

## Chapter 2

# ECONOMIC ANALYSIS AND REGULATING PESTICIDE BIOTECHNOLOGY AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY

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**Abstract:** This chapter discusses the role that economic analysis plays in pesticide regulation for plant-incorporated protectants and compares that to how economic analysis is used in conventional pesticide regulatory decisions. The goal is to provide a description, for research economists, of what makes economic research on agricultural biotechnology relevant to regulatory decision makers. It is our hope that in providing this perspective, economists will be able to develop a stronger sense of what types of research questions and approaches could actually inform policy. This enhanced understanding would serve the interests of those researchers seeking to make a policy contribution and could provide useful, independent analysis to help policymakers in making regulatory decisions.

**Key words:** EPA, biotechnology, transgenic crops, regulation, pesticides

## 1. INTRODUCTION

Many widely grown crops have varieties that have been genetically modified to protect them against insect pests, such as the cotton bollworm, pink bollworm, and tobacco budworm in cotton, and the corn rootworm and corn borer in corn. The U.S. Environmental Protection Agency (EPA) has regulatory oversight over agricultural pesticides, which include crops with “plant-incorporated protectants” (PIPs). “Plant-incorporated protectant” is the EPA’s term for pesticidal substances produced by plants and the genetic material necessary for the plant to produce such substances, made possible through the use of biotechnology. EPA’s regulatory responsibility for plant incorporated protectants is governed primarily<sup>1</sup> by three statutes: FIFRA, FFDCA, and FQPA (all explained later); the same legal authorities by which

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<sup>1</sup> The Migratory Bird Act and the Endangered Species Act also affect pesticide regulation.

EPA also regulates “conventional pesticides.”<sup>2</sup> To date, with one exception (Bt potato Cry 3A), all PIP registrations for commercial production have been time-limited conditional registrations. Each conditional registration under FIFRA 3(c)(7)(C) must be shown to be in the public interest. EPA uses certain criteria set forth in 51 Fed. Reg. 7628 (*Conditional Registration of New Pesticides*, March 5, 1986) to make this determination. Part of a determination of public interest is an analysis of the economic benefits associated with such a registration.<sup>3</sup> The benefits assessments are, to some degree, unique to PIPs, but also share common features with other economic analyses that are conducted as part of the pesticide regulatory program.

This chapter will discuss the role that economic analysis plays in pesticide regulation for plant-incorporated protectants and compare that to how economic analysis is used in other pesticide regulatory decisions. The purpose of this chapter is to provide a description, for research economists, of what makes economic research on agricultural biotechnology less (or more) relevant to regulatory decision makers. It is our hope that in providing this perspective, the practitioners of policy economics will be able to develop a stronger sense of what types of research questions and approaches could actually inform policy. This enhanced understanding would serve the interests of those researchers seeking to make a policy contribution and could provide useful, independent analysis to help policymakers in making regulatory decisions.

This chapter has three essential messages to research economists. The first is that for economists seeking to conduct policy-relevant research on regulating agricultural biotechnology, it is extremely important to align the questions and testable hypotheses with the issues and questions that arise in making actual decisions in regulatory agencies. The second message is that for research to be relevant to policy-making, the models used in such research must be empirically tractable and robust, employing data that are feasible to obtain and verifiable. Lastly, economic policy research on agricultural biotechnology must be communicated effectively to non-economists if the research is expected to inform policy formation and/or regulatory decisions.

These messages are important because, in spite of the potential for valuable insights, external economic research (from academic economists, for example) does not typically have much influence on the regulation of conventional pesticides, although there are exceptions. For plant protectant traits

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<sup>2</sup> Information on the regulatory framework for PIPs can be found at <http://www.epa.gov/pesticides/biopesticides/pips/index.htm>.

Regulations regarding registration of PIPs can be found at [http://www.epa.gov/pesticides/biopesticides/pips/pip\\_rule.pdf](http://www.epa.gov/pesticides/biopesticides/pips/pip_rule.pdf).

