmosphere has increased by about 30%. Since the beginning of the Industrial Revolution, more atmospheric

nitrogen has been fixed by humanity than by all natural terrestrial sources combined. Half of all accessible surface fresh water is used by humans. A quarter of the bird species on earth have been driven to extinction and two thirds of the major marine fisheries are fully exploited, over-exploited, or depleted. Data recently published in *Nature* indicate that these statistics, particularly on marine fisheries, are far worse than they were in 1997.

Need for the Precautionary Principle

Some trends in public environmental health are cause at least for more research and rethinking of regulatory policies, such as increases in autism, e.g. in California. The old arguments around environmental health were:

> *Oh come on, you environmentalists are always complaining about something. We're increasing life expectancy, infant mortality is going down,* etc.*, so what are you complaining about? We're all living longer. We are getting fatter, but, apart from that, we're really doing well.*

However, increased rates of some cancers, age-adjusted, are troubling, as are neuro-developmental diseases, including autism, reproductive disorders, *etc*. We have difficulty in assessing cumulative systems levels and interactive effects. Although we have evidence of global impacts, we have failed to predict outcomes.

What about future generations? Will we discount them indefinitely or start to factor in their needs and the long-term effects of our current actions? Silvio Funtowicz and Jerry Ravetz have stated that there are some situations where much uncertainty is coupled with far-reaching consequences. That matrix—high decision stakes and high uncertainty—falls into "post-normal" science. In fact, high stakes apply to many of our current choices.

We know that novel synthetic industrial chemicals contaminate the world's ecosystems, including our own bodies. The human food supply and those for other species are contaminated at levels of concern. Water is often contaminated at levels of concern. Look around, even at this continent, and consider again changing patterns of illness. Why has our 60-year history with chemicals caused so many surprises? Given those surprises, does it make sense to use the same kind of science to assess environmental and public-health effects of transgenic crops?

This is a wonderful quote from T.L. Hill:

> *It's a truism that humans have, and will always use, tools. Just as obvious is that technology, the use of tools, occurs in a social, political, cultural and economic context and it's never neutral. Tools are always shaped by their use, by the people or institutions which control their production and distribution, and by a culture which validates, circumscribes or discourages their creation and/or use.*

And we have heard overtones of that debate at this meeting. What kinds of cultural mechanisms are being used to validate or discourage the creation and use of biotechnology? Do we have a right to say no to a technology, and who are "we"? Are there wise ways to say yes to a technology? Can we increase our skill in predicting the consequences of a technology, and how do we understand the cultural, social and political differences that exist in other countries with regard to biotechnology?

The bigger the technological solution, the greater the chance of extensive, unforeseen side-effects. Clearly, scale matters. The greater the rapidity of human-induced change the more likely it is to destabilize the complex systems of nature. As stated by Aldo Leopold, speed also matters.

What is the precautionary principle? The 1998 Wingspread Statement on the precautionary principle (http://www.gdrc.org/u-gov/precaution-3.html) was as follows:

> *Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.*

At the 1972 United Nations Conference on the Human Environment, held in Stockholm, sustainable development was elevated to a global ethic. This was the first paring of the moral principles of social justice and environmental responsibility—themes that have played out in this discussion in terms of the development of biotechnology to ease hunger and how we think about environmental responsibility. The 1987 Brundtland Report, *Our Common Future*, stated that poverty is a cause and effect of environmental degradation. Present policies encourage environmental deterioration and deepen economic and social disparities. This led to the 1992 United Nations Conference on Environment and Development, from which came the statement of the precautionary principle and two derivative treaties, the Persistent Organic Pollutants (POPs) Treaty and the Convention on Biological Diversity, which led to the Biosafety Protocol. The POPs treaty and the Biosafety Protocol were the first treaties to incorporate what we now understand as the precautionary principle: 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.

The Europeans who developed the precautionary principle in the late 1960s and 1970s thought of it as an ethical directive. It was a philosophical guide, and that's why it was put into treaty preambles. It comes from a German word that literally means "for caring." It's a literal word that doesn't exist in English, translated by Conrad von Moltke while explaining a matter of German air-pollution law to the British.

The concept of it being an ethical directive in some ways is foreign to people in the United States. When I organized the Wingspread Conference, I thought if we could get it out of the realm of ethics and make it a *regulatory* tool, everything would be fine. We'd give it some teeth. But, I didn't understand that the precautionary principle is a tool that uses epistemology—How do we know? What do we know?—philosophy that deals with scientific uncertainty. But it also has an ethical dimension, as pointed out to me by the head of Cancer Prevention at the National Cancer Institute, Doug Weed, a philosopher as well as an MD. He said it was the first time he'd heard of a decision rule that actually coupled ethics with epistemology.

After 20 years as an environmentalist, dealing with ethics made me nervous. We're not expected to do that here in the United States, and I wanted to ensure that it was a strong regulatory device. It's a risk-management device rather than risk assessment. We do the risk assessment, and then decide if we need the precautionary principle. But that gets us into trouble. It's a poor way of doing business. After a technology is developed, it may be rejected by the regulatory process after many millions of dollars have been spent.

The precautionary principle needs to be an overarching ethic guiding everything from the research agenda to the judicial elements, using science in new ways to examine and to predict. It sets a public-interest research agenda to help guide technologies rather than to be used only as a regulatory device.

Sometimes it is said, "We can't possibly use the precautionary principle because we can't define it. It's too mushy. It's too soft." Nonsense. The precautionary principle always contains the same three elements. It always has plausible threats of harm. It always has lack of scientific certainty. And it always has precautionary action to prevent harm—not to manage it, to prevent it, which is the difference in philosophy. That's part of the philosophical backdrop. In the United States we subscribe to the philosophy that says we can measure risk, we can manage risk, and the earth has an infinite capacity to fix our mistakes, whereas the precautionary principle says let's use science as a predictive and preventative tool.

Harm

The precautionary principle addresses potential harm in environmental and public-health matters, especially in the Biosafety Protocol, in which it was first expanded into public health. It is being used also to address cultural and social harms. The International Society for Ethnobiology put the precautionary principle into its code of ethics to guide the scientific use of cultural and social knowledge to prevent harm to foreign cultures.

Not all types of harm are applicable. Harms that have been written into treaties are serious, cumulative, and irreversible. On the other hand, if a harm is easily avoidable, it makes sense to avoid it.

Lack of Scientific Certainty

Scientific uncertainty is a complex concept. Usually uncertainty with regard to the precautionary principle is in terms of cause and/or magnitude. Consider autism, for example, the causes of which we don't fully understand. My environmental and public-health colleagues often settle on one issue, e.g., mercury in vaccines. Well, it might. It might not. How do we address cause and effect and then how do we address magnitude? Uncertainty comes in as many flavors as ice cream, and we have indeterminacy, and we have ignorance. Uncertainty can be resolved with more data. We can get a better model. We can figure it out. Indeterminacy refers to the complexity of systems. And ignorance refers to what I don't know and what maybe nobody knows; there are some things that you know that I don't know, and there are some things that none of us in this room knows. So for some of these, we can get more data and should get more data to reduce uncertainty. Sometimes we have very complex systems and sometimes we just haven't asked the right questions. And the issue of the right question comes up over and over again in biotechnology.

I want to consider causation briefly. In the 1700s, Hume said that we don't perceive or see causes, we observe consequences and we infer causes. How do we know something causes a disease? Koch's postulates for infectious disease was one of the first sets of ideas that helped map out thinking about causation in Bradford Hill's criteria. In Koch's postulates, the organism must be present in every case, must be isolated from the diseased host, and grown in pure culture. The disease must be reproduced and the organism must be recoverable from the experimentally infected host. However, we've used Koch's postulates in non-infectious contexts, *i.e.*, old science for new problems, such as with endocrine disrupters, with which the postulates work less well. Certainly Hill's criteria work a little better, but they take a long time: consistency of findings, the strength of the association, the biological gradient, temporal sequence, biological plausibility, coherence with established facts, and specificity of association. Bradford Hill commented:

> *None of my criteria can bring indisputable evidence for or against a cause and effect hypothesis and none except for time sequence can be required as a* sine qua non. *All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge that we already have or to postpone the action that it appears to demand at a given time.*

Applying this to lung cancer, in 1945 we knew that incidences of lung cancer and cigarette smoking rise together. In 1950, we had a case-controlled study. In 1953, we knew tar causes cancer in mice. In 1954, we had follow-up studies showing an association between greater exposure and greater risk. Between 1954 and 1990, interesting things transpired in spite of the science. There were

lawsuits, and the tobacco companies declared to Congress that there was no proof that cigarette smoking causes cancer. At what point would you have taken action on cigarettes and tobacco? 1945? I don't know many people who would—not quite enough science. 1950? 1953? 1954? At what point do we come to a consensus within our democracy that evidence is sufficient? According to Hill, we already had enough information by 1954. Non-specificity is an issue that makes proof difficult to establish. Many diseases require multiple exposures, *e.g.*, smoking or allergenicity. Many diseases have multiple causes. There may be a long latent period between exposure and disease. Also, there may be windows of vulnerability, *i.e.* exposure is most hazardous when it occurs at a particular time. We know that at day 10 *in utero*, exposure to an organophosphate causes permanent hyperactivity in mice, but not on day 8 or day 12. Such windows of vulnerability can make causation difficult to establish.

Sometimes exposure is unavoidable, and there's no control population. Similarly genetically modified foods are ubiquitous in the food system. When an identified susceptible population is mixed in with the general population, then there's no identifiable endpoint.

Precautionary Action

Precautionary action is often viewed as cessation. I suggest that there's a much richer sense of precautionary action, and many different kinds. Precautionary action is anticipatory and preventive—unlike risk assessment—increasing rather than decreasing options. Factors must be monitored and reversed such as to increase the resilience, the health and the integrity of the system as a whole. Fred Kirschenmann criticized the interventionist approach where we deal with one part of the system at a time. How can we identify options that increase the resilience, the health and the integrity of the system as a whole, not just one part of it? By establishing goals, we have a means of evaluating options for meeting those goals.

Much has been written about the burden of proof lying with the proponents and not with the public. Chemicals policy in the United States provides an example. We have a "don't ask don't tell" system. Under the Toxic Substances Control Act, we don't test chemicals that were introduced before just a short while ago—all are "grandfathered" in. We wait until someone has been injured or there is enough evidence for court proceedings; still, the injured party bears the burden of proof. In some ways, it involves thinking about allocating responsibility, which comes from Donella Meadows's work on systems.

New technologies are launched largely without public consultation, which is a poor *modus operandi*. If we are to meet goals, we need to consider alternatives, looking for those that are least harmful, are reversible and those that increase the health and resilience of the whole system, and provide the most options. This approach was not dreamed up by environmental "wackos" or as a friend of mine in Washington says: "sane, reverent people." It is embedded in laws in

some form or another. The Department of Health and Human Services establishes health goals for a decade. The National Environmental Policy Act requires evaluation of alternatives when preparing environmental impact statements.

Decisions should be made through an open, informed and democratic process with all affected parties included, and not left to scientists. We must bring together the informed public mentioned by Charles Benbrook and by David Hoisington and Christopher Ngichabe. Since, the US regulatory system doesn't foster it, how do we involve all stakeholders in meaningful discussion? There is no good mechanism. Who speaks for whom is a large part of the discussion within biotechnology. Who speaks for people in Mexico or people in Kenya? Who is speaking for people in the United States? Many people would like to speak for others, but I believe that people should have the opportunity to speak for themselves.

Can we say yes to new technologies? Of course we can. We need the right yardstick for environmental predictions. In the past we have relied too much on data, and have lost sight of biological principles. *Homo sapiens* did not evolve in the presence of long-chain branching hydrocarbons. Rather than going back and testing every chemical, we should use biological principles and learn from evolutionary biology what nature does. In a book that I edited on the precautionary principle, Ted Schettler described the addition of manganese to infant formula because it's an essential micronutrient. Unfortunately it wasn't understood that manganese crosses the blood/brain barrier and high levels can be harmful. Although we didn't have good information on safety, we didn't consider the level of manganese in mother's breast milk. We didn't ask the right question: "What does nature do?"

We should consider instituting performance bonds, which are required, for example, in mining law. If you want to launch a new technology, put up the money. If the technology is found to be safe, you get the money back, otherwise, we get the money. The insurance companies could help establish such bonds. There has been discussion about posting bonds for the long-term performance of sites of decommissioned nuclear power plants. Similarly, in biotechnology, we need to set up means of monitoring and we need to establish early-warning systems.

Labeling

The pro-labeling argument is made usually in terms of consumers' right to choose—their right to information. I believe that the case for labeling is more important in terms of providing an epidemiological tool so public-health experts can track harm. Imagine you are an emergency-room physician with a patient showing a first-time allergic reaction and you want to know what caused it. If it was a genetically modified ingredient in a consumed food, how would you ever know it without labeling?

The following is a quote from James Maryansky at the Food and Drug Administration:

> *The possibility that bioengineered foods might have adverse long-term affects is an idea that keeps coming up.*

He said that we need to take another look at the science.

> *We haven't considered a monitoring program, per se. There's no endpoint we could look for. We think these foods are safe.*

It's impossible to monitor unless there's an identifiable health issue that can be traced. They've decided it's safe and are not looking for an endpoint. With no imaginable endpoint, we are in the same position as when chlorofluorocarbons were developed—CFCs that destroy the ozone layer. We knew that CFCs were stable and, without biological or geological principles for evaluation, assumed that they were safe. Although it wasn't foreseen, it doesn't mean that it wasn't foreseeable. So the question is: are some not-yet-foreseen endpoints foreseeable? Can we develop monitoring systems in the absence of known endpoints, and what early-warning systems can we create? We have actually achieved this with drugs. We have had many surprises with drugs pharmaceuticals and have developed a very different testing system for them. In the case of the diet drug phen-phen, an alert practitioner who examined a number of women noticed the occurrence of a heart-valve problem. By law, adverse drug reactions have to be reported, and a federal law specifically addresses vaccines. Although we don't necessarily know what adverse effects there might be with a new drug, a feedback route is in place that is not in place for biotechnology. Therefore, even in the absence of known endpoints could we expend scientific capital on developing monitoring and warning systems to detect results that at this point are not foreseen?

Most of us came into this room with a preconceived set of ideas. Ask yourself what information would be needed to change your opinion of agricultural biotechnology. Are there any events that would result in agreement to a total ban? And are there incremental actions that we could take in the event of other problems that would manifest themselves within the system? They're doing this at the US National Oceanic and Atmospheric Administration where they are studying fisheries; they agree on a step that they will take if they come up with certain science-based information.

We have different perspectives in the United States and Europe. In the Maastricht Treaty of the European Community, they adopted the precautionary principle. They put into place requirements for high-level protection and harmonization measures across Europe with which they are allowed to take provisional measures for non-economic, environmental reasons. Their policy on the environment directs the Community to take account of available scientific and technical data as well as environmental conditions in the various regions,

and then to appraise potential benefits resulting from action or lack of action. As already mentioned, the Biosafety Protocol actually uses the precautionary principle to address human health and biodiversity. It was a derivative treaty from the biodiversity convention. It's also mentioned in the preamble to the Protocol as an objective and in two operational articles.

Ethics and values are important in European decisions, whereas the United States prefers to make decisions on the basis of sound science, which generally means risk assessment. Another difference is that minority views on cutting-edge science have a place at the table in Europe; they see it as a component of the precautionary principle. Instead of dismissing a warning sign as a false positive, they take it seriously because it drives more science. In the United States, we want a very high level of scientific certainty before entertaining a conclusion. And we have a social contract that relies on post-market testing. We presume that if a company knows there's a problem it will do something about it.

The Current Trade Controversy and the Precautionary Principle

We've heard a lot both about African countries' refusal to accept aid and Europe's refusal to accept trade. Calestous Juma, at Harvard, former executive secretary of United Nations Convention on Biodiversity, said that we in the United States don't understand that, because so much of Africa was colonized, they are in a different position *vis-à-vis* the colonizer and want two things. Calestous suggested that that the former colonies want the benefits of technology. They don't want to be left behind, but at the same time they are cautious about being used as guinea pigs.

On 13 May, 2003, the USDA filed a WTO case against the European Union, calling their trade restrictions illegal and not science-based. The timing of that filing was interesting. At the time we announced that challenge, Colombia was soon to ratify the Biosafety Protocol, which happened a week later. We now have forty-nine parties to the Protocol, and fifty are needed for ratification. The assumption was that the fiftieth would come soon. So why file? There are mutually exclusive provisions about the relationship to trade treaties and I think that the United States looked at that and said that they don't want to have to adjudicate these exclusive provisions and they don't want to get involved with the Biosafety Protocol's conflicts. The precautionary principle would be a matter of hard international law for the first time, which would reinforce Europe's use of it. Moreover, the Protocol's nonparty provision encourages parties to it to encourage non-parties to comply. I think that the United States evaluated the legal implications and decided that it was too much of a hornet's nest. Is the United States afraid of a unicorn? Inquiring minds want to know.

There are four parts to the US challenge: consultation, a panel, the appeal, and then compliance. The United States will have to address a couple of

aspects, *e.g.*, whether an adequate risk assessment was undertaken, and whether other international standards apply. Burden of proof is a major part of the precautionary principle, and at the WTO there's actually a two-part process for the burden. The burden initially rests on the complaining party—in this case the United States and its allies—to bring a *prima facie* case of inconsistency with the sanitary and phytosanitary (SPS) agreements and once that *prima facie* case is made, the burden shifts to the responding party, in this case to Europe.

The role of science and uncertainty and the ability of countries to set their own health and safety standards are being contested. Al Gore wrote a letter around phthalates in children's toys and the precautionary principle that said that countries have a right to set their own health and safety standards. It's a matter of sovereignty, and I think that discussions about sovereignty will play out over and over with the precautionary principle. Again, we have different perspectives on the role of ethics. In sum, two worldviews are being contested. Is the unicorn a myth or a metaphor? A myth is a purely fictitious narrative. A metaphor is a figure of speech to suggest a likeness between two things—it's a comparison, with the same root as metamorphosis. Interestingly, the unicorn is part of folklore in many parts of the world. Asia has a legend. Some think that it comes from the African rhinoceros. It was mentioned by Aristotle as being in ancient Europe, *etc*. Its horn was a sovereign remedy against poison, and the unicorn could be tamed only by a pure and innocent person. It's a symbol of truth and justice. So, the precautionary principle: is it a twenty-first century remedy or an old European myth?

