Emerging Challenges for Biotech Specialty Crops

Pew Initiative on Food and Biotechnology

APHIS

USDA Animal and Plant Health Inspection Service

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INTRODUCTION

In the 20 years since the federal Coordinated Framework for regulating biotechnology was put in place by the United States government, the scientific community has learned volumes about crops and their genetic transformation. In recognition of the importance of specialty crops—fruits, vegetables, nuts and nursery crops—a workshop held in Washington, D.C., on January 18 and 19, 2007, sought to use this knowledge to identify regulatory challenges and to develop suggestions for enhancing the U.S. regulatory process for biotech specialty crops.

The workshop, entitled "Emerging Challenges for Biotech Specialty Crops," was sponsored by The Pew Initiative on Food and Biotechnology (PIFB) and the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). It brought together a small group of government regulators and scientific experts, industry representatives and policy makers from the biotech specialty crops sector to identify regulatory challenges and their potential solutions.

Specialty crops form a vital sector of the U.S. economy and of Americans' diets. Yet the development of biotech crop varieties with traits that could benefit farmers, consumers, and the environment faces stiff regulatory challenges. Because of the diversity of specialty crops, these challenges often go beyond those encountered by commodity crops like soybeans and corn.

The workshop came at a critical time for specialty crop producers and for APHIS, which is in the process of revising its biotech regulations. Presentations, focused group discussions, and break-out sessions indicated critical issues in need of attention and suggested practical and creative solutions and approaches to the challenges ahead.

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EXECUTIVE SUMMARY

In January 2007, thirty representatives of the specialty crops sector and government regulators convened for a two-day workshop, "Emerging Challenges for Biotech Specialty Crops," sponsored by The Pew Initiative on Food and Biotechnology (PIFB) and the Animal and Plant Health Inspection Service (APHIS). The idea for the meeting came out of a previous PIFB-sponsored workshop in June 2004 that addressed the potential impacts of the regulatory system on smaller entities or academic researchers. As a follow-up, the January workshop focused on the unique challenges biotech specialty food and feed crops encounter with the federal regulatory system.

"Our focus today is on how to get biotech specialty products through the regulatory system, on the mechanisms and regulatory changes needed, and the science to support this," said Sally McCammon, the science advisor to APHIS Biotechnology Regulatory Services.

Specialty crops—fruits, vegetables, nuts and nursery crops—collectively represent half of the U.S. $100 billion in farm gate receipts. The commodity crops, such as soybeans, corn, canola and cotton, represent the other half. But while the regulatory system has generally worked well for biotech commodity crops, researchers and developers of biotech specialty crops have struggled to cope with its cost and complexity.

The difficulties faced by biotech specialty crops relate to economies of scale, the diversity of specialty crops, and the variety of target traits in specialty crops research. Each specialty crop occupies a relatively small market niche, compared to the vast acreage of commodity crops. And, just one specialty crop, such as apples, may have dozens of diverse varieties, increasing research and development costs. In addition, traits that modify physiology in some way and that may be especially appealing for specialty crop producers tend to be more complex than the simple gene:phenotype relationship of herbicide tolerance or pest resistance engineered into commodity crops.

Finally, under the current federal regulatory system, each gene-insertion is considered a separate "event" in need of regulatory review by up to three U.S. agencies: APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). This has not been a problem for commodity crops such as corn, because once an event has been fully cleared through the regulatory process it can be transferred through cross-breeding into other varieties of the same crop without the need for additional regulatory review. But the biology of specialty crops often precludes this possibility, requiring instead the genetic transformation of each variety. Thus, a company wishing to produce several genetically engineered (GE) varieties of the same specialty crop must gain separate clearance for each engineered line, often from all three agencies.

Many participants were concerned that these and other issues have stalled the development of biotech specialty crops. As Sharie Fitzpatrick with Forage Genetics said, "The specialty sector needs to rebound. It will not rebound given the current situation, and if it gets additional burdens it cannot be expected to survive."

Therefore, the workshop focused on two things: 1) identifying the major regulatory challenges for biotech specialty crops, and 2) generating potential solutions.