<sup>3</sup> For an example of an analysis of the benefits of PIPs, see [http://www.epa.gov/pesticides/biopesticides/pips/bt\\_brad2/5-benefits.pdf](http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/5-benefits.pdf).

in genetically modified plants, however, there is a wealth of research by academic agricultural economists that could be useful to regulators. The overlap between important regulatory issues and areas of research that are interesting to economists has valuable spillover effects for those with regulatory responsibility.

The next section of this chapter provides a brief overview of pesticide regulation at the EPA. That section is followed by a section describing the role of economic analysis in regulating conventional pesticides. That role is then contrasted with the need for economic analysis to support regulatory efforts related to plant-incorporated protectants. The chapter concludes with a discussion of policy-relevant topics that may be of interest to academic researchers.

## 2. STATUTORY FRAMEWORK FOR PESTICIDE REGULATION

There are two main laws that give the EPA the authority to regulate pesticides in the United States. Broadly speaking, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) provide frameworks for registering pesticides and establishing tolerances,<sup>4</sup> respectively. Both statutes were amended by the Food Quality Protection Act (FQPA) in 1996. Together, these statutes provide the framework for regulating pesticides, including plant-incorporated protectants.

In 1947, FIFRA established the Federal role in regulating pesticides. FIFRA has been updated several times since 1947 and was most recently amended by FQPA, as noted earlier. Under FIFRA and FQPA, pesticides must be registered or granted an exemption from registration by EPA before they can be sold, and they must be periodically reviewed to ensure that they continue to meet the requirements of registration. Pesticide registration may be granted after a review of the human health and environmental risks posed by a pesticide (or pesticide product). In some cases, pesticides may be granted conditional registrations (i.e., time-conditional restrictions are imposed on the registration) if they meet certain criteria, including being found to be in the public interest. In these cases, economic assessments of public interest may play a role in the regulatory decision and have been particularly

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<sup>4</sup> A pesticide cannot be sold or used without a registration, and the registration specifies the ingredients of the pesticide, the particular site or crop on which it is to be used, the amount, frequency, and timing of its use, and storage and disposal practices. A tolerance is the maximum permissible level for pesticide residues allowed in or on commodities for human food and animal feed.

important in registration decisions for plant-incorporated protectants.<sup>5</sup> In all cases, the goal is to prevent any “unreasonable<sup>6</sup> adverse effects on the environment” (FIFRA Sec. 3 [136a]).

Under FFDCA, EPA establishes tolerances for pesticide residues in food. Tolerances are based on assessment of health risks from exposure to a given pesticide or class of pesticides. Under FFDCA, the standard for setting a tolerance is strictly a health-based standard: “a reasonable certainty that no harm” will result from exposure to the pesticide [FFDCA section 408 [6a] (b) (2) (A) (ii)]. This is a narrower standard than under FIFRA, and it precludes the balancing of benefits and costs of a pesticide in setting tolerances, except in extremely narrow circumstances (e.g., preventing public health risks or disruptions in the food supply). Either a tolerance or a tolerance exemption must be granted before a pesticide can be registered for use on a food crop.

Understanding the role of economic analysis in pesticide regulation within this statutory mandate, therefore, is key for those interested in conducting policy-relevant economic research on regulating agricultural biotechnology related to plant-incorporated protectants. There are opportunities for economics to inform the regulatory process, and the next section provides a general overview of these opportunities.