Should We Be Pharming With Food Crops?

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The field release of food crops genetically engineered for production of non-food products may be publicly perceived as an unacceptable risk, for scientific or other reasons. Of special concern are commodity food crops, such as corn, that are transformed to produce pharmaceutical or other industrial products possibly detrimental to humans. If such a transgenic product moved accidentally, or as a result of malicious intent, into the human food supply and was eventually detected, the perceived human-health risk—whether real or imagined—could cause a catastrophic disruption of the food industry. Such an incident could result in loss of livelihood for thousands of farmers, commodity handlers, food processors, *etc.*, even though the vast majority did not participate directly in, or benefit financially from, the production of the genetically engineered (GE) crops.

Why Pharming?

The in-depth knowledge that has been accumulated over years of study of the genetics, biology, biochemistry, cultivation, storage, and processing of food crops means that much of the information needed for genetic engineering, "pharming" (cultivation of a GE organism to produce a pharmaceutical product) and processing is already known, *i.e.* there is relatively little need for knowledge-base investment. Reduced need for funding is the main reason why food crops are attractive hosts for production of GE non-food products. Apparent low capital-investment costs of pharming are especially attractive for the pharmaceutical industry. "As Centocor vice president for medical research," Richard McCloskey stated, "the top four reasons to make Mabs (monoclonal antibodies) in transgenic plants are capital avoidance, capital avoidance, capital avoidance and capital avoidance" (Dry, 2002). The cost of field production is estimated to be about one eighth of the capital needed for construction of a fermentation factory (Pew Charitable Trusts, 2002). However, while the pharmaceutical industry may see reduced need for capital investment, in some cases farmers may be penalized for the pharming of food crops.

Liability Concerns

A wide range of arguments can be made for avoiding food crops as sources of non-food products. In nearly every case, concerns about liability can be raised. This is certainly the case with commercial pharming of corn. For example, the negative impact of pharming on sales of non-GE corn can be predicted from experience with first-generation crops engineered for herbicide tolerance: markets for US corn and soybean have shrunk, especially in Europe and Africa, and have cost farmers billions in sales. StarLink™ and other accidents have fueled consumer concerns about corn. Other crops have not been spared. Outcrossing by herbicide-tolerant GE canola in Canada has destroyed the limited organic canola industry. Proteins of transgenic origin found in Canadian honey in the European Union (EU) have resulted in a drop in honey exports to Europe by 55% (Smyth et al., 2002). Thus, savings in capital investment by the pharmaceutical industry may be shifted as risk to the food industry, but ultimately may be brought back to the pharmaceutical industry by insurance claims via the courts.

The food industry has taken a stance on production of non-food products in food crops (Cady, 2002):

> *We will not be satisfied with anything short of zero risk to the food supply by substances not approved for human consumption. We must be convinced that it is possible to design systems for absolute confinement and containment of crops producing non-food substances and that a mandatory regulatory framework is in place to assure all necessary protective measures will be taken by producers and users of these crops.*

Concerns have been raised also about environmental risks (National Research Council, 2002):

> *(T)he production of non-edible and potentially harmful compounds in crops such as cereals and legumes that have traditionally been used for food creates serious regulatory issues. With few exceptions, the environmental risk that will accompany future novel plants cannot be predicted. Therefore they should be evaluated on a case-by-case basis.*

Some feel that contamination is inevitable due to human behavior (Anonymous, 2002):

> *Current gene-containment strategies cannot work reliably in the field. Seed companies will continue to confuse batches, and mills will continue to mix varieties. Although "buffer zones" may theoretically control pollen dispersal (and gene spread), in practice farmers will be unable (or unwilling) to follow planting rules.*

For example, 30% of farmers failed to comply with refuge protocols required to maintain effectiveness of *Bt* corn (Dove, 2001). Thus, with existing confine-

ment methods, it seems inevitable that GE products unintended for human consumption will enter the food chain.

Regardless of the danger of any technology and the rigor of its standard operating procedures, humans are prone to errors of judgment and to failure to follow procedures. Atomic energy production is certainly one of the world's most highly regulated industries, yet for all of the tens of billions of dollars spent on safety, there have been thousands of accidents and victims, most notably at Chernobyl and Three Mile Island. For all the dangers of radioactivity, it does decay, even if the half-life runs to tens of thousands of years. In comparison, transgenic organisms are alive and have the potential to multiply themselves and their genes, possibly undetected, for years. Thus, even if confinement were a disciplined and well funded safety system with multiple layers of redundancy, accidents would be likely, and, in rare cases, GE plants could sustain and broaden their spread as an altered life form, with possibilities of harm to mankind and the environment.

Catastrophic Risk

The pharmaceutical industry has examples that allow us to focus on another aspect of human behavior that raises the potential of catastrophic risk: the intentional sabotage of a product. Pharmed commodities, especially if they are handled outside the confines of the factory, raise numerous opportunities for sabotage. The Tylenol®-tampering incident in the United States and similar occurrences around the world, including Japan, are examples. A stolen truckload of a pharmed commodity could be used by one of the millions already opposed to pharming, to shut down sales. The confines of pharmaceutical fermentation plants, greenhouses (Traynor *et al.*, 2001), growth chambers, and screen houses offer far more inherent security than field and farming operations that are frequently unguarded.

Theft of intellectual property rights is a common occurrence within the chemical and pharmaceutical industries. Notably, countries such as India and China (before WTO) have not respected some US pharmaceutical patents. Theft for commercial purposes from pharming field operations must be recognized as highly probable, leading to the possibility of a dangerous transgenic organism being produced outside of its original protective regulatory framework.

Risks From Environmental Factors

Beyond inconsistencies in human behavior, a vast array of environmental factors could result in a contamination or poisoning. Violent weather phenomena—hurricanes, storms, tornados, dust devils, and floods—must be expected to disseminate pollen, seed and even viable whole plants or plant parts, perhaps even to seed-production fields of the same crop type. Even spring frosts, which can emasculate self-pollinating crops, can dramatically expand the range of out-crossing beyond mandated buffers for pharmed crops.

Concerns about herbivores consuming product-bearing plant parts are rarely addressed. These include deer and game birds feeding for extended periods in pharmed fields and then taken for human consumption. A similar and all-too-common occurrence is escape of livestock—which could feed in pharmed fields.

Pharmed compounds may accumulate in predators, especially those feeding within an area of pharming that is large relative to their hunting range or which has a concentrated food source. A compound can be further concentrated over time in herbivores, predators, and micro-fauna if the pharmed crop is produced year after year in the same feeding range and is expressed in vegetative parts left in the field.

Contamination of groundwater or runoff through decay of product-expressing plant parts raises other liability concerns, especially where relative concentration and toxicity combine with resistance to decomposition.

The possibility of a recurrence of transgenic plants in a new location or in the same field could result from environmental factors. Rodents and birds can be expected to harvest, transport and store at distance, seeds produced in pharmed fields. No-tillage fields used for corn and soybean often have high populations of rodents since their nests remain undisturbed. Seeds buried by rodents or plowed below the wetting zone in irrigated regions can be expected to germinate at some point in the future. Similarly, seeds will remain dormant in irrigated desert fields if irrigation is discontinued for one or more growing seasons, perhaps long after oversight of the field is terminated. Environmentally induced and genetic seed dormancy can result in seed remaining viable for years under dry or low-oxygen conditions.

Moratorium

The unpredictability of nature and human behavior makes the possibility of absolute confinement, under current approaches, unrealistic, especially under field conditions. The financial risks and liabilities involved in producing non-food products in food organisms have already been demonstrated by the recent $3 million fine levied on ProdiGene. A more dramatic example is the StarLink™ accident, involving production of GE corn with the *Bt* Cry9C gene, which should have been restricted in use to animal feed (www.starlinkcorn.com). The eventual liability in this case could approach $1 billion. Facing claims of this magnitude, insurance companies may ultimately dictate a ban on the use of food organisms, at least for companies that seek to produce such crops in developed countries.

These concerns justify consideration of a moratorium on the use of food crops to produce non-food products. Research may eventually create the ability to stack many redundant biological confinement mechanisms into GE food organisms such that risk can be acceptably eliminated. If this becomes possible, reasonably safe production in some situations might become possible. Thus,

a moratorium rather than a permanent ban on the use of all food organisms is justified.

Conclusions and Recommendations

Pharmaceutical and industrial product companies are attracted to corn and other common food organisms as carrier organisms for GE products because of the in-depth accumulated scientific knowledge. In addition, positive changes have been made to these organisms over thousands of years of domestication, including large seed size, non-shattering seed heads, high yield, non-lodging, determinate maturation, lack of seed dormancy, photoperiod insensitivity, male sterility, and apomixis. This accumulation of knowledge and acquired characteristics could take decades of research and billions of dollars to reproduce in a potential non-food organism targeted for use as a carrier for production of non-food products. The United States and other governments and institutions should support knowledge-base and biological character development of non-food carrier organisms—such as castorbean or tobacco—to make them attractive to pharmaceutical and chemical companies for transformation and synthesis of GE products.

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The Philosophical Perplexities and Ethical Enigmas of Biotechnology: an Examination of the Regulatory Process in the United States

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My theme—"philosophical perplexities and ethical enigmas" associated with biotechnology—evolved from the *Ideas Matter* lecture series of the same name (http://oregonstate.edu/Dept/philosophy/ideas/biotech/), held at Oregon State University (OSU) in 2001 and 2002, and the 63rd Annual Biology Colloquium *Plant Improvement in the Genomic Age* at OSU in 2002. These events focused the attention of scientists engaged in biotechnological research on the wide array of ethical issues that surround the development and adoption of novel biotechnologies. The lack of resolution of many of these issues emerged as a persistent theme of both events, as did the responsibility of scientists to acknowledge and explore the ethical questions that underlie application of the discoveries that they make in this new and significant technology.

Ethics and Biotechnology

The ethics that underlie biotechnology are an important component of public concerns about genetically modified crops. These include concerns about the environment, human health, consumer rights and labeling, concerns targeted towards the poor and excluded, and arguments concerning sustainable, and what is viewed as "industrial," agriculture (Conway, 2000).

Ethical issues impinge on the debate surrounding genetically modified crops in a number of ways. These issues, progressing from the general to the more specific, include:

1. The value of international declarations of human rights as a possible basis for developing an ethical approach to the adoption of biotechnology globally.
2. The ethical standing of the environment and of non-human life in the development of these arguments.
3. The value of ethics in resolving the trade-offs between the environmental, economic and social costs and benefits of biotechnology.
4. The ethical responsibilities of corporations with respect to the development and introduction of biotechnology.
5. The role of ethics in the development and implementation of regulatory procedures that reflect societal values.

The most thorough analysis of ethics associated with biotechnology was undertaken by the FAO Panel of Eminent Experts on Ethics in Food and Agriculture (FAO, 2001). This analysis, which largely addressed the first three issues above, defined a set of core ethical standards, built from the International Declaration of Human Rights, and the current practices of the agency with respect to conservation and sustainable management of natural resources for present and future generations. Issue 4 is hotly debated beyond the realm of science, but Issue 5, concerning ethical responsibilities associated with the regulatory process, remains notably unaddressed.

Discussions about regulatory affairs often fail to move beyond highly technical arguments associated with specific tests or requirements. Regulations and their enforcement, however, provide the mechanism through which societal values confront the attributes and properties of new technologies, and determine whether they are acceptable.

MON 863 Corn and the EPA

In my verbal presentation, I applied an ethical perspective to the regulation of biotechnology by examining one facet of recent regulatory activity, *viz*. the review of impacts of transgenic corn expressing an insecticidal protein derived from a bacterium, on non-target organisms [specifically, *Bacillus thuringiensis* (*Bt*) Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR13L) in event MON 863 corn]. I reviewed data submitted by the registrant, preliminary evaluations by the EPA, and guidance on those evaluations provided by a FIFRA Scientific Advisory Panel (SAP) in August 2002 (EPA, 2002). A new conditional registration process has been issued by the EPA (2003). The basic ethical considerations underlying the regulatory process could be stated as follows (the author's list):

- Regulatory processes provide an opportunity to apply societal standards to an evaluation of the risks and benefits associated with a novel technology.

  The regulatory agency has a duty to develop procedures that reflect societal concerns, to adhere to published protocols and regulatory requirements, and to exhibit high standards of professionalism.
- Regulatory processes should promote human health and well-being and serve to advance beneficial technologies.
- Regulatory processes should help provide access by society to the benefits of technology.

  They should also serve to avoid suppression of other beneficial technologies.
- Regulatory processes should serve to protect the environment, defend biodiversity and to promote sustainable and productive agriculture.
- To achieve the above, regulatory agencies should apply current scientific standards.

In reviewing the data submission by the registrant in the case referred to above, and EPA's initial evaluation, the August 2002 FIFRA SAP expressed a number of concerns (EPA, 2002). Briefly, these included:

- The recommendations by EPA to the registrant regarding single-species testing were not considered appropriate.
- Field evaluation was not considered by the panel to be a substitute for tier-1 risk-assessment testing.
- The data reviewed by the panel did not support the EPA statement that MON 863 resulted in less impact on non-target invertebrates than conventional pest-management practices.
- The panel asserted that 3 to 4 years of experimentation were needed for field-based risk assessment.
- The protocol for tests on the lacewing, *Chrysoperla carnea* (Chrysopidae) was considered to be inadequate.
- A need was defined for development of acceptable standards for the design and conduct of laboratory studies.

In its conditional registration of protein Cry3Bb1 in corn event MON 863, the EPA (2003) included a number of additional requirements for the registrant. Those referring to non-target organisms included (condition 8) a requirement to submit laboratory tests for *Orius insidiosus*, a carabid beetle, and *Tetraopes* spp. (the red milkweed beetle), and (condition 9) a requirement for full-scale field or semi-field tests, including requirements to submit intermediate and multi-year results with stated statistical power, and to submit the final results to studies previously summarized in the submission reviewed by EPA and the FIFRA SAP.

An analysis of this process, based upon the general ethical considerations underlying the regulation of biotechnology, given above, concluded that EPA could adhere to these general ethical standards, and the expectations of society for an effective regulatory process by:

- Setting standards for an acceptable test design in *revised test guidelines* that acknowledge the recommendations of technical experts, and FIFRA SAPs (*i.e.* development of test guidelines that reflect current scientific standards).
- Improving the standard of evaluation, noting particularly the criteria for evaluating laboratory and field derived data, outlined by the FIFRA SAP.
- Rejecting tests that do not meet acceptable standards, rather than accepting them with the evident flaws within them.
- Withholding registration until acceptable tests are submitted, rather than submitting conditional registrations.

The benefits of adopting these recommendations for the EPA, and for society as a whole include the following:

- Moving beyond the *status quo* provides an incentive for registrants to submit packages that meet higher scientific standards.
- Improved guidelines would distribute the benefits of FIFRA-SAP guidance to subsequent submissions, and avoid having to repeat criticisms of the current process.
- EPA decisions would be based on clearer, more transparent criteria, and less upon "expectations" or variable expert judgment.
- An updated and revised process would provide a clear basis for rejection of submissions.
- An enhanced system would improve the credibility of EPA regulatory decisions in the international arena.
- Advances in the regulatory process would be consistent with the ethical responsibilities of the EPA towards society.

Conclusion

The ethical context for regulatory affairs, outlined in this analysis requires first and foremost that the highest standards are met by the regulatory agency on behalf of the society in whose interests it acts. Regulatory requirements and protocols must evolve with science and experience if the regulatory agency is to maintain the public trust and credibility in national and international debates surrounding biotechnology. In general, new agricultural technologies are not subjected to the kind of ethical scrutiny outlined by the FAO in its recent analysis. Regulatory requirements can be tuned to address some of these concerns, and, by doing so, could help resolve a debate that feeds upon the uncertainties surrounding these new technologies.

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Reflective Discussion on Module V and NABC 15

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Charles Benbrook: Many aspects of the issues that Carolyn Raffensperger, Tom Lumpkin and Paul Jepson addressed also came up earlier in the meeting and I'm sure other people would like to express their views. I'm going to make a few comments on some of the key areas and invite our Module V speakers to contribute to the discussion, then we'll move on when it seems appropriate.

In his comments, Paul focused on some of the ethical responsibilities that the FAO has set forth relative to access to food, food security and agricultural technology. Carolyn focused on the legal framework that has evolved from the incorporation of the precautionary principle, going back to 1972, as a paradigm to shape international consideration and decision-making on technologies that may pose some risks.

I'll start by talking about current standards of the US government relative to the acceptability of agricultural biotechnology. I remember Kay Walker-Simmons's comment that the standard against which an agricultural biotechnology in the United States is judged is conventional technology, conventional systems. I'm not arguing that that is not what the policy is, but many people take issue and disagree with that policy, because if no agricultural biotechnology is going to be perceived to have any risks worth worrying about as long as they aren't as bad the worst of conventional technology, it's really not a very demanding standard. It's certainly not one that's going to command public support for the benefits that appropriate applications of agricultural biotechnology can bring to the production of food and fiber. I would submit that the US government has made a strategic and political mistake in the international arena by adopting that as the standard, and that if agricultural biotechnology risks are going to be deemed as acceptable or unacceptable

relative to contemporary technologies and practices, at a minimum the standard should be the best available technology, which is the standard applied in many other areas of environmental regulation and management of natural resources. When Congress passes a Clean Water Act or a Clean Air Act, the process forces industries, farmers, companies, to adopt the best available technology unless it's completely unfeasible economically. So, I invite comments from our speakers on their degree of comfort in the current US government. Paul, I would say that it's also the EPA standard behind the MON 863 decision. They approved MON 863 corn (a *Bt* hybrid from Monsanto) because they felt that the risks were less than from conventional organophosphate-based insecticides and, moreover, the approval was for, was it a 2- or 3-year period? It was a short-term approval and it was quite clear that there would not be a huge acreage planted in that period of time, during which some more science could be done. So, EPA really embedded in its decision to register MON 863 corn despite the fact that substantial issues remained in its environmental and safety evaluation, because the EPA was convinced that it posed less risk than conventional organophosphate-based soil insecticides. How can the United States move towards a more rigorous health-protective policy?