Extensive discussion yielded several policy options: the development of a tiered risk-based regulatory assessment system; regulatory revisions to increase transparency and condense the timeline for product review; the development of information modules for standardized use in the application process; and the

development of white papers to address more complex and cutting-edge science issues expected to impact regulation.

Participants noted that these efforts could help move the regulatory system away from event-by-event regulation, and to prepare for new kinds of products and technologies that are, even now, arriving on the regulatory pallet. Workshop participants also noted that the more applications are submitted, the more the system would be pushed to progress on difficult issues.

The workshop came at an opportune time, for APHIS was in the midst of revising regulations for implementation of the Plant Protection Act (PPA) of 2000. The PPA took 17 years to complete and replaced 10 separate laws. It expanded the scope of what plants can be regulated, especially through the introduction of new definitions of key terms such as "noxious weed" and "plant pest." This has provided APHIS with expanded authority for regulating biotech plants. Therefore, the upcoming revision of the biotech regulations could have a large impact on biotech specialty crops.

The workshop thus provided participants and organizers with an opportunity to identify and discuss critical issues at a pivotal time. A number of lively presentations informed group discussions, and ideas were further elaborated in three break-out sessions on the topics of: 1) science questions that impact regulations; 2) data requirements; and 3) streamlining and fine-tuning the regulatory process. The many suggestions brought forward are reflected in the summary that follows.

SOLUTIONS TO EMERGING CHALLENGES

The process of developing a biotech crop is expensive and lengthy. The average time for development of a single biotech field crop can be eight to ten years, and the last several years typically include navigating the regulatory process, according to Ralph Scorza, a biologist with the U.S. Department of Agriculture's (USDA) Agricultural Research Service's (ARS) Appalachian Fruit Research Station. Specialty crops can take even longer. For example, Scorza has worked for 13 years (beginning with the earliest scientific investigations) on developing a plum cultivar resistant to plum pox virus, and his ARS petition is only now under consideration by APHIS.

While large commodity crop developers have ample budgets for R&D and for meeting regulatory compliance, the situation for most specialty crop developers is quite different. For instance, a typical tree fruit breeding program consists of one scientist, one technician, and graduate student help, Scorza said. In addition, the combination of long timelines to development, high costs, regulatory uncertainty, and consumer skepticism keeps away many potential investors in biotech specialty crops.

One result: the vast majority of genetically engineered crops approved worldwide are for commodity crops. Squash and papaya stand out as two GE specialty crop lines that have been approved and are on the market, whereas others have been approved but are not being marketed.

Despite this current imbalance, specialty crop producers see enormous potential for biotech crops that will benefit farmers, consumers, the environment and consumers, and can help alleviate hunger in many parts of the world. To help realize this potential, workshop participants identified a number of regulatory challenges and their potential solutions.

1. Develop a tiered risk-based regulatory system

To clear a genetically engineered crop through the regulatory process, developers must first show that it poses no significant risks to the environment, such as affecting non-target organisms; causing resistance in pest populations; or altering the fitness of either the crop or of native species (in the case of transgene escape). But just what constitutes a significant risk and what level of risk can be accepted?

Participants suggested that a tiered risk system could protect the environment while providing some regulatory relief. Although participants discussed "tiers" in a variety of different contexts, one general approach emerged. It suggested that products entering the regulatory process could be assigned to risk tiers that would be developed based on the scientific assessment of crops, traits, crop-trait combinations and transformation technologies.

Under a tiered-risk system, lower-tier products would require less data and information. Those in higher tiers—whether because of novelty or other scientific uncertainty—would require more information to fill gaps in knowledge. Participants noted that such a system could save developers and regulatory agencies time and money, and thus preserve regulatory resources for higher risk or less familiar products. Some participants suggested that a tiered system could lead to evaluation based on a variety of categories rather than on the traditional case-by-case approach.

Other suggestions included that tiers be developed both for field testing and the final federal evaluation process, and that the system remain flexible. Regulatory flexibility could allow a particular biotech crop's tier to change as it moves through field research based on information gathered. In addition, while a crop undergoing review for the first time might be in a higher tier, subsequent submissions for the same crop might fall into lower risk tiers. Many also suggested that regulatory agencies should devise a means to evaluate benefit, and to balance this against risk.