### 3. ECONOMIC ANALYSIS AND PESTICIDE REGULATION

There are several well-defined roles for economic analysis in pesticide regulation. In some cases, the role may be fairly narrow, such as in making decisions to balance risks and benefits for pesticide registration and reregistration where dietary risk is not of concern. In other cases, the role of economics may be broader, particularly under rulemaking, which is the process by which regulatory frameworks are developed and implemented and which require a thorough analysis of costs and benefits. Although a detailed description of economic analysis in the Office of Pesticide Programs is beyond the scope of this chapter, we provide a brief overview to aid in understand-

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<sup>5</sup> Plant-incorporated protectants are regulated under FIFRA and FFDCA, but herbicide-tolerant genes are not, because these genes do not have direct pest control properties. Herbicide tolerance, when introduced into the plant genome, is regulated by the U.S. Department of Agriculture under statutes other than FIFRA or FFDCA. A list of these statutes can be found at <http://www.aphis.usda.gov/brs/usregs.html#usdalaw>.

<sup>6</sup> The term “unreasonable adverse effects on the environment” means (i) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (ii) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (FIFRA Sec. 2 [136(bb)]).

ing what type of analysis may be important to regulating plant-incorporated protectants.

In making regulatory decisions on individual pesticides, the broadest role of economic analysis over the last 10 years has been in pesticide reregistration and tolerance reassessment. Under FQPA, EPA is required to reassess all pesticide tolerances over a ten-year span, ending in 2006. In the future, there will also be ongoing reassessments every 15 years under what is called registration review. Registration review is expected to begin in the latter part of 2006. Under both these programs, EPA recognizes that existing pesticides are productive substances that perform an important role, but also may potentially have adverse effects on human health and the environment. Under FIFRA, EPA is required to balance the risks from pesticide use with the benefits from having particular pest control options available.

There are limits, though, to how economic analysis informs findings and decisions pertaining to pesticide regulation. For example, when considering dietary risks under FFDCA, the Agency is required to make a finding of “a reasonable certainty of no harm” before allowing a particular use (or uses) to continue. This finding is made independent of economic analyses.

Although the “no harm” finding limits economic considerations, it does not eliminate them. Economic analysis can be very important in determining the least-cost way to achieve an acceptable “risk cup” under FQPA. The “risk cup” is a term that the EPA uses when describing setting the tolerances allowing for exposures from multiple dietary sources. If the risk cup is overflowing, then tolerances must be set to reduce exposure from some uses, and EPA seeks to accomplish that in a least-cost way. Because exposure is often the result of a pesticide being used on a number of different food sources (crops), and these crops often have diverse pest control issues, pesticides have different marginal productivities for different crops depending on factors such as pest damage issues, pattern and timing of pesticide use, potential pest control alternatives, and crop value. Economic analysis can be quite influential in determining the set of use restrictions that meet the risk cup constraint while minimizing economic loss from these restrictions. This type of analysis is grounded in agricultural production economics.

Under FIFRA, risks to both human health and the environment are evaluated and regulatory decisions are based on the FIFRA standard of “no unreasonable adverse effects on human health or the environment.” Economic analysis of pesticide benefits is a factor that may influence whether a pesticide will be registered or be found eligible for continued registration. For conventional chemical pesticides, analysts from the Office of Pesticide Programs’ Biological and Economic Analysis Division analyze the economic impacts of new uses of pesticides, registration of new pesticidal active ingredients, and potential restrictions on continued use of a particular pesticide. At the same time, the Environmental Fate and Effects Division evalu-

ates the environmental risks from different pesticide use scenarios, and the Health Effects Division evaluates the possible occupational risk from various use scenarios. These analyses are all taken into account by risk managers in proposing final regulatory decisions. These same types of analyses are also performed for biological pesticides evaluated by the Biopesticide and Pollution Prevention Division and for antimicrobial pesticides evaluated by the Antimicrobials Division.

Under the existing reregistration system under FIFRA, the role of detailed economic analysis has been particularly important when the reregistration decision poses particular challenges: pesticides that have high risks and high benefits. In cases where risks are low and benefits of pesticide use are also low, there may be little need for significant regulatory action. In cases where risks are low, but benefits of pesticide use are high, risk management is much less likely to lead to restrictions on use. Conversely, when risks are high, but benefits are low, risk management is likely to favor mitigation that reduces this risk. It is only in those cases where both risk and benefits are high that some sort of tradeoff is likely to occur, and for which economic analysis may be an important factor in determining the ultimate regulatory decision as to what pesticide uses should be found eligible for reregistration. The Office of Pesticide Programs is expected to complete its existing reregistration program in 2006, after which the registration review process will begin.