Paul Jepson: Rigor is evolving over time. Recent regulatory decisions have requirements for a lot more testing, which is admirable. When you look at the regulatory system, and I'm a student of these things, you ask broadly, "Is the system protected largely or is it not?" We have no evidence that the EPA has failed to be protective of environments, livelihoods, health, *etc*., in the decisions it has made. I'm talking about the details of how you get more rapid inclusion of scientific insight and methodology into the process. I have to say that when you look at the additional stipulations and requirements that have been made, the standard is, overall, rather high. As I mentioned, I have a series of detailed concerns about how that's applied and whether or not there ought to be a revision of that process in the longer term.

Benbrook: Okay. Carolyn. you're going to pass on this?

Carolyn Raffensperger: I am.

Benbrook: Tom, any thoughts?

Thomas Lumpkin[1]: Recent improvements in the regulatory system are very encouraging. We still have a long way to go to reach a proper comfort level. You mentioned that you didn't see any reason to be concerned about the EPA, but it was the EPA that approved the testing of StarLink™ corn. Even a first-year

[1]Dr. Lumpkin had to leave early.

agronomy student would have raised a red flag on its release because corn is outcrossing.

Jepson: In any regulatory system it isn't difficult to find examples of flaws. So I don't particularly want to comment on that other than the fact that, broadly speaking, immense efforts are taken to develop procedures that are protective but not so protective that they exclude the technology, and I'm afraid that the balance has to be struck by people sitting in offices in Washington DC, and it's a very difficult job. And the science is evolving, of course, during the period while the technology is being adopted, which is why there is apparent confusion and anomaly on occasion.

Benbrook: We have a complicated situation in that most of the genetically engineered crops that are planted widely today, certainly in their original forms, were submitted to EPA for approval in the early 1990s. The initial commercial approvals were granted as early as 1990 or 1991. Since the approval of *Bt* cotton, Roundup Ready® cotton and soybean, the various *Bt* corn events and then the Roundup Ready-*Bt* stacked corn, no other substantial event has been approved. The US government faces a difficult balancing act in that it is trying to improve the rigor and scientific quality of its ongoing assessment of these initial technologies while, at the same time, trying to get it right as new technologies are reviewed. There is tremendous tension, because the US government has stated consistently over the last decade that, in general, it perceives genetically engineered foods and crops to be substantially equivalent, to pose no unique risk and to be good, modern technology. Yet the US government is having to interact within the international arena where issues of risk and the quality of science supporting safety judgments are very much in play. A few months ago the Codex issued new guidelines for allergenicity testing of GM foods and it will come as no surprise to most people in this group that the early GMOs approved by EPA and the FDA were approved on the basis of science substantially less complete and rigorous than what Codex is now calling for. Somehow, we've got to bring the science supporting existing technologies up to scale.

Joseph Jen talked about the $3 million a year that the USDA is spending on biotechnology risk-assessment research. Probably most people in this room have a sense that that is a rather modest sum, given the total public and private investment behind agriculture biotechnologies. Jim Cook said there's somewhere between 900 and a 1,000 transgenic events in various stages of development in the United States, some in the greenhouse, some in small field trials, which puts the $3 million dollars a year investment into perspective. I do a lot of work in the pesticide arena. When a chemical company is either introducing a major new pesticide or defending an old one and bringing the database supporting its registration up to contemporary scientific standards,

just the core toxicology data set—the long-term reproductive, cancer, chronic feeding studies—cost about $3 million dollars for one pesticide. Most companies are glad if they can get through the health and safety testing for a major pesticide that's being newly registered or going through re-registration, for $30 million dollars. And for important products where there are contested regulatory issues, the two best contemporary examples being use of chlorpyrophos, an organophosphate insecticide that Dow Agrosciences engaged EPA very aggressively to try to preserve as many uses as possible, and atrazine, a corn herbicide that's found widely in drinking water in the mid-west that may or may not pose some level of cancer risk to people as a result of drinking-water exposure. Dow in the case of chlorpyrophos and Syngenta, used to be Novartis, have spent, I am sure, at least $50 million in creating the science base to defend the continued registration of those products. So, we need to realize that there is an enormous gap between the extent and rigor of publicly supported science being done to assess the risks of GM foods relative to the ongoing assessment of risks from pesticides. Moreover, I think my colleagues would agree that, given that we don't even know what to test for, we don't have endpoints, we don't have models, so there needs to be an even greater upfront investment by USDA to develop the sensitive long-term ecologically based screening protocols that are going to deliver the data that Paul felt was lacking to evaluate the MON 863 technology. It will be important for the USDA to ramp up that investment fairly rapidly from $3 million. Because of the perception that the USDA is really a promoter of the technology it might be appropriate for some of the hard-core risk-assessment research on GMOs to be funded through the NSF or NIH or other agencies whose mission is to develop the science base for state-of-the-art regulation. Any comments on the level of investment?

Kay Walker-Simmons (USDA-ARS, Washington, DC): Just for clarification, the USDA budget for biotech risk-assessment research includes approximately $3 million for NRI competitive grants and includes approximately $5 million for the in-house ARS research budget. So the total is $8 million—still just a start, but it's actually $8 million. And I would also point out it doesn't reflect an increasing interest from scientists for a number of reasons. Increasingly, scientists are becoming much more aware that the customer is always right and are trying—lesson learned—to develop strategies to reduce the amounts of transgene products in foods.

Benbrook: Thank you.

Raffensperger: I wonder if we need to take some of that funding and give it to different agencies. We have a certain set up for food and drugs, and for agriculture. I'm wondering if we couldn't give some money to the Centers for Disease Control. They have experience in monitoring outbreaks and coming up

with new public-health measures for tracking problems. We could give money to some other players to design systems that would help us to prevent big problems from becoming bigger.

Benbrook: Yes. As a tactical and political strategy, the US government would be very wise to diversify the number of players that are contributing to the science base on GMOs. Whether that will happen or not remains to be seen.

I want to switch gears and pursue a thought from Fred Kirschenmann. He talked about the need to solve for pattern, and, in his workshops summary, Bill Lacy mentioned how many people are uncomfortable about GM foods because the current developers and promoters of the technology are using it to address the symptoms of sick farming systems as opposed to fixing the underlying problem in those farming systems. If you are going to solve for pattern you need to understand what the important patterns are that are influencing the health, the productivity, the sustainability, of farming systems. I know Paul Jepson, at several points in his career, has had "aha" discoveries about the relationships of nonpartner organisms in the field that have a profound impact on what crop the farmer is able to harvest and what the farmer has to do to bring that crop through the process. He has gained insights into what some of those patterns are that had not previously been clear to people. I've been thinking about this for about 6 months: one of the most important patterns that we have not thought about or done any systematic research on—and it's a pattern that is profoundly relevant to the practice of biotechnology—how changes in agricultural technology affect the comparative rate of evolution across organisms within an agricultural system. I am becoming increasingly convinced, based on my reading of the scientific literature, that many of the problems in agriculture—animal diseases, antibiotic-resistant bacteria, infectious diseases, poor soil quality, resistance to pesticides—arise because farmers have done things with their farming system that increase the advantage of bacteria, pests, viruses, in terms of their ability to evolve, relative to the other organisms in that system, which have to maintain some kind of a balance if that system is to be healthy. Of course, the tools of biotechnology are designed to accelerate evolution by breaking down the species barrier, by promoting the expression of traits that are not normally expressed in a given plant, and I wonder if we need to ask questions about the pattern of rates of evolution and how technology impacts that. If we could solve that puzzle and not increase rates at which pathogenic bacteria evolve a greater capacity to harm farm animals or people, we might really be doing some long-run good. I invite your comments.

Jepson: Regarding the evolutionary processes, we don't have the tools to explore or to validate assertions like that. David Tillman has proposed that the evolution of weeds has been radically affected by modern agriculture, but most

of the pests we are faced with, in their evolutionary history, have adapted to exploit how we present the crops to them. Let's not think that pests are new. There are twenty-seven references to *Locusta migratoria* in the Bible, for example. We heard about GM maize and pesticide reductions in Africa to treat stem-borer. In my experience in East and West Africa, maize is attacked by a plethora of pests including grasshoppers, locusts, meloid beetles, stem borers—a whole variety of taxa, some of which are affected by *Bt*, some of which are not. To suggest that that technology alone will result in comprehensive pesticide reductions, or, as some of growers have suggested, that that's an overall solution to pest resistance, is absurd. Pest pressure arises because of the way we produce commodities, but we accept that trade-off and try not to compete. How we've affected the evolution of those organisms is open to question, and I doubt whether there's been a dramatic impact on the evolution in general of the life histories, voracity, *etc*., of most pests, diseases or weeds in the particular sense that you were referring to. We are managing the environment. We're part of it and agriculture has to be seen as a part of the landscape, so inevitably we're affecting the evolution of organisms in the longer term, but we're not in a position to argue that it is, by definition, a bad thing.

Raffensperger: Could you design an experiment to find out?

Jepson: Monitoring over eons. Our experiments are carried out on a time scale and spatial scale that allow proper statistics and proper voicing of hypotheses. Some of the things we're talking about are beyond the capacity of experimental science to answer. As a country, we have not bought into the idea of ecological long-term monitoring, but it would be a really great thing to start to do. Why haven't we done that? Well, Oregon is a 100,000 square miles—excuse the imperial units—with about 3 million people. And people say, "Why don't we have the level of ecological monitoring that exists in United Kingdom? Well there are nearly sixty million people there, and every county has a recorder for virtually every insect family. That goes back 150 years, and is a lot of monitoring. We're never going to have that long-term basis for evaluating what's going on with biodiversity, but somehow we need to start to amalgamate what monitoring is in progress to get some idea about the impacts of anthropogenic practices. But, we don't really have a basis for argument either way at this point.

Q&A

Audience Member: I have to disagree with the comment that regulatory agencies must have a balance between approving technologies and safety testing and safety regulations. As a citizen, I need to know that regulatory agencies are weighing my safety and my environment's safety over approving technologies. As a citizen, I don't want a balance, I want my safety first.

Jepson: I understand what you're saying, of course. Whenever a safety concern is raised, it becomes our highest concern. But the EPA has the difficult job, on our behalf, of striking a balance. Whatever agency does this, and in whomever you place your trust, those decisions have to be made one way or another, and certain limits and acceptabilities have to be determined by whatever process. We decide through the ballot box, through this enormous democracy, which ultimately affects the regulatory process. Now, I can understand your being unhappy with it, and other people are unhappy with it for the opposite reason. They consider it too costly, that there are too many tests, *etc*., but, somehow or another, a compromise is reached. The most difficult aspect of risk assessment is accepting that it's an equation. You make a certain number of measurements and in your best judgment based on those measurements, you determine whether something meets some defined level of acceptability. It's one of the most difficult things we do, and it applies to whatever form of agriculture and whatever are our methods of food production—high-tech science-driven or low-tech culture-driven—you end up having to strike a balance between some perceived risk and some perceived benefit, hopefully both measured in the best ways possible. We tend to have poor measurements of benefits. We see sub-high-school economics in arguing for some of the benefits of GMOs, but there also have been some very good studies, and I find it difficult to judge all the benefits. Also, it's very difficult to judge all the risks. Therefore, striking a balance between risks and benefits is difficult with all new technologies. At some level or another in society, we have to place our trust in an organization that does strike that balance.

Raffensperger: There's another perspective on that. We have devolved into that kind of risk assessment and that kind of cost-benefit analysis without asking some other questions. And I think it's a cultural value. It's our fault that we've gone into this ballgame. I think it's our view of science. In a 1996 budget speech, Al Gore said that all Americans understand that we need more research and development to promote global economic competitiveness. Almost anything else is subservient to that. I think we have an invitation to ask if that's really what we want it to do, if that's the only thing we want science and technology to be for. Jane Lubchenko, president of AAAS, has proposed another set of ideas for what science might do; this is where we bring in ethical norms. The Office of Management and Budget has proposed that we devalue the lives of the elderly in looking at the cost and benefit of environmental regulation. The EPA has come out with a different take on that. But it says that our elderly are not our elders—they are not important. This is a cultural value and it plays out in how those costs and benefits are estimated at agencies like EPA. So, this conversation is not simply about whether EPA is doing a good or bad job. It's about values and how they are taken into account and how we hold that conversation as a democracy.

Jepson: I don't believe that those values are excluded from the current process. I see them in abundance in the debate. I see them taken into account in virtually every forum I've participated in, including the final deliberations on whether or not to register certain products.

Raffensperger: I would never say they are excluded completely. But, even in your comments, about the need to balance cost-benefit—that language expresses a certain set of deeply imbedded values in our culture. Not at EPA or the immediate conversation of risk assessment, but in our larger culture, which influences that discussion.

Audience Member: Paul, regarding your comment that you see poor information on benefits—I'd have to say the opposite. I have seen, in this conference at least, poor information given on the risks, at least not satisfactory to me. That leads into my comment on the precautionary principle. Thank you for your questions on tracking the harms because they are the same questions that I've been trying to ask and have been repeatedly reassured by many here that scientific methods that are brought about by technology are sound, rational and objective. In the last 2 days, when I've asked questions on the precautionary principle I've received similar bland and obscure answers, that scientists agree on the safety, that the benefits far outweigh the risks, that fear of risk is irrational and that if something goes wrong, well we'll just repeal it and we'll take it back because in a few years there will be no traces of it in the environment. To me, if science wants to reach a crossroads with society then scientists are going to have to do a much better job in answering these questions. I'm not a scientist, but I've seen the wonders of natural life and one of those wonders is its ability to defy western science's attempts to simplify and control its innate tendency towards continual change as well as nature's interconnection where one thread tugs on another.

Benbrook: Do you have a question?

Audience Member: Not a question. I see this is as a central theme to this conference. It's important to say this, because a lot of people have the same concerns. I refuse to believe that we can throw this technology into any ecosystem and then simply take it out when it goes wrong. I would feel better if science acknowledged the risks to society to my face, rather than deny and reassure me that science has it under control, or give me a vague response that I may not understand science. As a person who's on the fence, I'm trying to understand all sides of this issue. I would trust that scientists are working on it. As a part of society I want to know the truth. I don't want to be patted on the head and be reassured. I want straight answers on this question. It just makes sense to me that the precautionary principle is the best way to approach

biotechnology, because going ahead without implementing it will not win the hearts of the society that I'm a part of. Thank you.

Benbrook: Everyone who has followed this issue and is a part of it wants to see science progress. I think that one of the things that we are going to have to admit in the United States is that the number of independent scientists who have a well grounded, in-depth personal knowledge about the risks and the impacts of transgenic crops, and experience from their own work, is surprisingly small. The number of people involved in that work and who are gaining independent expertise is going to increase, I hope, fairly rapidly. It won't settle the debate, but it'll place it in a more grounded context. Before the scientific community in this country can speak credibly with one voice on this, there needs to be a lot more independent science done and a lot more process to achieve a meeting of the minds. At an American Phytopathological Society or Entomological Society of America meeting, a majority of the scientists there might take the view of Jim Cook that we really understand this stuff, that there are no real concerns about risks. But, if you go to an Ecological Society of America meeting a much more substantial portion of the scientists will have some interest and questions about what the technologies might do. We're a long way from unanimity in the scientific community.

Raffensperger: And not just those disciplines. How many of those independent scientists actually understand how a combine works? We've been fascinated by the discussion about how seed banks have gotten contaminated because people didn't understand that you can't clean out a combine.

Anne Schwartz (Blue Herron Farm, Rockport, WA): About 165 people registered for this conference. There are fewer than sixty-five people in the room and that to me is a real shortcoming. Understandably, people have busy lives, but the discussion today captures the tensions that scientists and concerned citizens raise. One of the problems with getting these two groups to communicate is that scientists do tend to work, I won't say in a vacuum but in isolation from the impacts of their work on the rest of us. And as a person who's worked for many years on funding and research priorities at Washington State University, I see the direction that WSU is going in with their new biotech center and how much money actually goes into systems research such as Fred Kirschenmann talked about and such as those of us in the organic farming community would like to see advanced. We need to have more of the decision makers playing the role of the bridge between the scientists who are doing research that excites them and concerned citizens who ask, "What will be the impacts of this research?" It does feel like our efforts to bring these conversations into the public domain have been successful. I appreciate the media representatives who are here. I appreciate the fact that this is going to wind up in print, and it

certainly is my goal to see scientists and concerned citizens find a way to talk, and I think we've started that conversation.

Benbrook: Anne would you just stay right there for one second? Jim Cook raised an important question the other day. He asked what could be more organic than a gene? I've been thinking about that and I'd like to offer my answer to his question. You have deep roots in the organic community and perhaps you'd like to share your thoughts on what could be more organic than a gene. From the perspective of the organic community, the answer to that is an understanding of how farming systems impact the interactions between organisms that bring out or compromises the genetic potential of that farming system to produce a profitable, healthy, sustainable crop. That is what is more organic than a gene: the organic understanding of how that system functions. Anne, as a farmer, do you have a different one?

Schwartz: One of the ways I respond to how genetic engineering winds up in the public domain is to ask who controls it and who owns it. Issues around seed are complicated and difficult to get into the public discussion. They don't distill into sound bites very easily. As we look at the cultural history of seed, I find a higher degree of comfort as I listen to the talks about doing this research in the public domain and providing seed free to a community in need. That starts to make me feel a little more accepting of the technology. My barrier hits when I see the technology furthering the concentration of our food supply. If I leave discussion of the biological implications over here and just look at the political implications that's where my lines get drawn.