Jim Hancock of Michigan State University suggested one possible tiered-risk framework. To assess the environmental risk of GE crops, he said that APHIS should evaluate three main categories of information: 1) the geographical range of compatible relatives; 2) the invasiveness/weediness of the crop and its relatives; and 3) the phenotype of the transgene.

Product and Process in Risk Assessment

Hancock suggested the most critical factor in assessing risk is the plant's new phenotype, conferred by the transgene, and whether it would be neutral, detrimental, variable, or advantageous in the native environment. Combining information on the trangene's impact with knowledge of species distribution and weediness/invasiveness should lead to a determination of how much, if any, additional experimentation is necessary, particularly for the final regulatory assessment prior to commercialization.

"In many cases, thorough review of existing information should allow release with no further experimentation," Hancock said.

Steve Strauss suggested that two cross-cutting criteria affect level of risk: the trait itself and genomics information. Among the critical issues are the source and function of the gene. Is the introduced gene novel to the crop or homologous in a genomic sense, i.e., functionally the same regardless of its origin? In terms of function, is the trait domesticating? If so, Strauss argued that it would likely be beneficial on farms and plantations, but neutral or detrimental in the wild.

For example, he suggested that transgenes in poplar trees that cause dwarfism and sterility could be examples of the kinds of traits that would fall into the last category. "Can we assume that dwarf, sterile,

RELATIVE FITNESS IMPACT OF TRANSGENES

1: Neutral in the native environment (Marker genes)

2: Detrimental in the native environment (Male sterility)

3: Variable, depending on invasiveness of crop or native relative (Herbicide resistance)

4: Variable, depending on level of biological control (Pest resistance)

5: Advantageous in the native environment (Cold, drought & metal tolerance)

Adapted from a slide by Jim Hancock, Michigan State University.

shade-intolerant forest trees are less fit than fertile ones, and thus allow release to the environment on a small scale that is of no significance?" he asked. "Or does this need to be proven, and for each event, of the hundreds being tested in the research phase?"

Others suggested that cisgenic plants (those that use GE with sequences already found in the plant) or plants that use RNA interference (RNAi) to silence genes might be other modifications that present reduced risk.

Kathy Swords of Simplot Plant Sciences described how her company is developing new varieties with the use of genetic material from the target plant itself or from sexually compatible plants, an approach she said is closer to conventional breeding than is standard transgenics. Swords said that Simplot is using both marker-free methods and RNAi to develop varieties with traits that directly benefit the consumer, such as GE-improved potatoes for low acrylamide fries. She suggested that Simplot's approach could not only alleviate some public concerns about biotech crops, but should also fall into a lower regulatory risk category, and be less expensive to evaluate.

Discussion addressed the need to identify appropriate comparators for environmental assessments. The standard approach compares GE plants to their familiar, non-transformed counterparts to determine safety. But, participants pointed out that the growing availability of genomics information could allow the use of comparators other than the whole organism, and Sally McCammon stressed the need to identify appropriate new comparators. Steve Strauss suggested that gene homologs could be such a base comparator.

Some suggested that plans to ensure identity preservation (IP) of specialty crops—their strict isolation throughout the food chain—could also enter into the risk equation. For example, Don Emlay with Arcadia Biosciences described his company's proposal to grow biotech safflowers under a strict IP system only in Northern California. Arcadia's use of IP is routine, and such a system does mitigate risk. He therefore also questioned whether identity-preserved GE crops grown in a limited area should need an environmental assessment for the entire country.

Near the beginning of the development cycle, during the earliest stages of field testing, issues of risk assessment are also crucial to specialty crop producers. And it is during this stage that a particularly challenging issue first arises: adventitious presence (AP), the unintentional low-level presence of a GE trait outside of the GE crop itself.

Rethinking Adventitious Presence (AP) During Field Testing

AP, the low-level presence of unapproved transgenic material, can be the result of gene flow, whether by pollen carried on the wind or by other means. Gene flow has been the subject of extensive studies; for example, there has been 15 years of research into gene flow of GE sunflowers and potential environmental effects.

Such studies have shown that "Gene flow ... is a certainty," said Alan McHughen of the University of California at Riverside. Jim Hancock concurred, noting that transgenes will eventually escape as long as a compatible relative is nearby. The implication: "[F]urther research on the factors regulating gene flow are generally not needed," he said. Rather, what is needed is evaluation of the potential consequences of gene flow and of AP—and that gets back to the trait's phenotype.