Another regulatory area where economic analysis informs regulatory decisions is for emergency exemption requests for temporary registration of unregistered uses of pesticides (section 18 of FIFRA). The state lead agencies or another federal agency must petition EPA for these temporary registrations when emergency pest damage situations arise. Section 18 of FIFRA authorizes exemptions to the registration process under emergency conditions. The applications are usually submitted by state lead agencies that identify a pest situation that cannot be controlled by a registered pesticide. If the risks of the pesticide are sufficiently low, and the EPA finds the situation to be "urgent and non-routine," an emergency exemption can be granted if failure to grant the temporary registration would lead to significant economic loss.<sup>7</sup>

These exemptions are often important when there are emerging pest problems, and for small crops for which few chemicals are registered. One of the criteria for a section 18 exemption is that the emergency will cause a "significant economic loss" in the absence of the requested chemical, while using the next most effective registered alternative. Although economists do not grant an emergency exemption, the exemption is rarely granted without a finding of a significant economic loss. An exemption will also not be

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<sup>7</sup> Past emergency exemptions can be found at <http://cfpub1.epa.gov/oppref/section18/search.cfm>.

granted if the dietary or environmental risks are too high, even if the economic analysis shows the situation to be severe.

### **3.1. External Economics Research and Pesticide (Re)Registration**

Because of the way FIFRA, FFDCA, and FQPA are written, and the way economic analysis of pesticides is practiced at the EPA, external economic research plays a limited role in the day-to-day economic analysis required for registering and reregistering conventional pesticides. For reregistration of existing conventional pesticides, the economic questions are typically quite narrow, focusing on the impact of mitigating specific risks from individual pesticides through changes in use patterns with crop-specific or location-specific measures. In order to be relevant for these day-to-day decisions, economic research would have to estimate potential damage from marginal changes in use patterns for specific crops, specific regions, and specific pesticides, and evaluate the benefits of crop risk mitigation relative to the next best alternative for that situation.

With analysis that is narrowly defined by pesticide, crop, and pest, there are thousands of combinations one might analyze, all with specific data requirements and market knowledge. Academic research, therefore, could speak to either specific pesticide cases or develop models that are flexible enough, and for which there are sufficient available data, to tackle these case-specific regulatory analyses in a relatively short time frame. Unfortunately, this is fairly specialized research which appears to have limited appeal to the academic community given the way research is conducted in academia (longer time frames, limited data, directional vs. nominal results, etc.).

For economic research that does address pesticide topics, models that are developed in these studies rarely model the marginal policy decisions that may be instrumental in regulatory decisions. Typically, research results are general, or aggregated across pesticides (for example, considering the impact of total pest control expenditures on a farm, or in a region) rather than analyzing marginal policy decisions that are important to regulators (such as the value of a new pesticide compared to the next best alternative).

In addition to informing these marginal decisions, though, there is other external research that could be very valuable to the EPA for conventional pesticide regulation. Such research might include estimates of price (cost) elasticity for new pesticide registrations, or estimates of the value of additional information on human health or ecological risk, which would facilitate refinement of risk estimates. In cases where exposure-specific data allow one to depart from default assumptions about risk parameters, and lead to lower values for estimated risk, the need to mitigate risk may decline. Therefore, understanding the tradeoff between the cost of obtaining additional risk information and the cost of mitigation in the absence of such refining informa-

tion could help inform the regulatory process. Additionally, a framework for being able to analyze the costs and benefits to society of the pesticide regulatory program would be a valuable contribution in an era of increasing quantitative accountability.