Robert Wager (Malaspina University College, Nanaimo, BC): I'm a scientist and I'm trying to learn how to better educate the public about this issue and other issues of science. I've read a fair bit on the precautionary principle and it seems to me that it can be used to stop or ban virtually anything that has risk associated with it. Therefore, if we adopt the precautionary principle what would happen to the organic food industry that has well documented risks of pathogenic microorganisms, use of pyrethroids, which are likely carcinogens, use of copper sulfate, and others. And, before I get an answer, I'd also like to express my happiness in understanding that the regulations are improving and that there is an ongoing effort to increase the stringency of the regulations based on good scientific principles. That's a very good thing and continued improvements in regulations that are based on good questions can only benefit everybody.

Benbrook: Carolyn, do you want to respond to that?

Raffensperger: The early thinking on the precautionary principle, at least in the United States, ran the risk of doing exactly what you said. You bring it in late in the game and say, "Oh no, stop it." That's just kind of dumb. That's why setting goals helps, then you know what you are trying to accomplish and if you look at the larger system, comparing your alternatives for meeting your goals, then you can use the precautionary principle well. If it is used only as a risk-management tool—if you've done your risk assessment and then say, "Oops, this warrants this precautionary action, ban it—that's the problem that I see in bringing the precautionary principle in at the end game. It has to be brought in earlier and used to help society to meet its goals.

Wager: What would stop it from being used exactly the way I just put forward? It seems to me that full application will result in bans where there is any risk.

Raffensperger: Well, it's actually been used in interesting ways in Europe to force technology innovation. Instead of stopping everything, it's actually forced new and cleaner technologies. So your fear, in its almost 35-year history in Europe, has just not proven to be true. Where you do see the possibility of what you say is in international trade. Europe may say, "We don't want your biotech foods without labels. I suspect that they will apply conditions, like labeling, rather than actually banning it, but we'll see. I think you'll see it being used as a risk-management tool unlike in the larger framework that I laid out. So, at least the European experience is that it has not banned things or stopped technology. They didn't go back to horses and buggies in Germany, but they used it to do some very innovative things.

Jepson: One beneficial impact of adopting the precautionary approach has been greater and more rapid access by growers to newer and less-hazardous agrichemicals. I'm a European so I've seen this thing work. In practice, the regulatory methods and tests that are used—the packages that registrants submit—are not profoundly different, and at some level this debate about the precautionary principle *vs*. the science-based risk-assessment principle is a semantic argument. The reality of what is actually asked for, what is done, how the adjudication is made, is not terribly different. Let's not get caught up in somebody else's debate. We need to focus on the quality of the insight we have and the general acceptance that risk-assessment procedures are flawed. They're not perfect. Some systems are more flawed than others and we need to try to improve them. That's the key behind where we need to go. A more precautionary approach may benefit the system here, but the gradual, incremental, conditional approvals that the United States is giving—if you actually analyze that according to the precautionary principle—come out looking rather precautionary. I wonder sometimes at the semantics *vs*. reality.

Raffensperger: I agree that we need risk assessment to compare alternatives. There's no other way to do this. And we need science to give us the best information. This is not an anti-science thing. The precautionary principle has proven to be difficult in international trade, no question. International trade was difficult for Germany in terms of costs.

Wager: I believe it can be used to argue absolutely any point on any side of the issue.

Steven Garrett (WSU Cooperative Extension, Tacoma, WA): As an extension agent I try to interpret these technologies for others. I try to express the polarity, both sides of the argument, and let people make up their own minds. We've talked about the double standard of testing between pesticides and genetically engineered crops and it seems to me another double standard is running as a thread through this conference. Most of us agree that one of the strong benefits of genetic engineering is reduction of pesticide use. But we hear people say—especially from companies that produce both—that pesticides are safe. This strikes me as a problematic stance: promoting genetic engineering with something that is safe while reducing something that is safe. Could you comment on the ethics of promoting *Bt* this way, because it has a bearing on regulations and how we set up regulations and on how people assess risk.

Jepson: You're absolutely spot on in saying that this presents a dilemma to a company that, on one hand, is marketing an agrochemical and on the other hand is marketing a product that can reduce the use of that chemical. They are put into the position of arguing for reduced hazard while claiming that their regular chemicals are safe anyway. Of course, many conventional pesticides are not safe. They are rather hazardous if misapplied or even in conventional use. In modern farm practices they are used far less than in the past and in different ways, and are even being replaced with beneficial technologies like biological control. The term "safety" is misapplied by virtually everybody that uses it. We are using some extremely hazardous, toxic materials and we're trying to find ways of avoiding or minimizing their use, and one possible way of doing that is with biotech products. It is remarkable that the statistics from biotech trials for this country are showing for the first time productive agriculture in the absence of heavy pesticide use in the era of modern science. When you see the dramatic differences in natural enemy abundances between the biotech crop and the conventionally treated crop, it's a shock. In Oregon the growers of NewLeaf™ potatoes became biodiversity converts overnight because of the amazing abundance of organisms that recolonized that system when it was released from so much spraying pressure. Again, the term "safety" is often misapplied. Some very toxic materials can be used in a way where the risks are reduced but not removed. The hazard is always there and that's what we've grown to "accept" in the way we work.

Benbrook: There is good evidence, particularly in cotton not so much in corn, of substantial pesticide reductions. However, in the case of herbicide-tolerant crops, which account for two thirds of the acreage, the whole purpose was to allow farmers to rely more predominantly on herbicides. Herbicide-tolerant varieties are treated in the medium- to high-dose range—they have not reduced the volume of herbicides applied. So when you make statements about impacts on pesticide use, it's important to be specific to both the GM technology and the area. Reductions in insecticide use in Arizona and Mexico in cotton are much more substantial than in the southeast because of differences in ecology. It gets really complicated in a hurry.

Garrett: I don't think we can have that conversation unless we say upfront that it's of societal benefit to reduce pesticide applications.

Jepson: Right, and that's implicit even in the case industry is making.

John Browne (Judd Creek Nursery, Burton, WA): I'm the local-grade unwashed, and probably badly educated. While I was standing listening to the conversation, it occurred to me this the predilection of western reductionist science—whether it's extracting good whiskey out of beer or heroin out of opium or the pyrethrin out of a daisy—it's an ongoing thing. I'd actually prefer to deal with the devil that I know on at least a microbiological level than the devil that I've only met recently in the form of hallogenated hydrocarbons or our present subject. I guess my question is—

Raffesperger: I would just point out that the devil is a fallen angel.

Browne: Sure. This may be an ethics and economics, rather than an agricultural, question, but the GM debate seems to impel a two-world economic model. It puts the First World economies and technologies in one group and the Second and Third World community in another economy, like two side-by-side global economies. The generic and specific examples I have of that is the present economic model, of the Third World selling in the First World and then, on the other hand, to produce, say, DDT in the First World and only sell it in the Third World. Is there an ethical component to that or is this just human behavior and we'll have to put up with it?

Jepson: Thank you, John. There's a deeply ethical component to what you've raised, and its something we haven't mastered. If we offered the developing world access to American markets we'd do a great deal to raise the value of agricultural production in the developing world and achieve a great deal of progress thereby. It's a chronically difficult problem, globally dealing with trade with the developing world. I go to sustainable agriculture meetings all around

the world. One thing I've learned lately is of a parallel project going on in East Africa on maize pest suppression that uses modern science and technology in a way that is very sympathetic to a partnership with, in this case again, Kenyan growers of maize. If you look, in the pages of the *Journal of Royal Society*, *Proceedings of the Royal Society* or *Nature*, there is something described as "push-pull" technology—using indigenous Kenyan plants to repel the pests from entering fields and using the trash from those plants, to use an Americanism, to suppress striga, which is a major goal. And extracts from those plants are used to attract beneficial insects that feed on corn borers. This has been so incredibly effective that it's produced a new grower-science partnership that is one of the good news stories to come out of East Africa. African growers today were portrayed as "technology isolated." Well, I can tell you their not innovation-isolated. This is a way of growing corn in Africa that is extremely productive and effective, and I'd hate to think that the technology we heard about from Drs. Hoisington and Ngichabe would either be seen as a substitute or a replacement for such an extraordinary, capable and valuable way of developing and growing a commodity. I'd say a similar thing for breeding exercises in Mali where for thousands of years growers have been producing millet and sorghum, and maize more recently, and they practice a system of crop improvement there that has the admiration of crop geneticists the world over. Again, I'd hate to see that diminished by having centralized breeding that offers services back to that community when I don't believe that's what they really need. Ethics are behind this. Ethics play far too small a role in education in the United States. If we considered the ethical implications of what we do, sometimes we would curtail our activities.

Benbrook: Regarding the point that Paul made about research in Africa on striga and stem borer in the United States and USDA context, we heard this morning about a ramping up to over $100 million support for genomics—genomics being the cutting-edge basic science that needs to be done for the development and employment of the tools of biotechology. I assume none of us is laboring under the notion that applied systems approaches to agriculture—to solve a lot of the same problems—are getting anywhere near that kind of investment. In fact, the funding, academic positions and amount of work being done on that area is certainly down 50% from 10 years ago and at some institutions it's even more. Whether it's a conscious choice or not, we are putting a lot of new resources into building the scientific infrastructure for genetic engineering types of approaches. At least that's how it appears to a lot of people. And we are certainly disinvesting in the other types of science, which are public policy choices underpinned by values and ethics.

Gabrielle Roesch (Western Washington University, Bellingham, WA): Science and society at a crossroad could also mean science and ethics at a crossroad. Some

have said that scientists should not be addressing ethical questions, but should be left to society and policy makers. But, oftentimes, we see science authorized by its rationality and objectivity, and it is often proposed by scientists and industry people that if only we (society) understood the science of biotechnology then we would embrace its implementation. How can we engage in conversations about ethics when science is often viewed as superior to the ethical, social, cultural and political questions that arise when we discuss and consider biotechnology.

Raffensperger: Can I give a sideways answer to that? I came up with a new proposal for a legal standard for sexual harassment law. It's called the respectful-person standard and you can read about it in the Harvard Law Review. If we judged more of our work by whether it's respectful—*e.g.*, you know the trade issue of DDT and what we export and what we import—if it was not only rational but also a respectful decision that we would go a long way to being able to understand ethics especially in the face of uncertainty. The respectful-person standard probably sounds as loosy-goosy to some as the precautionary principle, but it's no more loosy-goosy than saying the word rational when what you mean is you disagree with me.

Jepson: The ethical debate in this country lacks both quality and depth. Scientists in particular, have sought the pedestal and have built the ivory tower, and have done a terrible job of explaining what the benefits of its technology might be and of considering the reasonable concerns of members of the public. You are describing a rather tragic situation that's not being helped by the increasingly polarized nature of the debate. And you're seeing the phenomenon of what happens when a shockingly new idea is introduced to society, and it's not going as well as one might have hoped.

Carol Gonsalvez (Hilo, HI): I'd like to speak for a group of people who have no word here today. How much voice will you allow the poor in the world to have? I've seen them, especially in Thailand, because we work with them, trying to help them improve, to have transgenic papaya because there's no other way to have healthy papaya crops. Every day our collaborator says that people come to her station in Thailand and ask, "Can I have the seeds?" They are asking for virus-tolerant seeds because that's the best they can get. They eat papaya there in northeast Thailand as a stable food and here we are—we think we know everything—but, really, who should decide? We need to think of all the stakeholders. We are stakeholders and the poor are stakeholders. How many of them are here today speaking for themselves? Because, they don't have money, they can't come to this meeting. As we close, I want us to think about the world, the needs, and could you sitting there tell me how much voice are you willing to give them in this discussion?

Jepson: Gaining access to the indigenous peoples of the world, the poor and the excluded, and having their voice play a role in the way we shape our science is extremely difficult. I suppose as individuals we have to make choices in how we do that. I have spent a lot of my career working in places in the world where agriculture is not part of a cash economy, it's part of a subsistence economy, and hopefully I have made contributions to management of pests in those countries. But, it's a pathetically small contribution compared to the enormity of the challenge. All I can say is that through our participation in overseas programs where we actually meet with growers in parts of the world where the agricultural economy is impoverished, the understanding gained hopefully influences the research we do. I hope it's had an influence on me. I do a fair amount of work with the FAO, which has developed in the past 10 to 20 years the farmer field school principle, which has had hundreds of thousands of participants. It's a principle that seeks to learn from growers first about the problems they have and the way they manage their systems and then to find ways of assisting them to reach conclusions about how they can take things further. That's been really successful. If you do a Google search on community IPM you can see how important and successful that's been. It reverses the model of Green Revolution, the top-down way of imposing science on cultures around the world and I think it has a lot to offer. But that's all I can say. We make pathetically small individual contributions. It's a deeply concerning issue and there's no easy way around it. I'm sorry I can't give you a better answer.

Raffensperger: You've asked it so beautifully—democratic participation is essential. I wish it were up to me to figure out how to get more voices here. It's not. I wonder if that's not a role for more of the social sciences in figuring that out. I don't know a lot of the world very well. I know a little corner of North Dakota where our farm is, and I know how farmers feel there—disenfranchised from the conversation, powerless in the face of government telling them what to do, whether it's my neighbor who wants to shoot his coyotes or whatever else, and the inability to pay for their kids' school fees or even buy their kids glasses because they can't afford the basics of life. That's just the little corner I know, and they feel that they have no voice. It's a striking problem. We're sitting in this extraordinary hotel—I had papaya yesterday with my tofu egg-rolls—and it's a key problem.

Bonnie Rice (Washington Sustainable Food and Farming Network, Bellingham, WA): I took a part in planning this conference and assisted bringing in different viewpoints. Because of the expense involved, many people cannot be here. I hope the discussion does not stop here. There is much concern, which has been obvious throughout the meeting, and a lot more discussion is needed. It's very appropriate for people in public institutions, especially the land-grant universities, with their mission of serving agriculture and rural communities,

to find more ways to engage the public in dialog on this issue. There hasn't been nearly enough dialog. I heard Dr. Cook say that the scientific community decided they've got to move ahead of this. They see enough benefit. That is not something that I wanted to hear or that I accept. People in this country and around the world are not going to stand for it. We need to look at questions like what right does the United States have to force this technology literally down people's throats?

PART IV

LUNCHEON & DINNER ADDRESSES

The Papaya Story: A Special Case or a Generic Approach?

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The approach of developing virus-resistance in plants by expressing the coat-protein gene of the target virus is one of the truly great contributions in plant pathology and agriculture in general. It can be used for nearly all groups of plant viruses. Yet, since its development in the mid-1980s, only two virus-resistant transgenic crops have been commercialized in the United States: squash and papaya. In this short article, I will examine the papaya case and elucidate the factors that drove the investigators towards commercialization, and ask the question: Was this a unique case or might it be a generic approach?

Papaya and Papaya Ringspot Virus in Hawaii up to 1992

The Hawaiian papaya industry is based on the 'Hawaiian solo' variety, which is derived from a line that was introduced to the state about a century ago. Its characteristics are its small size (typically about 1 lb in weight), a sweet and pleasant flavor, and good shipping quality. 'Kapoho' became the dominant cultivar, grown nearly exclusively on Hawaii Island in the Puna district. The Puna district, in which papaya has been grown since the early 1960s, is unique in Hawaii because it has largely a lava-based soil, and, although it has about 100 inches of rain per year, it enjoys lots of sunshine. Thus, a combination of good drainage, abundant rain and sunshine, the availability of large tracts of land for lease at a reasonable price, and absence of papaya ringspot virus (PRSV) made the Puna district ideal for raising 'Kapoho' papaya. In fact, in 1992, Puna was producing 95% of Hawaii's papaya.

The ringspot virus is the most important viral disease of papaya worldwide. It was discovered in Hawaii in the 1940s by Jensen who coined the name. In the 1950s, the virus began to cause severe problems on Oahu Island, where Hawaii's commercial plantings were located. Some have surmised that the virus discovered by Jensen was milder than the strain that caused severe damage in 1950s. The papaya industry was forced to relocate in the 1960s to Puna, where it flourished.

Although free of PRSV, Puna was potentially in danger of getting the virus, because it was found in the early 1970s in Hilo, a town located about 19 miles from the main papaya growing areas in Puna. The state recognized this potential problem and the Hawaii Department of Agriculture (HDOA) utilized a small crew to rogue PRSV-infected trees in Hilo and surrounding areas. Much credit is due to HDOA for delaying the spread of PRSV.

Research was started in our laboratory in 1978 to develop PRSV-control measures, given the potential that the disease would inevitably move to Puna. The virus was purified, characterized, and antiserum produced allowing rapid detection. Cross-protection was the first approach we used, resulting in a mild mutant being produced and tried on Oahu Island. The approach provided economic returns to farmers on Oahu, but was not adopted widely because the mild strain caused distinct symptoms in the winter months. Some cultivars, such as 'Sunrise,' showed significant symptoms, and rather involved logistics were necessary to produce the mild strain and to inoculate plants. In the mid 1980s, we started developing transgenic papaya that expressed the coat protein of the mild PRSV mutant that we had developed in our cross-protection approach. A lesson to be learned—as will be seen as the papaya story unfolds—is that, when possible, one should work towards solving a problem before the problem occurs in the target region.

Industry in Crisis—Transgenic Papaya Commercialized: 1992–1998

The research team consisted of Jerry Slightom (molecular biologist), Richard Manshardt (horticulturist), Maureen Fitch (then a graduate student of Manshardt and an expert in tissue culture), and me (virologist). Our primary goal was to develop a timely practical solution for controlling PRSV and we had the good fortune of obtaining moderate but consistent support from special USDA grants that were earmarked for improving agriculture in the Pacific region. The PRSV coat-protein gene was cloned, engineered into the transformation vector, and transformations of embryogenic cultures were initiated with the gene gun in 1988. We also had the distinct advantage of having the counsel and use of the facilities of John Sanford, the co-inventor of the gene gun.

