PURDUE UNIVERSITY

PURDUE EXTENSION
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PESTICIDE BENEFITS ASSESSMENT

Pesticide Benefits Assessment

EPA Balances Risks and Benefits

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Introduction

The Environmental Protection Agency's Office of Pesticide Programs (OPP) regulates most aspects of pesticides, including the review of registration studies submitted by the registrant and the evaluation of pesticide label format and content. The EPA process of registering pesticide products addresses health and environmental issues by restricting how, when, and where registered pesticides may be used.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), OPP is required to consider the benefits that pesticides provide to the United States public. Benefits assessments measure the potential economic impact of EPA's regulatory decisions. That is, if EPA considers restricting the use of a pesticide, the economic loss is determined for both the pesticide user and the consumer.

If the risks of continued use of a pesticide are relatively high, the projected benefits have to be very compelling for retention. If the risks of continued use are low, or if they can be easily managed, a benefits assessment may offer insights into reasonable and prudent measures to further limit those risks. In some cases, low risk pesticides require no benefits assessment.

The information contained in a benefits assessment allows EPA to compare risk mitigation strategies to the effects of each strategy on the user and to the public. EPA balances risks and benefits during its evaluation and considers mitigation options short of cancellation. In any given situation, however, EPA may view the risk so low that use of the pesticide does not require management — or so high that use must cease.

Federal Law Requires Consideration of Benefits

The legal standard for pesticide registration is set forth in FIFRA Section 3(c)(5)(cc). It allows EPA to register a product when "it will perform its intended function without unreasonable adverse effects on the environment." Under FIFRA Section 2(bb) the phrase *unreasonable adverse effects on the environment* is defined as "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." EPA interprets this standard to require that the agency weigh the risks and benefits of pesticide use in making regulatory decisions under FIFRA.

FIFRA goes on to state that EPA shall consider the risks and benefits of public health pesticides (such as those used to control disease-vectoring mosquitoes) separate from the risks and benefits of other pesticides (such as those used on field crops). FIFRA states, "The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticides under this Act, the Administrator shall weigh any risks of the pesticide against the health risks, such as the diseases transmitted by the vector to be controlled by the pesticide. " Obviously, Congress placed a special requirement on EPA to carefully examine the impact of its actions on pesticides used in public health programs.

Pesticides are a valuable tool in the production of food and fiber.