This does not imply that external economic research has not been useful to EPA; it has. Particularly helpful are partial equilibrium models of agricultural markets and research that can help estimate the consumer and producer surplus effects of policy changes. For example, EPA economists have devoted substantial effort working on issues surrounding the Montreal Protocol, which phases out methyl bromide (an ozone-depleting pesticide fumigant), but allows for continuing use in special cases where alternatives to methyl bromide are not technically or economically feasible. External economic research in this area has also been quite helpful, because it tends to focus very closely on the issues surrounding policy decisions. Examples of recent work that will be helpful to the EPA in future methyl bromide work are Carter et al. (2005) and Goodhue, Fennimore, and Ajwa (2005). External economic research has also been particularly helpful for the regulation of biotechnology products, which we discuss below.

### **3.2. Rulemaking**

Another important area for economic analysis in regulating pesticides is rulemaking, the process by which legislative mandates are implemented into specific actions and protocols. Because rulemaking has the potential for imposing regulatory burdens on the regulated community and society at large, these regulatory activities have engendered a set of requirements for economic analysis, both by statute and by executive branch requirement (Presidential executive orders, Office of Management and Budget directives). These economic analyses are subject to public comment and are reviewed by the Office of Management and Budget (OMB).

For the rulemaking process, economic analyses must consider multiple policy options and contain quantitative and qualitative evaluation of the benefits and costs of the proposed regulations. A regulatory analysis will also contain a justification of the regulatory action, an analysis linking the proposed regulation to the desired outcome, an identification of second order costs and benefits, the distribution of benefits and costs, and the impact on small business. EPA is currently proposing a number of rules related to pesticide regulation, including those dealing with pesticide registration data requirements, amendments to procedures for emergency exemptions (including determination of a significant economic loss), procedures for continuing



review of registered pesticides (called registration review), and third-party submission of data generated with human subjects.<sup>8</sup>

### 3.3. Conditional Registration

Another important role for economic analysis is for a Public Interest Finding (PIF). A PIF provides information in support of a conditional registration under FIFRA 3(c)7(C), rather than an unconditional registration of a pesticide under FIFRA 3(c)5. In order to conditionally register a pesticide under FIFRA 3(c)7(C), EPA must make a finding that the conditional registration is in the public interest. A PIF will include some level of economic analysis.

EPA can conditionally register a pesticide or product under several sets of circumstances described in 51 Fed. Reg. 7628 (*Conditional Registration of New Pesticides*, March 5, 1986). These include when there is a need that is not met by currently registered pesticides, when the new pesticide poses less risk to health or the environment than registered alternatives, or when the benefits of the new pesticide exceed those of alternative means of control, both with registered pesticides and non-chemical techniques. The last of these criteria provides one entry point for economic analysis.

Historically, for conventional pesticides there has been a limited amount of EPA-initiated economic analysis for PIFs, because other conditions are sufficient for finding that a conditional registration is in the public interest (i.e., the pesticide meets the criteria for a reduced risk pesticide). All of the PIPs (pesticides produced in genetically modified plants) have had PIFs prior to the Agency granting a conditional registration. Compared to PIFs for conventional pesticides, these PIFs generally include a much more comprehensive economic analysis, and are generally combined with a benefits assessment; they are described in more detail below.<sup>9</sup>

## 4. ECONOMIC ANALYSIS AND BIOTECHNOLOGY REGULATION

Almost all of the registered PIPs to date have been for Cry (crystalline) proteins isolated from different species of the soil bacterium *Bacillus thur-*

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<sup>8</sup> The economic analysis for emergency exemptions can be found at <http://docket.epa.gov/edkfed/do/EDKStaffAttachDownloadPDF?objectId=090007d48031dbdd>. The economic analysis for reregistration review can be found at [http://docket.epa.gov/edkfed/do/EDKStaffAttach\[-\]DownloadPDF?objectId=090007d48081e7b3](http://docket.epa.gov/edkfed/do/EDKStaffAttach[-]DownloadPDF?objectId=090007d48081e7b3). The economic analysis for registration data requirements rule can be found at [http://docket.epa.gov/edkfed/do/EDKStaffAttach Down\[-\]loadPDF?objectId=090007d48065b8d7](http://docket.epa.gov/edkfed/do/EDKStaffAttach Down[-]loadPDF?objectId=090007d48065b8d7).