By 1990, we had obtained seventeen transgenic plants of 'Sunset' and 'Kapoho.' Sunset, a sib of 'Sunrise' that has red flesh as compared to the yellow-flesh 'Kapoho,' is grown extensively in Brazil, but not in Hawaii. Our preferred target was 'Kapoho,' but it was more recalcitrant than 'Sunset' in regenerating plants from transformed embryos. Clones of the transgenic lines were developed and tested for resistance to PRSV by mechanical inoculation under greenhouse conditions in 1991. To our joy, we identified a resistant line, designated "55-1," which was resistant to a Hawaiian isolate, PRSV-HA. Following our practical philosophy, plans were quickly made to do a field trial at the Waimanalo field station of the University of Hawaii on Oahu. The field

test consisted of clones of 55-1, other susceptible transgenic lines, and nontransgenic 'Sunset.'

The field test was started in April 1992, and, coincidentally, PRSV was discovered in Puna in May 1992. This discovery sticks out in my mind because I happened to be in Hawaii when it was reported, and Steve Ferreira, a plant pathologist with whom I was collaborating on cross-protection, and I were among the first to see the pocket of PRSV-infected trees. The image of the small pocket of infection and the devastation that would occur within only two years helped to spur our efforts to control PRSV. Another lesson in the papaya story is that we went straight to testing clones of transgenic plants in the field. We could have, and we did later, obtain seeds from the transgenic R0 line and then tested the R1 plants in the field as is normally done. However, this approach would have delayed the initial field trials by about two years—disadvantageous considering the speed at which PRSV spread throughout Puna.

As the virus spread rapidly in Puna, we moved to determine the resistance of line 55-1 under field conditions on Oahu Island. The HDOA's massive efforts to suppress the spread of PRSV by roguing infected trees helped to slow the spread of the virus, but by October 1994, it had spread to such an extent that further control efforts were abandoned. This further accelerated the spread, because infected fields served as continuous sources of virus spread by aphids.

By 1995, the papaya industry in Puna was in crisis. This translated to the industry in Hawaii as a whole, because Puna was growing 95% of the state's papaya. In the meantime, the field trial in Waimanalo provided convincing evidence that line 55-1 was resistant to PRSV. Manshardt developed two cultivars that would be subsequently commercialized, 'SunUp' and 'Rainbow.' 'SunUp' is transgenic line 55-1 'Sunset,' which is homozygous for the single coat protein gene insert. 'Rainbow' is an F1 hybrid of 'SunUp' and nontransgenic 'Kapoho'. The development of 'Rainbow' proved decisive because it is yellow-fleshed, which is preferred by consumers and farmers in Hawaii, it has hybrid vigor which results in increased yield, and it has suitable shipping qualities.

While 1995 was a crisis year for the papaya industry, it was also a pivotal year in our research efforts because we were able to establish a large field trial on a commercial papaya farm that had gone out of business because of PRSV. The field trial was important because it was to be done in the area where we wanted to control PRSV; it allowed us to test 'SunUp and 'Rainbow' under the target climatic conditions; it served as a basis for farmers to observe the plants and fruit since they would need to be convinced of the resistance and of horticultural qualities; and it gave us a firm basis for observing the transgenic papaya as we initiated the process of deregulation by APHIS, EPA, and FDA. Steve Ferreira joined the team and directed the field trial that was started in October 1995. It provided convincing evidence to researchers, farmers, and packers that the transgenic papaya was, indeed, resistant to PRSV under severe virus

pressure, had horticultural qualities that farmers and packers liked, and that productivity of 'Rainbow' was very high. Under severe virus pressure, the calculated yield of 'Rainbow' was about 125,000 lb/acre, as opposed to 5,000 lb/acre for nontransgenic 'Sunrise.' The latter yield was low because of early infection by PRSV.

A lesson learned from the field work is that trials that serve several purposes—such as obtaining critical scientific data, simulating commercial conditions, and serving as forums for observations by farmers, packers, and consumers—are very useful in shortening the time required for commercialization. From 1996 to 1997, petitions were prepared and submitted to APHIS and EPA to deregulate the transgenic papaya, and documents were prepared for consultation with FDA on food-safety aspects. The transgenic line 55-1, which was the parent of 'SunUp' and 'Rainbow,' was deregulated and consultations were completed by the end of 1997.

The commercialization of the transgenic papaya was led by the Papaya Administrative Committee (PAC), which consists of growers who have agreed to be in a USDA marketing order that allows the taxing of a percentage of the proceeds that are obtained from the sale of papaya from packing houses. This approach was necessary because the investigators had no backing from commercial companies. The PAC enlisted a lawyer, Mike Goldman, who was successful in obtaining the necessary licenses for commercialization.

Seeds were distributed free to growers on May 1, 1998, almost six years to the day on which PRSV was discovered in Puna. Since seeds were not available in sufficient quantities for all farmers to have what they desired, the distribution were based on the degree of PRSV damage experienced and the acreage grown. All of the farmers had to view a video on the transgenic papaya and sign an agreement that the seeds would be not be planted outside of Hawaii. Essentially, the transgenic papaya could be grown only in Hawaii, but fruit could be sold wherever transgenic papaya was legally accepted wordwide.

Commercial Transgenic Papaya in Hawaii: 1998–Present

A survey on adoption of the transgenic papaya by farmers was taken, starting in 1998 until the end of 1999. Results showed a rapid adoption rate (adoption being defined as the obtaining and actual planting of transgenic seeds) by a great majority of the farmers in Puna; 'Rainbow' was by far the dominant transgenic cultivar, and resistance to the virus held up in commercial orchards. It was also observed that transgenic papaya adjacent to highly infected fields remained resistant, which allowed growers to directly reclaim infected fields without prior elimination of the orchards.

The stability of resistance under field conditions was always a concern, to growers and to investigators. This was especially true for the widely planted hemizygous 'Rainbow,' because our greenhouse tests had shown susceptibility to isolates of PRSV from Guam, Taiwan, and Thailand. Fortunately, inoculation

tests showed that 'Rainbow' was resistant to numerous isolates collected in Hawaii. Nevertheless, a program to consistently monitor for resistance-breaking Hawaiian strains was started and continues to the present. Hawaii is cognizant of the need for constantly monitoring to help ensure the long-term stability of the resistance of the transgenic papaya. In particular, it is crucial that care be taken against the introduction of exotic strains.

The impact of transgenic papaya has been dramatic and measurable in yield. In 1992 when PRSV was discovered there, the region was producing 95% of Hawaii's papaya, amounting to $53x10^6$ lbs of fresh papaya being marketed locally and abroad. The virus caused production to decline to $26x10^6$ lbs annually in 1998, when transgenic seeds were released. However, by 2001, Puna was producing about $46x10^6$ lbs primarily due to the planting of 'Rainbow.'

The impact is also apparent in allowing the growth of non-transgenic papaya in Puna. Non-transgenic papaya is crucial to Hawaii's industry because Japan, an important export market, requires it. Japan has not yet approved the introduction of transgenic papaya. Numerous observations had clearly shown that planting of non-transgenic papaya next to infected fields results in almost no economic return. Although spatial isolation can result in increased economic returns from non-transgenic plantings, prior to the release of the transgenic papaya, isolation from infected fields was virtually impossible in Puna. After release of the transgenic seeds, large tracts of transgenic papaya—along with destroying abandoned infected orchards—served as effective isolation from PRSV to allow the economic regrowth of non-transgenic papaya in Puna. Thus, Hawaii continues to produce nontransgenic 'Kapoho' to satisfy the Japan market. Without the transgenic papaya, it is my opinion that this practice would not have been possible.

Although transgenic papaya is now an entrenched component of Hawaii's fruit production and is a dominant reason why resurgence of PRSV has not occurred to a large extent in Puna, the industry is not without its problems. In the past, overproduction has resulted in oversupply and lower prices to farmers. In contrast, production of papaya can be limiting because, although it is produced year-round, the crop has troughs in production during which demand cannot be met. Lastly, as a consequence of PRSV, Hawaii lost much of its market share during the 1990s. All of these factors affect the well-being of Hawaii's papaya industry. If not for the transgenic papaya, however, production would have continued to decrease in Puna, perhaps resulting in the demise of the industry, which is second only to pineapple in Hawaii.

A Unique Case?

An analysis of the papaya case reveals that it is unusual in comparison with other commercialized transgenic products in that it was developed and commercialized outside the direct influence of companies. Our primary

objective was simply to develop a control measure for a potentially severe problem, rather than to create a profit. The urgency of obtaining a commercial solution became apparent after PRSV was discovered in Puna, by which time we had already identified a resistant transgenic papaya. Also, papaya is not a major crop and thus is of little interest to large companies. Although we have not calculated the cost of the project, it was rather modest because it was carried out mainly as a normal university-type project in which a series of grants was obtained to fund long-term research. The project was never a full-time endeavor of the research team. The blending of expertise definitely helped in making progress through all phases.

The timely start of the field trials was a major factor in moving us quickly to our goal. Several important aspects were contributory. The first was the practical attitude of the team in moving directly to a solution rather then being unnecessarily side-tracked in investigating interesting observations. The second crucial condition was the willingness of APHIS to work with us. We also benefited by being able to analyze the squash petitions that had been recently submitted by Asgrow Seed Company, with whom I was collaborating. And, in retrospect, one can say that the climate surrounding GMOs was largely "friendly" during our efforts to deregulate the transgenic papaya.

The deregulation of the transgenic papaya by EPA entailed the development of rational arguments and the generation of data that the coat protein was already present in infected plants at higher levels then in transgenic plants. Furthermore, the cross-protection approach had utilized thousands of mild-strain-PRSV-infected plants from which the cross-protected fruits were consumed, with no reported ill effects. Consultations with FDA went smoothly because our analysis of the plants showed that the transgenic papaya differed from the nontransgenic counterpart only in its disease-resistance.

It can be argued that the papaya case is unique in that it addressed a crisis in which there were no other practical and timely solutions. In my opinion, solving a problem involves a spectrum of cases that provides incremental steps as well as the final key that provides the solution. The papaya case is more towards the latter but by no means does it remain a final solution, especially since we know that there are strains of PRSV that can overcome the resistance possessed by 'Rainbow.' Perhaps a more germane question is: should a biotechnology approach be taken only when all others have failed? I feel that biotechnological approaches constitute just one set of tools among many that may be used, and not necessarily as a last resort or in dire circumstances. Again, when we took up the papaya case, the biotechnology approach provided a rational solution within our capability, no more no less.

It has been mentioned that the amount of data that we had to present to the regulatory agencies was rather small, and that we should have tested the transgenic papaya for a longer period of time before releasing it for commercialization. There are no simple answers to such assertions, except to realize that

risk is a relative term that is weighed in light of the potential benefits of the solution. As noted, the Hawaiian papaya industry was in crisis in 1995, and things would have gotten worse if the transgenic lines had not been released. It might be argued that if the transgenic papaya were tested for 10 years before being released, people would feel safer, but it might have been too late to save the Puna papaya plantings from total demise. One will never know. However, we followed the proper steps in moving through the deregulatory process. Five years have passed since commercialization, so we have had at least that much time to observe consequences and more as each day goes by.

Time has shown that transgenic crops must be examined on a case-by-case basis, and that different countries have different requirements. For example, we have had to generate more information on the transgenic papaya in developing our documents for Japan. The same is true for the regulatory stages that transgenic papaya has to go through in Jamaica, where we have a technology-transfer program. Perhaps the information we have gleaned from our work with papaya in Hawaii will help us address future questions relating to transgenic papaya elsewhere.

SUMMATION

This communication has briefly described the rationale that we used to develop and commercialize transgenic papaya in Hawaii. The impact is obvious five years after seed release. In 2003 the GMO debate is much more intense than it was in 1996–1998, when we worked towards deregulating and commercializing the transgenic papaya. Will the transgenic papaya for Hawaii remain a unique case? Time will tell. It is my personal opinion that progress on developing rational approaches for using GMOs will come only through continued dialogue, showing respect for all views and a willingness to work towards safe but realistic solutions.

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Q&A

Audience Member: To what extent is Hawaii's crop transgenic today?

Gonsalves: I would say 50/50. It's about 50% transgenic and 50% non-transgenic. Japan occupies 30 to 35% of Hawaii's market and it's a very lucrative market, and so they have to grow non-transgenic papaya. One of the big farmers grows non-transgenic papaya, in isolated locations, essentially surrounded with buffers of transgenic papaya to try to cut down on the virus going in. Now, one may ask if transgenic papaya has been found in Japan? Yes, in a couple of cases one papaya tested positive. I'm not surprised at all. My goodness, with the millions of papaya that we ship, some are bound to get through, but Japan's reaction was very reasonable. They did not ban the papaya. They said that Hawaii had to improve security. Japan has been very fair—very tough—but very fair in our application to get it deregulated.

Audience Member: Viruses have a tendency to mutate. Are you noticing any diminution of effectiveness? Also, have any studies been done to appraise negative health effects from these papayas? Even though they look good, have you fed them to laboratory animals?

Gonsalves: Resistance may not hold up because the virus may change. Recombination between the virus and the transgene may occur and, naturally, this was something we were worried about. So, we went all over the Hawaiian Islands, collected over 300 isolates and inoculated them onto transgenic papayas just to see if we had strains that would break down resistance, and no, none of the strains has done so. Since the release in 1998, only a handful of plants has shown infection so we have no evidence that the transgenic resistance is breaking down. Based on the uniformity of the viral isolates and the mechanism of resistance, I don't think that it will break down unless a strain comes from Guam or from Thailand. We know that the Thailand strain

will overcome the resistance of the Hawaiian transgenic papaya. Now, in relation to safety—this is an interesting question. I'll tell you what we did back in 1995, which goes along this line of reasoning. Lots of virus-infected papaya had been consumed for many years and we did not observe any ill effects. Therefore, even though I did not do feeding studies, I had no reason to believe that this transgenic papaya would be harmful because many people had been eating virus-infected fruit. In fact, you will recall, I utilized cross-protection whereas in Taiwan they inoculated millions of papaya trees with the virus and then ate it, and nothing happened. That was the reasoning. Now, did we do any feeding studies? No, we did not do any feeding studies. As far as getting it through EPA or APHIS or FDA, we did not do any feeding studies. In green papaya, there is a natural compound called benzyl-isothiocyanate. Just by hearing the word "cyanate" you know that this is a poison. So, we tested for the presence of this compound, but we did not do any animal feeding. Does Japan require animal feeding? No, but they require extensive characterization of the papaya. I will say that this transgenic papaya, after going through all of the stuff that we have to go through for Japan, is probably one of the most characterized genetic products now on the market.

Audience Member: One of the things that really turned the Europeans around was Dr. Árpád Pusztai's work on genetically engineered potato, and his firing was front-page news across Europe. It really gave the biotech industry a black eye over there. Why not feed papaya to rats and show that there's no problem with it. Then you can take that research to people, label it and have consumer acceptance of it, rather than the suspicion that will arise when such studies are not done which causes consumers to feel that they cannot trust it.

Gonsalves: That's a good point—to prevent criticism why don't we feed the transgenic papaya to rats? Actually that has been done in Jamaica with no ill effects. You know, why we didn't do that? Frankly, I never thought about it. I never thought about doing rat feeding and so forth. Now if there is an established feeding method and if it passes that test then it's safe—I think that's great. Recently there was an article commenting about potential allergenicity of our transgenic papaya, because it has a string of certain six amino acids and so forth. The question of allergenicity did come up and, in my simplistic thinking, I thought, "My gosh we've been eating this stuff for so long and there's been no reaction." But now we have to do it for the Japan application. We have analyzed all this stuff. We have checked it out. We have shown that this protein is digested within 4 seconds. And we are doing that because they say that we have to do it. Same thing with weeds—this thing is virus resistant, it may become a weed. So people ask why we didn't do weed studies. Well I'll tell you our reasoning. Since the early 1900s, the state of Hawaii has been keeping records on weeds. They have very good records on the weeds of Hawaii, and papaya has

never been mentioned as a weed. The virus was introduced in 1945 and papaya was never noted as a weed. Should we have done those studies to prove it is not a weed and how long do you do it? That's the kind of "criticism" that might come of our work. I explained this thinking to APHIS. Now you can debate whether we are irresponsible or not.

Audience Member: Would you explain your story in terms of research funds and where they come from? Are they public or private? In connection with intellectual property rights, you indicated that the seed is free—is that still the case? Who controls that part of the papaya industry?

Gonsalves: As I mentioned, the first research fund was $5,000 from the governor's initiative, but basically it was USDA special funds. You might call it a pork-barrel fund. It was Section 406 and now is T-STAR type funding that the University of Hawaii obtains through various means to help this transgenic work. No funds were obtained from companies. The amount of funding actually was very little. In 1988 we obtained a grant of $117,000 for 3 years to support Richard Manzar and me. We had to do what we had to do to get the job done. It wasn't because we didn't get enough funding. It was because there was a problem out there, we were going after it and I'm forever grateful to the University of Hawaii for even allowing a guy from Cornell to work with them on this problem. Now, in relation to intellectual property rights, well, this transgenic papaya has all the genes and the markers that many of the genetically engineered crops have. It has the 35S promoter, it has the *npt*2 gene, and so forth. Well, Monsanto owns the 35S promoter. Jefferson owns the GUS gene. Diatec owns the leader sequence. Fortunately we had patented the coat-protein gene and the gene gun, because it was done when Cornell had the patent. We had to go through the intellectual property right process. Naturally we had no money, so we went to the Papaya Administrative Committee. They pursued it. Now, on purpose, I did not look at other licenses to see how much they cost, but I can tell you it cost hardly anything. Negotiations had to be made with Monsanto, and it did not cost much. The papaya administrative committee controls the licensing. They are composed of growers, so, early on, they had to figure out how they were going to distribute the seeds. They figured out a lottery system, and the seeds were essentially distributed free. The only catch was that they had to sign a license that they would not take the seeds and grow them outside of Hawaii, because part of the license was that the transgenic papaya could be grown only in Hawaii. The farmers had to watch a 30-minute video on what is transgenic papaya and all of that stuff, and after they did that then they could have the seed free of charge. Just recently I heard that the growers association is beginning to sell the seeds because they want to make money so they can raise more seeds. I think it is about $20 an ounce.