Don Emlay presented one case in point: a safflower line engineered to produce GLA, gamma linolenic acid. Reviewing the product's safety considerations, Emlay said that GLA is found naturally in a number of existing foods as well as in oils, and capsules are readily available as a dietary supplement. GLA is continuously present in human cells where it aids in normal biological function. Arcadia Biosciences transformed safflower by inserting a microorganism gene that converts linoleic acid to GLA.

Emlay stated that safflower is not a weed, and that the GLA trait confers no selective advantage to related wild relatives. But, to prepare its application for regulatory approval, the company determined the potential significance of the AP presence of GLA in non-GE safflower. Their studies indicated that if every acre of GE safflower outcrossed at a rate of 0.1%, an average serving of safflower would have 14 milligrams of GLA. "We believe this would be an unintended exposure but not a health issue," he said.

Others suggested that a perceived "zero tolerance" for gene flow has been the downfall of many potential GE specialty crops. Karen Hokanson of the University of Minnesota noted that there have been a number of products ready for commercial approval, but not approved, and others whose applications were withdrawn, are still pending, or never came in. "What sent crops back to the shelf was the gene flow issue," Hokanson said.

Participants asserted that recognizing lower levels of risk should imply higher tolerance for AP. They also stressed the need to define acceptable levels of AP during research and development phases. One factor to consider is scale, and whether research would be conducted at such a scale as to represent a real exposure to the environment.

Sally McCammon cautioned that, "We will need a lot of good science to say that a small amount of pollen flow doesn't matter" if the public is to accept such regulatory changes.

2. Move away from event-by-event regulation

Participants suggested that regulation within a tiered-risk assessment framework could allow the system to move away from event-by-event regulation. This would provide considerable regulatory relief to biotech specialty crops, by easing the requirement that each new GE plant line or event in the same crop go through the regulatory system.

A tiered system could be structured to allow regulators "to bundle modified events on the basis of [transgenic] constructs, rather than variety by variety," Kathy Swords said. "This is especially important for crops like potato that are vegetatively propagated," she added.

Ultimately, a tiered assessment system could allow regulators to make decisions about whole categories of crop/trait combinations, while also developing categories that are excluded or exempted from the regulatory process.

Another alternative to the event-by-event approach would involve expanding and formalizing APHIS' underutilized "extension" process. These provisions streamline the regulatory process for new submissions that are essentially similar to those that have been previously evaluated. Although few specialty crops have passed final regulatory review, thus providing a limited number of such "templates" upon which to build, this could change quickly if developers are able to take advantage of the extension process.

Moving away from event-by-event regulations would have an impact beyond that on specialty crop producers, and beyond the United States, as an event-by-event approach is now used internationally, allowing comparisons and discussions that affect public perceptions and trade.

3. Increase Transparency and Condense the Timeline

Participants stressed the need for a fully transparent regulatory process, with clear requirements, and a short, predictable timeline for decisions.

Sharie Fitzpatrick of Forage Genetics reviewed her company's experience in taking a new Roundup Ready (glyphosate-tolerant) variety of alfalfa through the regulatory process. It took five years to achieve initial deregulation of the product, including 13 months of the preliminary consultative period prior to submitting an application for regulatory review. Forage Genetics is hoping that the process will be streamlined by the time they submit biotech alfalfa varieties with other environmentally beneficial traits.

Some participants commented specifically on the need for clear requirements during field trials in order to pave the way for final regulatory clearance. In particular, some noted a lack of clarity around regulators' concerns and requirements regarding gene flow. Ralph Scorza described field data requirements as "rather nebulous." He noted that while this may offer the opportunity to tailor requirements to the crop in question, without consultation the applicant is likely to be left guessing.