<sup>9</sup> The benefits assessment and PIF for Cry2Ab2 Bollgard II cotton can be found in the Registration Action Document, [http://www.epa.gov/pesticides/biopesticides/ingredients/tech\\_\[-\]docs/brad\\_006487.pdf](http://www.epa.gov/pesticides/biopesticides/ingredients/tech_[-]docs/brad_006487.pdf).

*ingiensis* (Bt), and their genes have been genetically engineered into corn, potato, and cotton. These proteins provide protection against different classes of insects depending on the Cry protein. Other plants that are the result of biotechnology, such as soybeans genetically modified to provide resistance to the herbicide glyphosate, are not regulated as pesticides because the engineered trait does not fit the definition of a pesticide; these traits allow the glyphosate, for example, to be metabolized by the plant so that it does not affect the crop. This means that weeds can be controlled by glyphosate, but the plant remains unaffected. EPA does regulate the herbicide, but not the genetically modified plant that is resistant to it, because the plant does not control the weeds that are pests, so the genetically modified plant is not a PIP. The Food and Drug Administration and the U.S. Department of Agriculture do regulate crops that are genetically modified to be herbicide-tolerant.

Most Bt PIP registrations have been time-limited conditional registrations for full commercial use. These registrations must be reviewed prior to the Agency making a decision to allow continued use of Bt PIP. EPA reassessed all of the risks and benefits of the Bt (Cry1Ab and Cry1F) corn PIPs and cotton (Cry1Ac) PIPs in 2001 (see EPA, 2001). During this reassessment, the tolerances for Cry1Ab and Cry1F in corn and Cry1Ac in cotton were reassessed as required under FQPA, and the EPA determined that there was a reasonable certainty of no harm from dietary exposure to these PIPs. Under FIFRA, EPA performed an economic analysis of the benefits of these PIPs from the date on which they were first registered in 1995 through 2001. The benefits of these PIPs and their risks were both important in allowing these PIPs to be conditionally registered for another limited period of time.<sup>10</sup> Unlike the recent history of regulation for conventional pesticides, external economic research by academic economists has played an important role in the registration decisions for Bt and is expected to continue to do so in the future.

For a benefits assessment for a PIP, some economic issues are similar to those for conventional pesticides, and some are unique to this type of agricultural biotechnology. As for conventional pesticides, EPA is interested in estimating the change in profits at the farm and industry level due to the adoption of a PIP, which directly influences the propensity to adopt the pesticide product (in this case, a PIP) and informs the degree of exposure and/or risk. Any change in the grower's ability to manage risk or the quality of the crop is also important in the adoption decision. A typical analysis would also consider other possible benefits, such as changes in current patterns of pesticide use. In the case of PIPs, an important consideration is the degree to

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<sup>10</sup> A benefits assessment for Bt corn can be found at [http://www.epa.gov/pesticides/biopesticides/pips/bt\\_brad2/5-benefits.pdf](http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/5-benefits.pdf), or at [http://www.epa.gov/pesticides/biopesticides/ingredients/tech\\_docs/cry3bb1/2\\_e\\_cry3bb1\\_benefits.pdf](http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/cry3bb1/2_e_cry3bb1_benefits.pdf).

which a PIP can displace use of conventional pesticides and reduce human health and environmental exposure from these pesticides.