Audience Member: Hawaiian farmers adopted this technology because they had a shortage of papaya and they didn't have other options. And you talked about the virus being spread in many different countries. Do you anticipate that in Japan and similar markets there would be a shortage of available non-transgenic plants in the future?

Gonsalves: I don't anticipate a shortage of non-transgenic papaya in Japan. The Philippines is beginning to ship papaya to Japan, so I don't think there will be a shortage.

Audience Member: But you mentioned that the virus is getting worse in many places.

Gonsalves: Oh yeah, it's occurring in the Philippines, so they have started projects to develop genetically engineered papaya. This product is a good sustainable solution. But I don't know whether it will be adopted, because of the factors that we are talking about it. Another thing: the transgenic papaya in Hawaii is better than the non-transgenic papaya. We tried to transform the current cultivar, Kapoho, and we couldn't. We can now, but back then we couldn't. Kapoho is a yellow-flesh papaya which the growers all want. But, we succeeded in transforming a red-flesh papaya. To make red yellow you have to cross with the yellow and the yellow is dominant. We made a cross between Sunset and Kapoho. Now, for years, Hawaii had just inbred Kapoho. When we made this cross—now it's through no brains of ours because we had to get a yellow-flesh fruit, but we got a hybrid that outyields Kapoho and bears 3 months before it. It tastes just as good, so actually people would rather have the transgenic than the non-transgenic. I don't think it's because they lack non-transgenic, no, I think they'd rather have transgenic, plus it's cheap. All papaya is sold the same: 69 cents a pound.

The Rise and Fall of NewLeaf Potatoes

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AMVAC Chemical Co.
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From 1995 through 2001, genetically modified potatoes were sold in the United States and Canada under the brand name NewLeaf™. These potato varieties were relatively popular with growers because they replaced pest-control practices involving intensive use of pesticides with technology that was present in the potato seed. Market tests indicated that the concept of reduced pesticide use through biotechnology was also interesting to consumers. Despite being popular with growers and consumers, sales of NewLeaf™ potatoes plummeted after the 1999 growing season. I will outline some of the factors that made these potatoes popular, and then examine the issues that led to the rapid decline in sales and their eventual removal from the market. With that information as a background, I will attempt to evaluate the challenges and opportunities for biotechnology adoption in the potato industry in the future.

The Need for Biotechnology in the Potato Industry

Potato is one of the most widely grown vegetable crops, and is planted on approximately 1.3 million acres in the United States each year. Potato production is a high-cost, risky enterprise. Total cost of production exceeds $1,000/acre in most regions, and can be double or triple that in regions with high pest pressure. A high proportion of these production costs are associated with the use of pesticides (Figure 1).

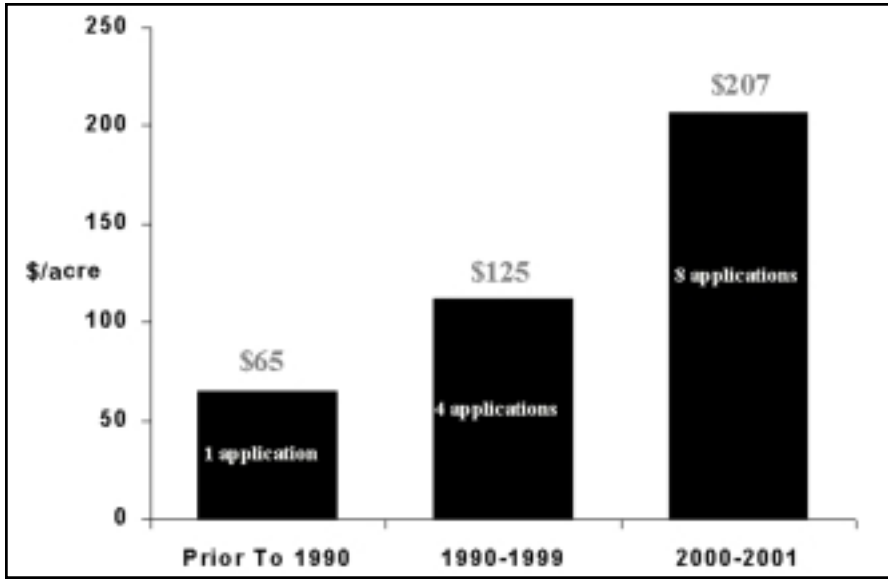

Figure 1. The cost of pest control in various US potato-production regions (data collected from various sources).

Potatoes are vulnerable to attack by many insect, disease, and weed pests. As a result, over 80% of the acreage is treated with herbicides, insecticides, and fungicides (Weise *et al.*, 1998). It has been estimated that reducing pesticide use by 50% would result in a 27% reduction in potato production, while a 100% reduction in pesticide use would reduce yields by approximately 57% (Knutson *et al.*, 1994).

An alternative to pesticide use would be to employ genetic resistance. Considerable effort has been made to find and incorporate sources of resistance to major pests through traditional breeding techniques. However, most of the widely grown varieties remain at least partially susceptible to a wide range of pests. Part of the difficulty in using traditional breeding to develop pest resistance is that potatoes have a very diverse genetic background, and crossing two varieties leads to a wide range of characteristics in the offspring. Therefore, it takes enormous space and time to identify new varieties that have both the pest resistance and the agronomic characteristics that will make them suitable for use on a commercial basis. It is not unusual for potato breeders to take more than 15 years between the initial cross and release of a new variety.

Biotechnology offers a way to incorporate genes for resistance to pests, without many of the complications associated with traditional breeding. Vayda and Belknap (1992) noted that the potato is an ideal candidate for molecular manipulation due to the ease with which it can be transformed. Initial efforts

led to the introduction of insect-resistant potatoes that contained a gene encoding for the CryIIIA protein (Perlak *et al.*, 1993). Expression of this protein in the leaves provided protection from the Colorado potato beetle, one of the most damaging pests. This was followed just a few years later with the introduction of varieties with resistance both to the Colorado potato beetle and to the potato leafroll virus (Thomas *et al.*, 1997). Applications to control these two pests account for over 80% of insecticides used in potato production in the United States.

Initial Market Reaction

The NewLeaf™ Russet Burbank potato was introduced with much fanfare in 1995. The industry had been anticipating it for several years, and had closely watched the research and regulatory trials (Knorr, 1994). The initial planting was only 1,500 acres, but quickly grew to 50,000 acres as seed stocks become available and more varieties were introduced (Figure 2).

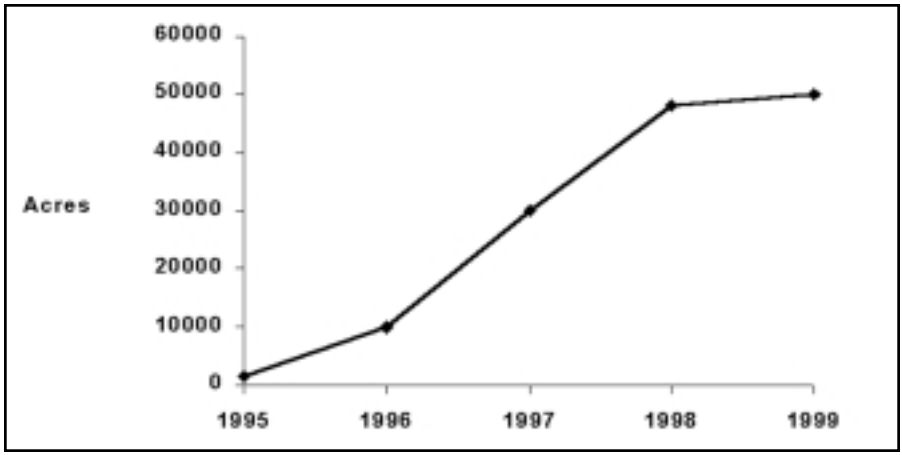

Figure 2. Adoption rate of NewLeaf potatoes in the United States and Canada (unpublished NatureMark data).

A couple of factors coincided with the introduction of NewLeaf™ potatoes that contributed to the market success. The first had to do with the difficulty the industry was having in controlling the Colorado potato beetle. This insect has a history of developing resistance to synthetic pesticides, which limits options for control and puts even more selection pressure on the remaining chemistries. The second factor was that generally mild winters in the major potato production regions during the early 1990s had led to high pest populations, especially of the green peach aphid. This aphid is the major vector of the potato leafroll virus, and because of these high populations the virus was

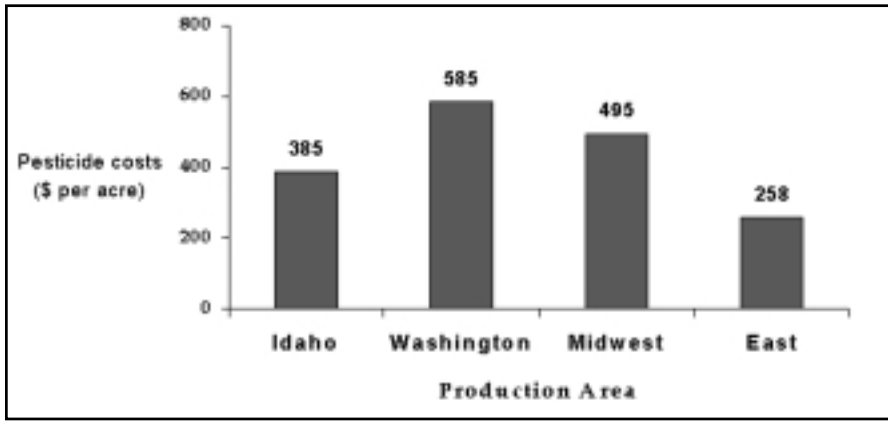

Figure 3. Recommended insecticide spray programs and associated costs per acre for the PNW (G. Reed, Oregon State University, personal communication).

becoming a widespread problem throughout the Pacific Northwest (PNW). As a result of these two situations, insecticide use and associated costs of insect control had increased rapidly (Figure 3).

Growers who planted insect- and virus-resistant NewLeaf™ potatoes were able to reduce insecticide costs significantly. A survey of twenty commercial farms in 1998 and 1999 found that, on average, the number of applications were reduced both in Idaho (short season) and in Washington (long season). Furthermore, tuber quality was improved due to elimination of defects associated with leafroll virus infection. A recent case study by the National Center for Food and Agricultural Policy (NCFAP) reported that insecticide use in the PNW states, Idaho, Oregon and Washington, could be reduced by 1.45 million pounds per year, with a net economic impact of over $58 million, if potatoes resistant to Colorado potato beetle and virus were planted on the 620,000 acres grown in those states (Gianessi *et al.*, 2002a).

Factors were working against the adoption of this technology within the industry. The technology agreement that all potato growers signed prior to planting these potatoes specified that a refuge of non-tranformed potatoes had to be left to reduce the potential for development of resistance to the CryIIIA protein. This resistance-management strategy was developed in a coordinated effort with leading entomologists (Hoy, 1999). Switching varieties during the planting operation was a complication that many potato growers were not used to. A second factor that worked against market adoption was the introduction of new class of insecticides (Imicloprid). These products, introduced at about the same time as NewLeaf™, offered an effective conventional pesticide alternative to producers struggling to control beetles that were becoming

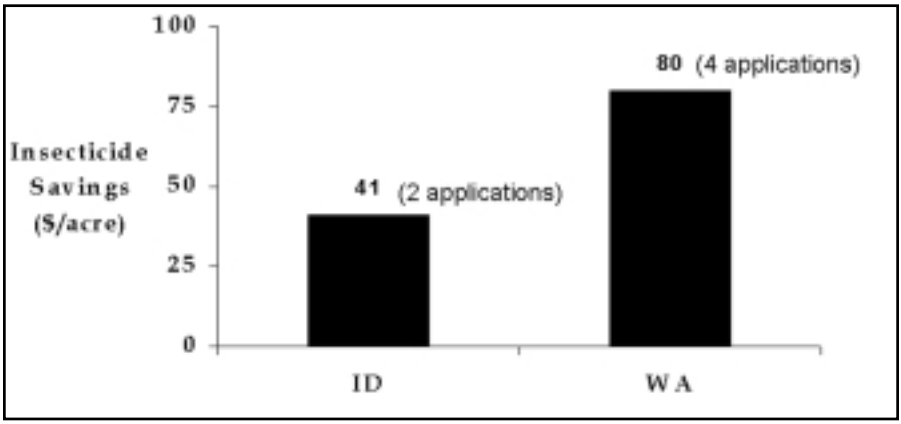

Figure 4. Grower savings on insecticide costs and applications when planting NewLeaf™ potatoes with insect and virus resistance (averages for twenty locations, 1988 and 1989) (unpublished NatureMark customer survey).

resistant to other insecticides. Despite these factors, the introduction of NewLeaf™ resulted in the fastest adoption of a new variety in the history of the United States potato industry.

Factors Leading to the Close of Business

While it was clear that potato growers were gaining economic advantages from the use of this technology, entities higher in the marketing chain were trying to figure out how it would impact their business. About 60% of the potatoes produced are processed prior to entering the market, ending up in restaurants and other food-service outlets across the country. Potatoes were one of the few commodities that had been transformed through biotechnology and were readily identifiable as a food item on restaurant menus. When the public debate over the risks and benefits of biotechnology began to garner attention in the media, potato processors and retailers had to take a very hard look at how they were going to respond to any potential controversy. An initial attempt was made to segregate the genetically modified potatoes so that customers who requested non-GM products could be accommodated. However, the necessary testing protocols and segregation techniques were not well developed. As a result, processors found that the NewLeaf™ potato was not adding value to their business, and was, in fact, causing them to change practices in response to market demands. As market signals to growers from the primary buyers of their potatoes became less certain, many decided they could not afford the risk of planting NewLeaf™ potatoes. The acreage declined rapidly after the 1999 season. In 2001, Monsanto decided to close the potato division to focus on other opportunities for their biotechnology efforts (Figure 5).

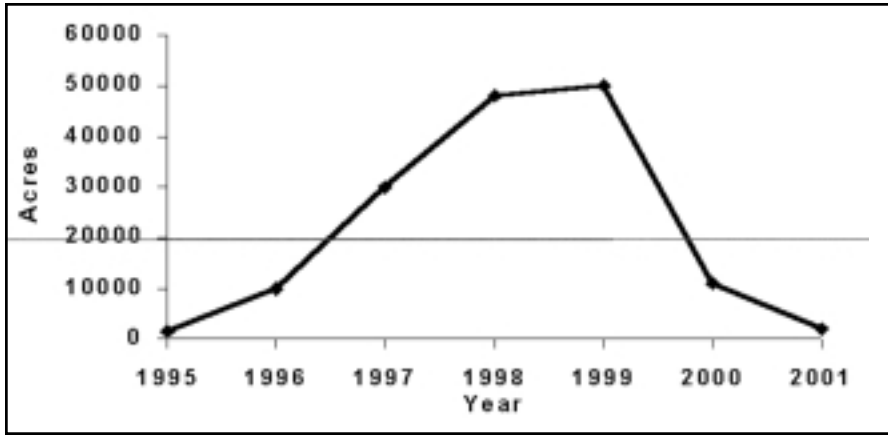

Figure 5. Acreage of NewLeaf™ potatoes in the United States and Canada, 1995 through 2001 (NatureMark, internal data).

Similar types of marketing situations were developing in the corn, canola, cotton, and soybean markets. A key question is, why did the potato business fail when this technology is still being used on millions of acres of other crops? I believe at least two factors contributed to the rapid demise of the NewLeaf™ potato business. The first factor was the relatively low acreage. Despite the rapid adoption and favorable response of growers to the technology, it represented a very low proportion of total production. By 1998, NewLeaf™ varieties accounted for less than 4% of all potatoes in the United States and Canada. The decision to close the business had very little impact on the supply of potato seed for the 2001 and 2002 growing seasons. Individual producers who had been relying on NewLeaf™ seed for a significant proportion of their planted acreage had to go out and find new seed sources, but this did not cause widespread market disruption. This is in contrast to other major crops, where the substantial portion of planted acreage in genetically modified varieties could cause significant market disruption if alternative seed sources had to be found.

A second factor relates to the expense of bringing the NewLeaf™ potatoes to market. Potatoes undergo the same regulatory process as other crops, costing millions of dollars to complete. These costs are recovered by charging technology fees when the seed is purchased. However, with a relatively small acreage base, companies are hard pressed to recover all development costs. A further complicating factor is that potatoes are very slow to propagate; it takes years to increase seed stocks to the point where substantial acreage can be planted.

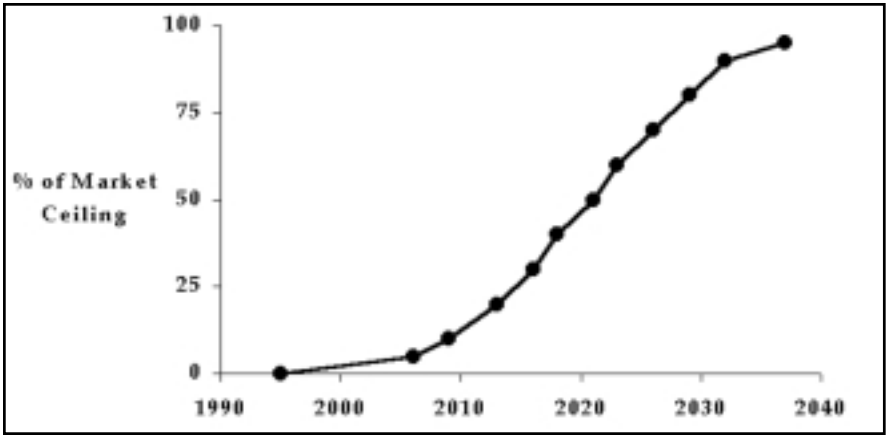

Figure 6. Predicted adoption rate of genetically modified potatoes based on a model of similar technologies (adapted from Guenthner, 2002).