Transparency

The main suggestions for regulators regarding increased transparency were:

- Given the diversity of specialty crops and the limited resources of producers, have clear provisions to walk a company and other applicants through the process. In particular, provide more assistance to newcomers;
- Provide early consultation to avoid future problems. This could include an "Enhanced Guidance Document" to provide product-specific guidance developed during a brief, optional, preliminary consultation period (e.g., 60–90 days);
- Provide for expedited and enhanced federal services for early-in-class or first-in-crop applicants in order to reduce the "novice burden" on the early innovators taking high financial risk;
- For field trials, customize requirements early in development, addressing issues such as: type of data needed, number of field locations, number of seasons and scope; and specific field test performance standards;
- In general, make a clear distinction between what regulatory agencies "need to know" vs. what would be "nice to know";
- Make better use of the Coordinated Framework, including having a lead agency and better coordination of the overlapping requirements of APHIS, FDA and EPA.

Develop Condensed, Predictable Timelines

Another major concern was that timelines for decisions from regulators remain uncertain, even where they are stipulated in the regulations. Uncertain timelines add to cost and discourage investors. In addition, timeliness is critical for many specialty crops, as new varieties may only be marketable for a few seasons before being replaced by others with greater appeal.

Suggestions include:

- Keep the timeline and process from submission to decision as short as possible. Some urged that the process be limited to one growing season;
- Keep defined data and information requirements stable for a given period. Some suggested that requirements should remain static at least through the years of crop development. They noted that a moving target of increasing or changing requirements can add to the timeline and incur increased costs.

4. Develop information modules and white papers for use in applications for regulatory clearance

Scientists have acquired an enormous wealth of new information on the biology of crops, crop traits, genomics and gene transfer techniques. Some of this information may be needed as scientific background to assess the possible environmental risk of a new biotech crop. Currently, however, each petitioner must reinvent the wheel, individually researching and compiling the necessary information. The development of publicly available, standard information and data modules could greatly expedite the writing and evaluation of new submissions.

The modules would represent the best available and agreed upon scientific information. In essence, this would help develop and enhance regulatory "memory." Applicants could cut and paste from these modules in preparing their applications, and then consult with regulators regarding what additional data or information would be needed to complete the application in the specific case.

The modules could also minimize the tendency of regulatory agencies to ask for information simply because it has always been requested. And, data modules would have the benefit of freeing up resources within regulatory systems in order to focus on emerging considerations.

Module topics could encompass relevant information on crops, traits, and crop/trait interactions and how they relate to potential risks. This could include information on invasiveness/weediness, outcrossing, and wild relatives. Other modules could include the information about basic tools and methods, such as various promoters, terminators and marker genes along with transformation technologies. Such modules could be referenced or used as components of the actual application, reducing the need for generating *de novo* the standard application segments.

The modules could also be used to facilitate the development of the tiered risk categories discussed above. For instance, evaluation by regulators of modules on certain topics could lead to the outright acceptance of some tools and methodologies, and the placement of others in appropriate risk tiers. As one example, several participants suggested that a scientific review of *Agrobacterium tumefaciens* as used in plant transformation could lead to its removal as a regulatory trigger.

Sources for module development could include: existing crop profiles; National Academy of Sciences publications; published Floras (e.g., with botanical keys and information on location of wild relatives and natural hybridization); and evolutionary studies and breeding histories with information on inter-fertility of compatible relatives. Organization for Economic Cooperation and Development (OECD) biology consensus documents are already sometimes used as actual modules by applicants and regulators.

Ideally, data sets prepared for past application packages for regulatory approval could be summarized and made available. Petitions to APHIS are posted on the APHIS website and available to the public. However, in order for others to be able to use this information in modules, the original applicant would need to give permission.

The development of white papers on broader topics could also address more recent, cutting-edge technologies coming in to use and summarize information regarding more controversial or complex issues needed by regulators to make informed decisions.

Participants identified seven scientific areas that could be clarified through a process of compiling existing knowledge and holding discussions to distill the topics. The distillations could also identify any outstanding gaps in knowledge. These areas are: 1) insertional mutagenesis; 2) pleiotrophic/epistatic/location issues; 3) domestication traits; 4) genomics approaches; 5) cisgenic technologies; 6) defining environmental consequences of gene flow; and 7) scale effects. These white papers would be made available through publications.