Several economic issues are unique to regulation of PIPs. One example is the economic consequence of different types of resistance management, including refugia design. Because Bt, in particular, is considered an important resource to some agricultural production systems (both with the conventional production system and the organic agricultural production system—the Agency is interested in maintaining the sustainability of Bt in all of its forms), there is substantial policy interest in maintaining the productivity of this resource. One regulatory policy that attempts to maintain productivity of Bt is the institution of specific insect resistance management (IRM) requirements. The refuge requirement for non-Bt crops that is intended to maintain a pest population susceptible to the action of Bt has been an important part of the IRM requirements. An understanding of the economic consequences of different types of refuge design, and the costs of maintaining different levels of pest susceptibility through these refugia, is expected to be critical to the decision process as EPA revisits these conditional registrations in the coming years.

External economic research is particularly relevant in this area, due in large part to the limited decision space for analysis. For Bt technology, there are only 3 crops currently on the market (field corn, sweet corn, and cotton), and the Bt crops are targeted mainly at only five or six pests (there are other pests in which Bt has suppressive effects or even control effects compared to registered pesticide alternatives). Unlike the vast number of pest/crop combinations germane to regulation for conventional pesticides and the difficulty for an academic researcher in choosing which combinations might be of policy interest, Bt presents a fairly compact and predictable set of policy-relevant production scenarios to explore. The models of pest control have a few dimensions that can be calibrated with realistic data, and there are a finite number of choices to consider in the analysis. For example, in analyzing refugia, the farm-level choices may include the share of land planted to Bt, the share planted to refuge, and the type of refuge to adopt (e.g., level of pest control in the refuge, internal vs. external refugia). Equally important are the incentives to growers and industry: will compliance with refuge requirements be compatible with grower interests such as yield and profitability, or will they appear to be restrictive, viewed as a prohibitive cost rather than a benefit to growers?

Agricultural biotechnology is a fairly new field and it has generated substantial interest among economists, providing opportunities for innovative research and peer recognition. This has been driven in part because EPA has mandated specific IRM requirements as conditions of registration. Because of the refuge requirements, agricultural economists have been asked by a number of stakeholders to determine or predict the economic impacts of

these requirements. No one wants regulatory requirements to be burdensome. The area of IRM requirements has stimulated much interest among academic researchers, government, and industry—especially growers. These requirements have focused interest among external economic researchers on their impact on agriculture and society. The Biopesticide and Pollution Prevention Division has worked with a number of these agricultural economists in the past 10 years and has used their research in its analyses of the impact of IRM requirements [for example, Hurley, Babcock, and Hellmich (2001), Livingston, Carlson, and Fackler (2004), Mitchell et al. (2002), Frisvold and Tronstad (2002), and Hurley, Mitchell, and Rice (2004)].

For external economists wishing to contribute research that could inform biotechnology policy, this is a fertile ground for research, with some caveats. First, there are a number of emerging innovative approaches for exploring the economics of refugia choice and resistance management, but in applying innovative models, there is an attraction to simplifying other parts of the production system to make a given model tractable. Given the importance of previous research in providing insight into pest control economics, particularly the damage abatement approach (such as Lichtenberg and Zilberman 1986), it might be shortsighted to overly simplify production models of crop production solely in pursuit of resistance management results.

Additionally, direct applications of resistance management models are critical, which may favor some degree of modeling parsimony, and it is also important that models be verified or calibrated to actual situations with real-world data. This makes it easier for economists and biologists at EPA to understand and use the models, and more importantly, makes it possible for the models and their results to be explained to policymakers. Models and results need to focus on the policy choices that actually face a policymaker, with special consideration toward the practical fact that policy formation favors relatively simple and straightforward instruments and/or mechanisms. This is especially important to remember when policy complexity generates only negligible improvements in measuring welfare.

Finally, it is important for external researchers to appreciate that economic analysis supporting regulatory work usually must take an *ex ante* view, considering what will happen in the event of a new registration or regulation. Research that is solely backward-looking has limited relevance to a policymaker. On the other hand, *ex post* research can be very valuable in simulating or inferring the potential consequence of future regulatory options. Much of the current research on the economics of Bt crops is *ex post* but provides information about several important issues surrounding the benefits of Bt: adoption behavior by growers, the impact on profitability, the value placed on the technology by growers, the extent to which that value is risk premium (or discount) when biotechnology changes the risk that farmers face, and changes in conventional pesticide use by farmers—all have been

studied by economists. To the extent that this type of result can be used to generate insights into the possible economic consequences of future policy choices, such research could be influential in informing policy decisions.