What is the Future for Biotechnology in the Potato Industry?

The great opportunities and challenges that faced the potato industry in the period during which the NewLeaf™ potato was marketed remain to this day. The challenges of low acreage and high development costs will continue to make the potato a less attractive crop for private companies. Public institutions may be able to pick up some of this work, but the hurdle of regulatory approval will remain a key roadblock. Lack of segregation practices in the seed-potato and commercial crops will also make it difficult to deal with export issues in countries that have regulatory policies and timelines different from those in the United States. Most large food retailers and consumers still have not recognized direct benefits from the application of biotechnology in potatoes. Without these direct benefits, they may remain wary of this technology.

These challenges are balanced by some equally intriguing opportunities. Potatoes remain an excellent crop for improvement through biotechnology. Case studies by the NCFAP have reported the potential for fungus-resistant plants to reduce pesticide use by millions of pounds in the United States and Europe (Gianessi *et al.*, 2002b; 2003). Pest-resistant traits represent only the first wave of the application of this technology. Potatoes with increased solids, better storage characteristics, and improved nutritional content have been evaluated in field trials. Because potato products are consumed so widely, they also represent a valuable platform for introduction of health-related attributes, such as edible vaccines. The same characteristics of genetic diversity that make

potatoes so difficult to improve by conventional breeding provide opportunities to identify and transfer many useful genes through biotechnology.

How will this struggle between the challenges and opportunities play out for the potato industry? I don't have a crystal ball to gaze into the future, but I can cite the work of one agricultural economist that looked at this question. Guenthner (2002) modeled the adoption rate of new technologies such as diet soda, microwave ovens, and processed potatoes. By looking at technologies that had safety and consumer-acceptance issues in common with genetically modified potatoes, he was able to come up with a formula that describes the three phases of market acceptance for these products. According to his model, genetically modified potatoes should go through the introductory phase by 2010, and reach a market peak some time after 2030 (Figure 6). As someone with a strong interest in future of the potato industry, I hope that he is right.

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Q&A

Craig Winters (Campaign to Label Genetically Engineered Foods, Seattle, WA): One thing that became a major issue in Europe was the firing of Árpád Pusztai. It hit the front page of all the European papers and generated some traction in the consumer and environmental movements that maybe there was some problem with genetically engineered potatoes. We were surprised that Monsanto didn't duplicate Dr. Pusztai's study to show it was faulty. Then, all of a sudden, the potatoes were removed from the marketplace that aroused suspicion that maybe there were problems with those potatoes. Did Monsanto try to duplicate Dr. Pusztai's studies?

Thornton: I'm not going to speak for Monsanto. I will say that, during the time I was with NatureMark, they did animal-feeding studies on the initial Bt potato showing there were no adverse effects. I don't know the specific animals they used. Somebody from Monsanto may wish to comment. They felt that they had such a body of evidence that this stuff was safe that they just didn't see a need to repeat that study. Again I don't want to put words in Monsanto's mouth so, if somebody wants to comment, they certainly can.

Audience Member: Those studies have been repeated. First of all I'd like to say that the work that is referred to by Árpád Pusztai did not involve NatureMark. He created a transgenic potato with a snowdrop lectin. He wanted to know whether by introducing a gene, in this case a lectin gene, would in some way interfere with the normal growth and development of the potato. His results suggested inhibitory effects. Other scientists looked at his methodology and found flaws in it, and subsequently repeated the studies, addressing those flaws, and found no problem. That research is available, and I don't think it had any impact on the story that we have just heard. The answer to your question is that the studies were repeated, but not by Monsanto.

Thornton: I agree with that comment. I don't think that particular story had a big influence on what happened in the potato industry here in the United States.

Audience Member: Is Monsanto maintaining the germplasm of the new wheat in the hope that the market will turn around?

Thornton: As I understand it, as of just a few months ago, yes they maintain a tissue culture bank of all the commercial varieties as well as all the copies of all the transformation events, and things like that. This technology is basically on the shelf, not in the trashcan.

Opportunities for and Challenges to Plant Biotechnology Adoption in Developing Countries

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The theme of this conference, *Biotechnology: Science and Society at a Crossroad*, is particularly relevant to developing countries, where decisions concerning the use of agricultural technologies profoundly affect large numbers of people. Currently, 80% of the world's population lives in developing countries. By 2050, the United Nations estimates that the global population will increase by roughly 3 billion. This population increase will occur primarily in developing countries, with 90% of the total then living in areas now classified as less developed (United Nations, 2002).

Over the past 50 years, there have been substantial increases in food production and reduction in poverty in the developing world. Despite these favorable trends, the biggest health problem in developing countries remains malnourishment. About 800 million people still consume less than 2,000 calories a day, and are chronically undernourished (FAO, 2002a). A recent analysis indicates that 127 million pre-school children suffer from vitamin-A deficiency, which can cause blindness and early death (West, 2002). Iron deficiency is common, with about 400 million women of childbearing age afflicted by anemia. As a result, they give birth to underweight children and are more likely to die in childbirth. Roughly 24,000 people die each day from hunger and hunger-related causes, three-quarters of them children.

While many correctly argue that the root cause of such hunger is poverty, some seem to miss that, in predominantly agrarian societies, the root cause of poverty is lack of sufficient food and income from small-scale farming. China and India each has over 500 million people living on small-scale farms. Sub-Saharan Africa has over 400 million and this number is increasing rapidly, despite rapid urbanization (FAO, 2002b). In the poorest countries, like Malawi, over 90% of the population depend on small-scale farming for their livelihoods. It is in rural areas of such countries that the most severe poverty occurs. In Asia and Africa, over 75% of one billion people living in extreme poverty, earning less than a dollar a day, live in rural areas, and are dependent on agriculture for their meager incomes (World Bank, 2003). They are often hindered by traditional farming methods, increasingly depleted soils, shrinking plots of land, scarce and unreliable water, inequitable land-distribution patterns, and inefficient or unfair markets. Yet they have few, if any, good non-agriculture-dependent livelihood options.

Clearly, these small-scale farmers and their governments should have the major say in deciding which roads to take in promoting further agricultural development and food security for all. Unfortunately—at least with regard to agricultural biotechnology—this is not likely to be the case. Rather, decisions are being made now in industrialized countries and in global fora dominated by rich countries that will significantly influence the choices available to developing countries. As these decisions are made, we should at least try to give greater consideration and greater voice to the billions of small-scale farmers these decisions will most seriously affect.

An Integrated Approach

The questions for this conference thus become:

- What opportunities exist for biotechnology to contribute toward improving agricultural productivity, expanding markets, and stimulating employment and income generation in developing countries?
- What are the risks associated with using biotechnology in developing countries?
- What challenges do these countries face in realizing the more promising of these opportunities and in mitigating the risks?

Agricultural biotechnology is clearly not *the* solution to poverty and hunger. Rather, it is simply a set of powerful new tools that can facilitate the production, multiplication, and distribution of improved crop varieties. Improved crop varieties, in turn, represent just one of the contributions that science and technology can make to agricultural development. Equally important are agro-ecological research, agronomic research, enhanced soil fertility, integrated pest management, water-resource management, and integration of crops and livestock. Farmer-participatory research draws on indigenous knowledge and

allows all technologies to be brought together in ways that are synergistic and improve the productivity and profitability of the farm.

Just as important as inputs from science and technology are roads, credit, extension, access to fertilizer, input and output markets, land reform, institutions that effectively serve smallholder farmers, and policies that favor, or at least do not penalize, them. Where these factors come together in the same place, at the same time, as they have in large parts of Asia, they provide greater food security and economic growth through small-scale agriculture. These generate greater income that is often used for health care and education. Better educated, healthier and wealthier farm families, in turn, contribute to further agricultural development, to off-farm economic activities, and to overall national economic growth (Delgado *et al.*, 1998). Biotechnology can make an important contribution to this economic development process as a component of a crop-improvement program that is a component of a broader agricultural development program.

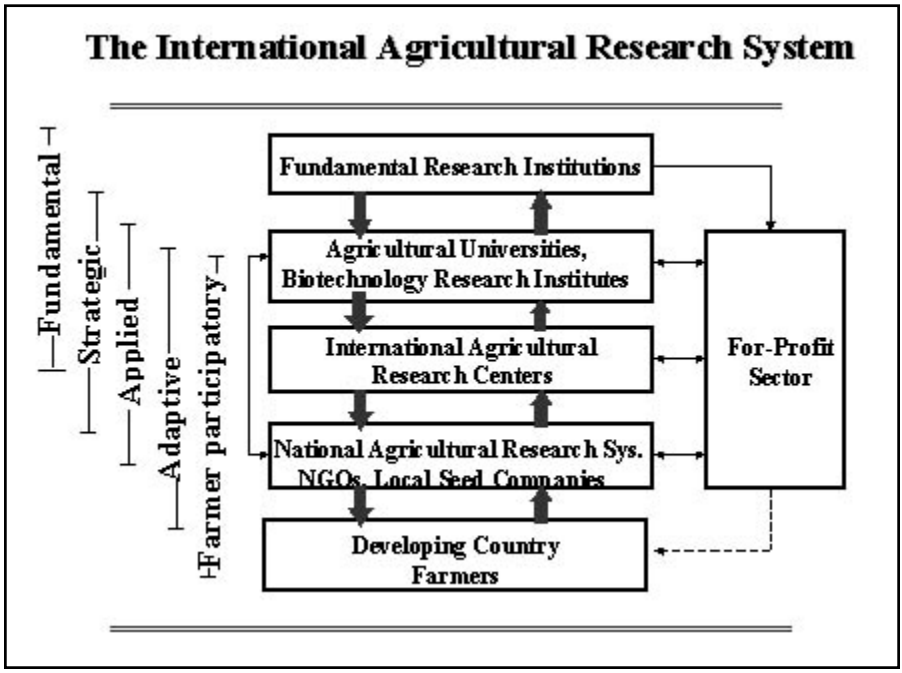

Figure 1. The international agricultural research system.

The International Agricultural Research System

Fortunately, in agriculture, the public sector has traditionally played an important role both in research and in the production of end products that

address the needs of the poor and hungry. Agricultural universities, agricultural research agencies and extension services have been established in most countries and charged with developing and delivering new technologies to farmers, usually in the form of better seed and improved agronomic practices. The international agricultural research system, depicted in Figure 1, was established in the 1960s and 1970s, specifically to develop better crop varieties and improved farming methods for smallholder farmers in developing countries.

Sixteen international agricultural research centers (*e.g.*, the International Maize and Wheat Improvement Center based in Mexico, the International Rice Research Institute based in the Philippines, and the International Institute for Tropical Agriculture based in Nigeria), play a central role by producing breeding lines and other "global public goods" that are made freely available to everyone.

Interestingly, our host institution, Washington State University, was directly involved in one of the early and most important accomplishments of this international system. In the 1950s, Orville Vogel, the legendary USDA wheat breeder at Washington State, had obtained a dwarf variety of wheat from Japan. He crossed it with North American wheat to produce the first semi-dwarf winter-habitat varieties that had higher yield potential. They were rapidly adopted in the United States. But long before he had released any semi-dwarfs, Dr. Vogel shared a few of his early-generation seeds with Norman Borlaug in Mexico. There, through much breeding effort, the semi-dwarf trait was transferred to the local spring-habitat wheat varieties. The first Mexican semi-dwarfs were released in 1962. Shortly thereafter, they were shared with India and Pakistan, where they performed surprisingly well, and the Green Revolution in Asia was under way (Hanson *et al.*, 1982). Today, the vast majority of improved varieties of staple food crops grown in developing countries are the product of such public-sector international agricultural research collaborations.

Evenson and Gollin (2003) recently summarized an extensive review of the outputs and impacts of this international network. They examined the development and adoption in developing countries of modern varieties of eleven crops over the period 1960 to 2000. As in the case of wheat, many of these varieties employed dwarfing genes that gave them shorter, stiffer stems, channeled greater photosynthate into grain, and made them more responsive to fertilizer. From 1960 to 2000, over 400 public breeding programs in over 100 countries released over 8,000 modern varieties of the eleven crops. Greater than 35% of these varieties were based on crosses made at international centers. Even most of the hybrid maize, sorghum, and millet marketed by local seed companies in developing countries were based on "platform" varieties generated by these public-sector breeding programs.

TABLE 1. INCREASES IN YIELDS IN DEVELOPING COUNTRIES, 1962 TO 2002 (FAO, 2002B).

Crop	1962 (t/ha)	2002 (t/ha)	Increase (%)
Wheat	0.9	2.7	200
Rice	1.8	3.9	117
Maize	1.2	3.0	150
Sorghum	0.7	1.1	57
Potato	8.6	15.2	77
Cassava	7.5	10.7	43

Table 1 summarizes the yield increases in developing countries that have occurred for several crops over the past 40 years. For rice, maize, and wheat, which together provide more than half of the food energy consumed in developing countries, average yields have more than doubled. With increased production, food prices dropped, average caloric intake rose and there were corresponding gains in health and life expectancy. In Asia, the proportion of the population suffering from chronic hunger dropped from 40% to 20% while the overall population more than doubled.

However, adoption of the modern varieties and benefits derived from them were not evenly distributed. They performed best with an adequate supply of water and fertilization. In Asia and Latin America, poor urban consumers, who spend a large proportion of their income on food, clearly benefited from lower prices. Farmers whose productivity rose more than prices fell gained additional income. As a result, large regions of Asia experienced economic growth. Some farmers who produce most of their own food and sell little, benefited from increased productivity. Some farmers who buy most of their food and sell cash crops benefited from lower food prices. But farmers who primarily grow and sell staple food crops, and who had limited productivity gains while food prices fell, benefited little and in some cases suffered economic losses. A key goal of biotechnology should be to help those farmers who gained little from the Green Revolution.

In sub-Saharan Africa, there were only minimal increases in yields, yet significant increases in production still occurred. This was achieved by extending the area under cultivation and mining the soil of plant nutrients through shorter fallow periods. But production has not kept pace with population growth in Africa, and a decade-long drop in per-capita food

production continues. Today, Africa faces a food crisis and an environmental crisis, both resulting from low-input, low-yield agriculture.

The small-scale farmers in Africa and in other regions, who benefited little from past innovations, need what Gordon Conway has coined a "Doubly Green Revolution" (Conway, 1999): a scientific revolution that helps farming families over a broad range of agro-ecosystems achieve sustainable advances in productivity and profitability per unit of land, labor, and capital, while restoring the long-term productivity of their farms. Such new agricultural technologies should focus on foods consumed by the poor, be scale-neutral, minimize external inputs, maximize inputs internal to the farm, focus on traits important to poor farmers (*e.g.*, stress resistance), benefit mixed cropping systems, and enhance human nutrition. This will require an approach that employs exciting new farmer-participatory methods, draws on the best of agro-ecological research combined with judicious use of fertilizer to help restore soil fertility, and crop genetic improvement achieved through conventional plant breeding and biotechnology (DeVries and Toenniessen, 2001).

Opportunities for Biotechnology

With regard to crop biotechnology, three forms of its application are now benefiting poor farmers:

- tissue culture, based primarily on advances in plant cellular biology,
- marker-aided selection, based on our ability to analyze plant and plant-pathogen DNA and detect the presence or absence of particular DNA sequences, and
- genetic engineering, based on recombinant-DNA technology and the ability to incorporate new genes into plant chromosomes.

Genomics and related methods in bio-informatics are a fourth type of technology currently generating vast quantities of data, but still at an uncertain early stage of application.

Tissue Culture

Protocols for regenerating whole plants from single cells or clumps of cells were first generated over three decades ago. Today, these protocols form the basis of micro-propagation technologies that are relatively simple and widely used in horticulture and with ornamental and other crops. Used properly under sterile conditions, these techniques have the added advantage of excluding nearly all diseases from the regenerated plantlets. Profitable new industries based on such micro-propagation have been established in Asia and Latin America, and increasingly in Africa. Tissue culture greatly speeds up the dissemination of improved varieties of crops such as cassava, sweet potato, and banana that have low multiplication ratios under traditional vegetative propagation. In the East African highlands, where banana is a staple crop, micro-propagation of

improved and disease-free seedlings is becoming a small-scale business that is improving food production and generating increased income for small-scale farmers and rural laborers involved in production and distribution both of the seedlings and the banana harvest (Wambugu & Kioime, 2001.)

Anther culture is a special form of tissue culture that can speed breeding. It has already contributed to the production of new rice varieties that are spreading rapidly in developing countries. Anther culture results in homozygous doubled haploid lines of use to breeders in making predictive crosses and for the production of true-breeding varieties, so farmers can save a portion of their harvest as seed for subsequent plantings.

In Asia and Africa, anther culture is being used to produce promising new varieties resulting from crossing different species of rice. If different species are forced to cross by breeders, they produce progeny with low fertility and low yields, due to poor chromosome pairing. However, when such progeny plants are passed through anther culture, the regenerated plants have perfectly paired chromosomes and are fertile, yet contain DNA (and genetic traits) derived from both parents of the original cross. At the West Africa Rice Development Association (WARDA) in Côte d'Ivoire, anther culture is being used to combine the best traits of Asian rice (*Oryza sativa*), such as high-yield potential, with the best traits of African rice (*Oryza glaberrima*), such as early maturity, weed competitiveness and drought tolerance (Jones, 1999). By using anther culture to produce thousands of lines with different combinations of traits derived from Asian and African cultivars, WARDA has been able to identify over a dozen highly promising lines, which farmers then evaluate through participatory varietal selection. The first of these "New Rices for Africa" (NERICAs) are now being grown by over 20,000 upland farmers in Guinea, where they are more than doubling yields. These rices could well be the beginning of a Doubly Green Revolution for Africa, achieved through new methods of participatory plant breeding, biotechnology, and integrated nutrient management.

Current research on anther culture of cassava is aimed at generating in-bred lines for crossing to produce advanced hybrid varieties. This could lead to yield increases from hybrid cassava similar to the major advances that occurred with hybrid maize. In the case of cassava, such hybrid varieties would most likely be disseminated to national programs as "clean" true seed and then disseminated to farmers as cuttings.