5. Prepare for new types of products and technologies

New types of products and technologies continuously raise new questions for the federal regulatory system which needs mechanisms to anticipate and address emerging questions. One example of a new product that may shortly arise is GE switchgrass for use as a biofuel. Upcoming technologies include cisgenic plants; novel transgenes created *in vitro* based on function, rather than being derived from an organism; and transgenes that have been deleted from edible parts of the GE crops.

While data and information modules and a tiered risk assessment system would provide frameworks from which to view new products, this may not be enough. Participants suggested two additional routes to prime the regulatory system for new products and their associated scientific questions.

The first is perhaps obvious, but needs recognition: build precedence. Companies and public researchers need to pursue submitting applications for regulatory clearance. The goal would be to push the regulatory system through submitting applications, and create a history that can be referenced.

Several participants noted that very few specialty crop products have actually gone through the system. "Go to it. Do it," urged Ralph Scorza. Dennis Gonsalves with the Agricultural Research Service in Hawai'i agreed: "It's a shame to see that so few specialty crops have been commercialized," he said. "So long as you stay in the mode of just talking, you will be strictly academic. Once you get into the system, you learn what's important, what's not, and what to pay attention to."

Secondly, participants suggested that hypothetical products could be run through the regulatory process. Hypothetical case studies could identify potential bottlenecks, data redundancies, data gaps, and knowledge that must be addressed for an efficient and fair treatment of the new products.

For example, the system could be tested with a hypothetical petition for a biotech switchgrass. "Right now there's a $2 billion train going down the track. At some point APHIS is going to have to jump on it," said William Goldner of the USDA/Cooperative State Research Education and Extension Service's Small Business Innovation Research program. A high-yielding switchgrass engineered for improved water use efficiency could provide one hypothetical test case. It could challenge the regulatory system to weigh risk against the immediate public benefit of new biofuels.

6. Legal concerns

In the workshop's far-ranging discussion, participants highlighted several legal concerns that may affect potential applicants or federal agencies. The primary concern was liability. In Hawai'i, for example, organic farmers are bombarding growers of GE papaya with lawsuits, Dennis Gonsalves said.

Participants noted that potential applicants' perceptions of high risk associated with liability are hindering scientific progress. Indeed, many said there is a general need for the specialty crops community to better understand their legal risks. They also noted the need to address the increasing burden of lawsuits shouldered by APHIS in approving applications for field testing or deregulation.

A second legal concern was over how new definitions under the Plant Protection Act (PPA) would be interpreted. Of particular concern was the possible interpretation of the term "noxious weed." Steve Strauss noted that, under the PPA, a "noxious weed" could potentially be regarded as any plant that poses a hazard to trade, and, if so, all GE crops could be defined as pests.

Sharie Fitzpatrick urged that new regulations should not build new biases or provide uneven relief from burdens, saying, "Define the process, compress it, simplify, commit and do not regress."

CONCLUSION

Over the course of one and a half days, workshop participants elaborated steps that could significantly improve the federal regulatory system for specialty crops. They noted that firm reliance on science, a tiered-risk system that moves away from event-by-event regulation, the use of data and information modules, the development of white papers, and a more transparent and predictable regulatory process, would ultimately aid not only specialty crops, but agriculture in general.

Regulators and developers of specialty crops emphasized that continued progress requires the ongoing involvement of all stakeholders in the refinement of the regulatory process. Public comment by the scientific community is needed not only at key junctures, but also all along the way—especially with regard to proposed regulatory changes from the federal agencies. In addition, participation through submitting petitions and pushing the system will help shape the regulatory process.

For the past six years, the Pew Initiative on Food and Biotechnology has provided a forum to engender principled discourse among primary stakeholders, with a strong commitment to science and policy. This Emerging Challenges for Biotech Specialty Crops Workshop was the final such endeavor to be hosted by PIFB.

Participants noted the invaluable role of these forums, and the need to develop alternative means to continue the scientific discussions. They also noted the need to follow thorough on the ideas generated in this workshop, including the development of data and information modules and white papers. Participants suggested a number of possible venues to do so, including through the Specialty Crops Regulatory Initiative and the convocation of expert panels to identify, examine and seek consensus on particular subjects.

While recognizing the strong basis that has been laid for future biotech efforts, the workshop participants also underscored the urgency for action if specialty crops are to continue to fulfill their vibrant role in the U.S. economy and on the tables of consumers.

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