## 5. THE FUTURE

For the motivated research and/or policy economist working in this area, one natural question is: what are the opportunities for policy-relevant external research in the near future? Among the several agricultural biotechnology platforms, Bt crops are still the most important sector for EPA: they combine two areas of interest to agricultural and resource economists (biotechnology and pesticides); there is a clear regulatory schedule; and a significant portion of large-acreage crops are planted to Bt varieties.<sup>11</sup> The conditional registrations for Bt PIPs expire in the near future, with some Bt cotton registrations expiring in 2006 and some Bt corn registrations expiring in 2008.<sup>12</sup>

As EPA considers renewing these registrations, benefit reassessments by the EPA will continue to favor products that can decrease health and environmental risks and reduce the use of conventional pesticides, and economic analyses will help inform these decisions. Moreover, new PIP technology targeted at the same crop and pest situations as existing Bt products will require a nuanced economic analysis because the conditions of a conditional registration will be harder to meet when there are already effective Bt products available and the expected marginal benefit of additional Bt registrations may be more subtle than attended the original registrations. For example, more attention might be focused on location-specific models.

To provide appropriate regulatory oversight and to ensure that the effective Bt products remain effective, EPA values policy-relevant economic research on resistance management, monitoring, and refuge requirements, topics for which economic analyses are still evolving and where more research is needed. Recent research on grower attitudes to resistance management is particularly helpful, and bioeconomic models of resistance can be very data-intensive, but valuable. Since EPA considers pest susceptibility to Bt a common property resource, where a policy goal is to avoid depletion of this resource, then one area of possibly useful research could be exploration

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<sup>11</sup> Bt corn is planted on about 26 percent of the corn acreage, with another 9 percent planted to stacked gene varieties that control insects; and about 18 percent of cotton acreage is planted to Bt cotton, and 34 percent to stacked gene varieties that control insects (USDA 2005). Estimates of acreage planted to biotechnology varieties can be found in the USDA/NASS document *Crop Production—Acreage—Supplement*, available at <http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bba/acrg0605.pdf>.

<sup>12</sup> A full list of Bt registrations and expiration dates can be found at [http://www.epa.gov/pesticides/biopesticides/pips/pip\\_list.htm](http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm).

of whether there is a market mechanism that leads to a cost-effective and sustainable resistance management plan. For example, how effective are contracts designed by the registrants of Bt crops in promoting resistance management strategies that are incentive-compatible to growers of Bt crops?

Research on resistance management is most likely to help inform regulatory policies if it contains several elements of importance to EPA. Research that explores refuge requirements for Bt crop/pest combinations, specifically looking at cost-effective and sustainable refuge choices in a dynamic way, could be particularly helpful. This type of analysis could help EPA refine refuge requirements that are both feasible and efficient. To that end, it is important for bioeconomic models of resistance to be workable and applicable to different situations, such as crops with single and multiple pests, crops with single and multiple pesticides, and areas or fields with single or multiple crops. Location- and crop-specific analysis is most likely to be influential in informing future regulatory decisions for PIPs.

There is a challenge here for academic economists and for regulators—a challenge to strengthen lines of communication. How can economists interested in relevant policy work on agricultural biotechnology provide useful and timely information to EPA? How can EPA communicate to policy economists which issues are directly relevant to regulatory decisions for PIPs? Where PIPs are concerned, there is potentially overlap in research areas of interest to academic economists and the information that regulators in the Office of Pesticide Programs seek to help inform future decisions. It is likely that this shared interest will maintain policy relevance for the next several years, and EPA is hopeful that strengthening communication among researchers and regulators will generate work and collaborations that are productive and useful to each.

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