Marker-Aided Selection

This technology is based on the ability of laboratory scientists to detect specific sequences of DNA at specific locations on the chromosomes of an organism. For plant-breeding purposes, a useful DNA marker is one that is easily detectable, is genetically linked to one or more useful traits, and generates some reproducibly different signals (usually different band positions on a gel) for each of the two parent plants used in a cross. Using such markers, breeders

can determine the inheritance of linked traits in progeny at the seed or seedling stage even if the trait is expressed only in the mature plant. Marker-aided selection (MAS) is particularly useful for traits like root depth and vigor that are difficult and/or expensive to score using phenotypic screening.

MAS has multiple applications in crop improvement, but, to date, has proved most useful as a tool to speed backcrossing of qualitative traits such as many forms of disease resistance. With marker-aided backcrossing, a desired trait can be moved to a superior variety in four to six generations rather than ten or more required without markers. For example, in January 2002, the government of Indonesia released two new rice varieties, 'Angke' and 'Conde,' which were derived by disease-resistance breeding augmented with MAS to pyramid bacterial blight resistance genes into commercially adapted varieties (Bustamam *et al.*, 2002).

MAS holds great promise also in breeding for complex quantitative (multi-gene) traits like drought tolerance. To achieve a desired quantitative trait, the genes controlling the trait, termed quantitative trait loci (QTLs) must be present in their most favorable format. By mapping these loci and using their markers to track their occurrence in large numbers of genotypes, it is possible to identify the markers associated with plants that have the most favorable genetic make up. The right combination of QTLs can then be duplicated in a breeding program using the markers.

Currently, many research groups worldwide are attempting to demonstrate the success of MAS in breeding for drought tolerance in cereal crops. A key challenge faced by these groups is determination of genomic regions (*i.e.*, QTLs) that enhance performance across varying combinations of water-stress conditions, growth stages and environments. Ribaut *et al.* (2002) examined the genetic control of the drought tolerance that has been successfully introduced into maize varieties in southern Africa. They focused on the molecular-genetic dissection of component traits that are associated with this tolerance, and identified QTLs that are associated with components-of-yield of crops under drought stress.

Recent approaches for improving drought tolerance in pearl millet have focused on the development of QTL molecular markers for drought tolerance during the vulnerable flowering and grain-filling stages (Yadav *et al.*, 2002). One QTL, which explained 23% of yield under water deficits, was common across environments and has been integrated into pearl millet breeding programs using markers. In sorghum, drought that occurs after flowering is particularly detrimental to yields, and the "stay-green" trait (*i.e.*, delayed leaf senescence) has been associated with greater drought tolerance. Sanchez *et al.* (2002) reviewed the mapping of "stay-green" QTLs for drought tolerance and reported that four are consistently associated with the trait in field experiments and explain 53% of the phenotypic variation.

Genetic Engineering

This is a collection of techniques that enable scientists to move genes from one organism to another including between species. It is the most controversial of the agricultural biotechnologies, in part because it is new and viewed by some as somehow "unnatural," and because—as with all new technologies—there is no way to know the long-term impacts. However, as reported by James (2002), since 1996 there has been a steady increase in the worldwide area planted to transgenic crops with 58.7 million hectares (145 million acres) harvested in sixteen countries in 2002. Roughly six million farmers worldwide grew transgenic crops in 2002, 90% of whom are small-scale growers in developing countries, mostly China.

Genetic engineering is most commonly employed as a means of introducing a new trait when naturally occurring variation is absent or insufficient within the target species. A good example is golden rice: lines that are engineered to synthesize provitamin A (β-carotene) in the endosperm. As reported by Beyer *et al.* (2002), further advances have occurred in the development of golden rice, with mannose now used as a selective agent so that new lines contain no antibiotic resistance. Synthesis of β-carotene is now achieved by adding only two genes, daffodil phytoene synthase (*psy*) and bacterial phytoene desaturase (*crt*I), with rice-endosperm-specific promoters. These new "clean" lines are being crossed by breeders at IRRI and other institutions in Asia with local varieties that are well adapted to regions where vitamin-A deficiency is prevalent.

Another well known example is resistance to chewing and boring insects, which is lacking in many crops. Such resistance has been engineered into several crops with gene constructs derived from the bacterium *Bacillus thuringiensis* (*Bt*) that encode proteins that disrupt the digestive system of specific insect pests.

Transgenic cotton varieties containing *Bt* genes are now grown commercially in China, South Africa, Mexico, Argentina, Indonesia, and India. Pray *et al.* (2002) have followed the adoption of *Bt* cotton in China, which began in 1977. By 2001, 3.5 million Chinese farmers, growing on average 0.42 hectares, planted 1.5 million hectares of *Bt* cotton, roughly 31% of the area planted to cotton in China. More farmers are now benefiting from *Bt* cotton in China than there are farmers in the United States. The rapid spread of *Bt* cotton was driven by farmers' demands for a technology that increases yield, reduces insecticide use and costs, reduces insecticide poisonings and requires less labor. Initial yield increases were in the 5 to 10% range and modest increases continue, suggesting that farmers are learning to manage *Bt* varieties better. There is no indication that insect pests are becoming resistant to *Bt* cotton. The use of insecticides in China has been reduced substantially due to *Bt* cotton. The use of formulated insecticide fell by 20,000 tons in 1999 and by 78,000 tons in 2001, the latter being roughly a quarter of all of the insecticide sprayed in

China before the adoption of *Bt* cotton. Cost savings for farmers are now beginning to push down the price of cotton, so consumers will also benefit. *Bt* technology is being used increasingly in China as a component of integrated pest management strategies.

The Beijing-based Biotechnology Research Institute of the Chinese Academy of Agricultural Sciences originally developed many of the *Bt* cotton varieties (Fang *et al*., 2001). In fact, in China, public-sector institutions have produced and field-tested transgenic varieties of over fifteen different species, including many minor crops (FAO, 2003).

Public research institutions in countries such as China, India, and Brazil, which have both excellent scientific capacity and greater "freedom-to-operate," are likely to become the primary employers of plant biotechnology to deliver useful new varieties of tropical crops to farmers with limited purchasing power. The private sector is increasingly concentrating on only a handful of major crops and profitable markets. And, owing to proprietary property and regulatory constraints, public-sector institutions in industrialized countries find it increasingly difficult to commercialize products of plant biotechnology without corporate sponsors.

CHALLENGES

Proprietary Property

The genetic improvement of plants is a process in which each enhancement is based directly on preceding generations and requires the physical use of the material itself. Most of the important food crops originated in what are now developing countries, and much of the value in today's seeds has been added over the centuries, as farmers selected their best plants as a source of seed for their next planting. Traditionally, these land races and the indigenous farmer knowledge associated with them were free of charge to collectors and, hence, to the world community. In exchange, public-sector research and breeding programs, like those of Drs. Vogel and Borlaug, added valuable traits and returned scientific knowledge and improved breeding lines as "global public goods" to developing and developed countries alike.

However, the rules of the game are changing.

Over the past decade, in industrial countries, applied crop-biotechnology research and the production of improved varieties have increasingly become functions of the "for-profit" private sector (Barton and Berger, 2001). This has led to a significant increase in the total plant-science and crop-improvement research, but the results of such research are generally protected by intellectual property rights (IPR) of various forms, including patents, material-transfer agreements, plant breeders' rights, and trade secrets. Increasingly, this is true of results from public-sector research as well.

Industrial countries have made IPR an important component of international trade negotiations, using them to exploit their competitive advantage in

research and development. Countries joining the World Trade Organization, for example, must have IPR systems that include protection of crop varieties, according to the Trade Related Aspects of Intellectual Property Rights (TRIPS) provisions. The least-developed countries have until January 1, 2006, to implement such IPR systems.

Because poor farmers cannot afford to purchase new seed for each planting, it is important that developing-country IPR laws are modeled on plant-variety-protection systems that include provisions allowing farmers to save and replant seed and plant breeders to use varieties for further breeding. This is in contrast to the utility patent system that extends protection to the seed and progeny of patented plants so breeders cannot legally use protected varieties as breeding material.

Ironically, a major IPR change that is threatening the operations of the international agricultural research system comes from public, not private-sector, research institutions. To promote technology transfer and product development in the United States, the 1980 Bayh-Dole Act gave universities and other public-funded research institutions the right to obtain patents on, and commercialize, inventions made under government research grants. Similar arrangements have emerged in Europe, Japan, Australia, and most other industrialized countries. The result is that, while many biotechnology discoveries (*e.g.*, pathogen-derived plant resistance to virus infection) and enabling technologies (*e.g.*, *Agrobacterium* and biolistic transformation methods) are still generated with public funding in research institutions and agricultural universities, these discoveries are no longer being treated as "public goods." Rather, they are being patented and licensed, often exclusively, to the for-profit sector. Such discoveries now primarily flow from the public sector to the for-profit sector and, if they flow back out, usually come under material-transfer agreements (MTAs) that significantly restrict their use, usually for research purposes only, and often include reach-through provisions to capture results of future research.

Since crop genetic improvement is a derivative process, each increment made through biotechnology now comes with a number of IP constraints, with new IP added with each transfer or further improvement. To deal with this predicament, the private sector is becoming greatly centralized through mergers and acquisitions into a global oligopoly dominated by five firms that are also the major marketers of pesticides. These mergers were made in part to accumulate the IP portfolios necessary to produce biotechnology-derived finished crop varieties with "freedom to operate" and, in part, to gain control over a new technology that is threatening their pesticide markets.

The publicly funded agricultural research community, for the most part, lacks "freedom to operate." Leading academic researchers are primarily interested in research competitiveness. They readily sign research MTAs to gain access to the latest tools, but are then restricted from further transferring their research products. Many universities now have technology-transfer offices where maximizing licensing and royalty income is just as important

as technology transfer, and often achieved by granting exclusive licenses. The net result is that improved plant materials produced by academics are highly IP-encumbered and commercially useful only to companies having an IP portfolio covering most of the technologies used. Golden rice is a well documented example: some forty patents and six MTAs were potential constraints to its dissemination (Kryder *et al.*, 2000).

The international agricultural research system does not have a significant IP portfolio and, as a consequence, the traditional flow of materials through the system is breaking down, particularly where useful new technologies and improved plant materials had flowed from public-sector researchers in developed countries to international centers and national crop-improvement programs in developing countries. Africa, in particular, is being short-changed of the benefits of biotechnology because, unlike Asia and Latin America, its public sector has little capacity to use biotechnology for the benefit of poor farmers, even in countries where the IP is not protected. Africa is much more dependent on partnering with others, but publicly funded researchers in industrial countries are no longer partners who can freely share their most important discoveries and products.

New mechanisms are needed to re-establish and re-invigorate the linkages between universities and the international agricultural research system, and to build new linkages to the expertise and resources of the private sector.

Progress is being made. In the public sector, several of the leading agricultural universities and plant research institutes in the United States (University of California, Cornell, Michigan State, University of Wisconsin, North Carolina State, University of Florida, Ohio State, Rutgers University, Donald Danforth Plant Science Center, and the Boyce Thompson Institute) have joined with the Rockefeller Foundation and McKnight Foundation, both of which support plant biotechnology research in developing countries, to establish a Public-Sector Intellectual Property Resource for Agriculture (PIPRA) (Atkinson, *et al.*, 2003).

These institutions have generated much of the intellectual property in crop biotechnology, but they have also entered into exclusive licensing agreements for this IP with the private sector. These agreements often eliminate their ability to share their technologies with other public-sector institutions, such as national and international research centers that are working on new crop varieties for poor framers in developing countries.

For many of our public universities, the practice of exclusive licensing has also constrained their ability to generate specialty crops for farmers of their own states—a mission that is part of their charters. There are dozens of new transgenic varieties of crops—strawberries, apples, lettuce, *etc.*—in university greenhouses around the country, plants that can grow without pesticides, that would benefit both local farmers and the environment, and that were paid for with taxpayer dollars, but are not being brought to market. Neither the

universities nor small companies have sufficient IPR to commercialize them, and the companies that hold the rights are interested only in major crops like corn, soybean, and cotton.

The irony is that, collectively, the universities have exclusively licensed away the IPR they themselves now need. To correct this problem, the institutions involved in PIPRA will promote licensing strategies that favor retention of some of the rights to their own technologies, while still realizing a return on licensing the major market rights to the private sector. The licenses they grant will, therefore, no longer be exclusive. The institutions will retain and share rights to use their technologies for humanitarian purposes, and also for the development of specialty crops for which markets are small and are of no interest to the large private companies. By maintaining a public database, PIPRA will also provide information about technologies that are now available to the public sector without IP constraints. It will also explore IP pooling mechanisms designed to help scientists develop new crops that can truly reach those that are most in need. (More information may be obtained at www.pipra.org.)

The African Agricultural Technology Foundation (AATF) is another new institution the Rockefeller Foundation is helping to establish. It will promote public-private partnerships that benefit African agriculture. The AATF is an African-based, African-led institution, a facilitative organization that will operate by creating partnerships with existing organizations. The AATF will not be aimed primarily at distributing finished products. Rather, it will be a focal point where Africans can access new materials and information on which technologies can be built. It is a way of giving very poor nations the tools to determine what new technologies exist in the public and private sectors, which ones are most relevant to their needs, how to obtain and manage them, and how to develop nationally appropriate regulatory and safety regimes within which to introduce these technologies.

The AATF will transfer materials and knowledge, offering its partners access to advanced agricultural technologies that are privately owned by companies and other research institutions on a royalty-free basis. In exchange for access to these technologies, the AATF will identify partner institutions that can use them to develop new crop varieties that are needed by resource-poor farmers, conduct appropriate biosafety testing, distribute seed to resource-poor farmers, and help create local markets for excess production. Most of the major international seed companies and the United States Department of Agriculture have expressed serious interest in working with the AATF to accomplish its goals. The AATF will provide the organizational stimulus to bring together the elements of the public-private partnerships. The existence of new technologies with great potential, not only for food security but also for income generation by resource-poor producers, and the willingness of companies to collaborate make this the right time to bring these elements together. (More information may be obtained at www.aftechfound.org.)

Regulations

Poor management of IPR is only one of the ways the public sector has been handing over control of agricultural biotechnology to the multinational corporations. As suggested in Figure 2, increasingly onerous and expensive biosafety regulations are also a major cause. In the United States, the cost of obtaining regulatory approval of a new transgenic crop variety can be as much as $30 million. Even the big companies are abandoning research programs if the size of the market does not warrant this level of investment. Small seed and biotechnology companies are essentially priced out of the market unless they partner with the multinationals, and the public sector may be left out as well. Ironically, environmental and consumer groups—who warn against corporate control of agriculture—often work to establish regulations so costly that only multinational corporations can afford to obtain regulatory approvals.

Figure 2. Through exclusive licensing of intellectual property and expensive biosafety regulations, the public sector is enabling a few large multinational chemical companies to gain control over the application of biotechnology to crop improvement.

If developing countries put in place biosafety regulations that are equally onerous, they too are likely to find themselves highly dependent on multinational corporations as their primary sources of advanced new crop varieties. Here again golden rice serves as a good example. If developing countries enact costly biosafety regulations, or if they require golden rice to be approved first in

the wealthy countries where it was invented, it will be impossible for the public research institutions that developed it to afford the cost of obtaining regulatory approval.

Regulatory uncertainties and constraints have also delayed commercialization of transgenic crops produced by national researchers in developing countries. In Thailand, scientists working for the National Center for Genetic Engineering and Biotechnology have produced transgenic local varieties of papaya, highly resistant to prevalent strains of papaya ring spot virus. These varieties underwent 3 years of field tests and performed very well, but approvals to commercialize have repeatedly been delayed (McLean, 2003).

As with IPR, the public sector needs to find better and less-expensive ways of addressing legitimate regulatory concerns, if it is to continue to play an important role in producing new crop varieties for the hundreds of millions of small-scale farmers who will not be served by the large companies. If not, the public sector in agriculture may find itself in the same situation as the public sector in health—generating exciting research results, but seeing them used only by the private sector to develop products that can generate profits.

Public Acceptance

Public acceptance of transgenic crops and genetically modified (GM) food, or rather, lack thereof, is a major constraint to the adoption of plant biotechnology, particularly in Europe. This should not be too surprising, since none of the GM products currently on the market provide any benefits to consumers or, for that matter, to food processors or food retailers. Current transgenic crops primarily benefit seed suppliers, farmers, and the rural environment through reduction in insecticide use. Orchestrated campaigns against GM foods have consequently found a receptive audience amongst urban consumers.

The situation in developing countries may well be different. In many, a majority of the population are farmers as well as consumers. They would see the benefits and risks of transgenic crops as farmers and the benefits and risks of GM foods as consumers. As such they would be able to make a much better assessment of overall benefits and risks. They just need to be given the opportunity to do so.

Conclusions

It is easy to reminisce about the good old days when Orville Vogel and Norm Borlaug routinely shared early-generation breeding lines and when breeders from throughout the world could be sent to the United States or Mexico for training and go home with the newest semi-dwarf varieties to test in their own countries. However, a return to those days is neither likely nor truly desirable.

Profit incentives and the private sector do generate and deliver useful products. And, reasonable regulation of new technologies and education of farmers in their application can enhance and prolong their usefulness. Think of

the benefits that would be derived if as much effort were put into prolonging the usefulness of natural insect-resistance genes as is now being put into prolonging the usefulness of *Bt* genes. But, in today's global market, property rights, regulations, and liability concerns seem to have gone too far and made access by the poor to new agricultural technologies too difficult.

Getting good farm technology to over two billion poor, small-scale farmers in developing countries in a way that is responsible and sustainable is likely to remain a public-sector responsibility. It will require that governments, public research institutions, non-governmental organizations, and corporations devise new ways of doing business and of forming partnerships that accommodate the interests of the majority of the world's people located in developing countries, as well as the concerns of the technology providers, users who can pay, and consumers in wealthy countries.

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