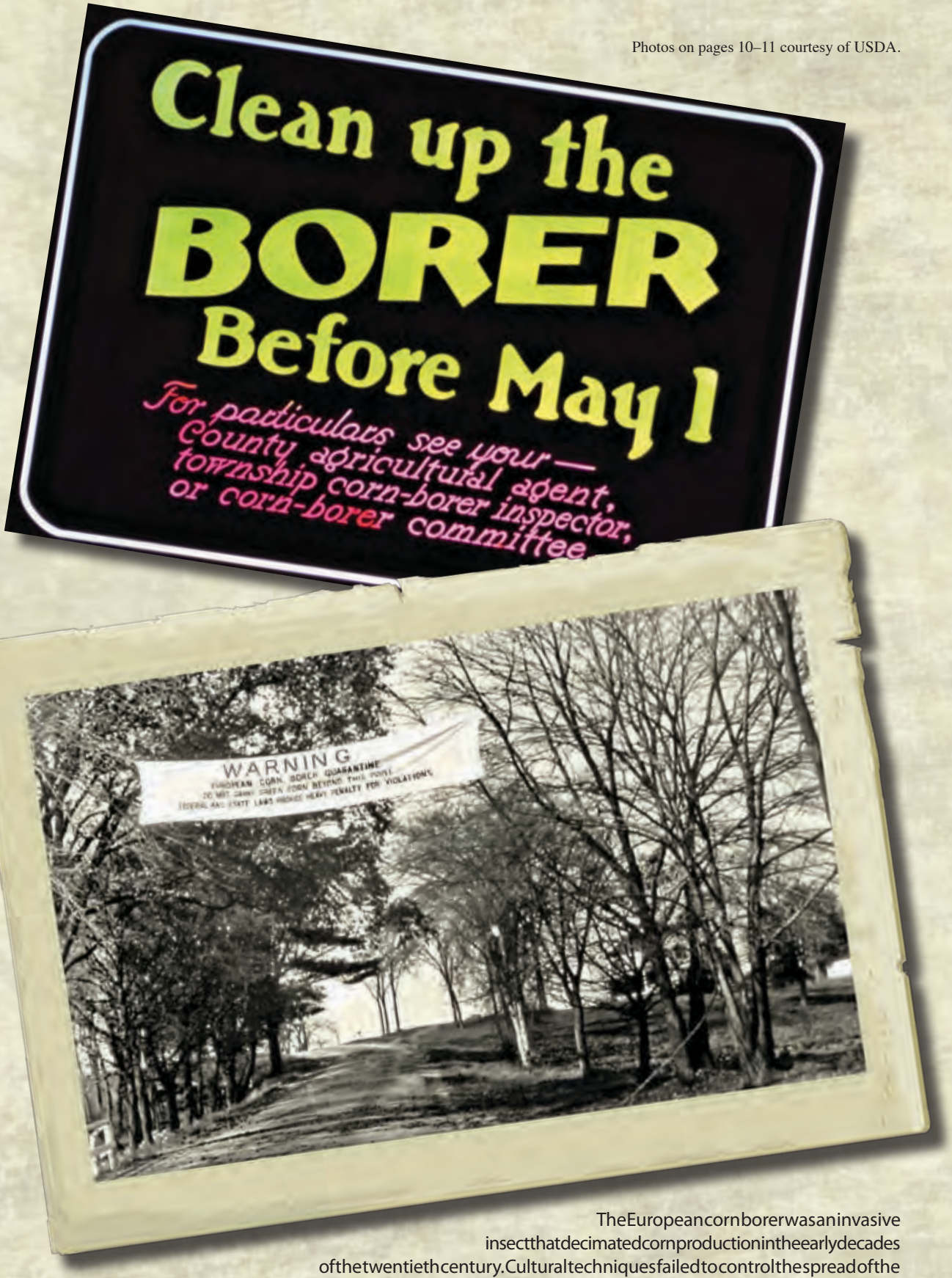
Chris Evans

Glenn Nice

Invasive weeds such as garlic mustard (above) and purple loosestrife (below) can destroy natural habitats. A university weed scientist evaluates the efficiency of a pesticide in reducing the negative impact of invasive weeds on native plants (right).

Bernd Blossey, Cornell University

Photos on pages 10–11 courtesy of USDA.



The European corn borer was an invasive insect that decimated corn production in the early decades of the twentieth century. Cultural techniques failed to control the spread of the insect across corn acreage across the Midwest. Insecticides played an important role in maintaining crop yields while agronomists worked on improving the genetics of corn hybrids to deal with this emerging insect pest.


DO NOT PLOW UNDER
Cornstalks, Corn Stubble, or Garden Weeds
BURN THEM
KILL THE EUROPEAN
CORN BORERS
HIDING IN THEM
Consult L. H. WORTHLEY,

Benefits Assessments Used in Pesticide Registration Decisions

In 1976, EPA expanded its benefits assessment methods and published their protocol in the Federal Register (Volume 41, Issue 102, pages 21402-21405, 1976). Examples from the text in the Federal Register read as follows:

> "As used in the guidelines, the economic impact of the regulation is equated to the anticipated loss in benefits from the use of the pesticide. For agricultural pesticides, the analysis will focus on the impacts on farmers, farm productivity, and consumer costs associated with farm productivity. Similarly, analysis of other pesticides will focus on the impacts on other user groups and related effects on the economy."

Consideration of benefits information is a requirement in EPA's decision-making process whether it involves the review of a new active ingredient, an Emergency Exemption under Section 18 of FIFRA, or an existing registration. The amount of benefit information needed to make a risk/benefit finding under FIFRA varies with the type of action being considered.

Review of New Uses of Pesticides

EPA generally does not require manufacturers (registrants) to submit product efficacy data. If a pesticide doesn't pose risks of concern, EPA assumes that the manufacturer's efforts and the cost of presenting the product for registration are offset by its market potential. EPA also assumes that the new product's benefits to users and consumers outweigh any negligible risk.

It takes 10 years and $190 million from the time a molecule is discovered until EPA registration is granted.

EPA assumes that the manufacturer of a pesticide understands what their customers need in pest control products. Photo courtesy of Purdue University Extension Entomology.


NEW HOLLAND
BALE
900

EPA must understand how a crop is grown and harvested to better quantify the role of a pesticide in preventing weeds, insects, or diseases from reducing yield and quality. Understanding the benefits helps EPA put the risk mitigation measures into perspective.

Page 14: Mint flowering in a field, being cut, drying as hay in wind rows, and being chopped and blown into a wagon-mounted distillation tub.

This page, top: The yellow tub is connected to a hose that delivers steam to the harvested mint. This process of steam distillation extracts the essential oils from the hay.

Middle: The extracted mint oil is run through a water-cooled condenser and floats on top of the water.

Bottom left: The pure mint oil is put into barrels.

Bottom right: The hay left in the distillation tub is allowed to cool and then recycled.

At the time of registration, EPA generally does not collect data that would allow comparison of new product efficacy to that of pesticides currently on the market; i.e., a detailed benefit review is not always conducted at registration. Although efficacy data generally is not required as part of the original submission, it is required under the Code of Federal Regulations, 40 CFR Part 158.640 and Pesticide Regulation (PR) Notice 96-4, June 3, 1996. Each manufacturer must develop and maintain efficacy data in case EPA requests it to conduct a benefit assessment of the active ingredient (e.g., in response to a pattern of adverse reports, complaints, or changes in governmental policies).

An efficacy data waiver at the time of registration is not provided for all products. Efficacy data is required for pesticides intended for use on public health pests (mosquitoes, flies, rodents) and structural pests (termites). Registrants must submit efficacy data along with their registration request. This is necessary because, in some instances, the efficacy of the pesticide may not be obvious. For example, EPA has generally requested efficacy data for soil treatment termiticides to determine whether the pesticide will remain effective for at least five years.

EPA also requires that applications for disinfectant products show whether the products will control microorganisms such as bacteria and fungi. It is also important that a solution used as a disinfectant for cleaning counter tops in a surgery room does, in fact, kill germs, because failure might place human health at risk. EPA can take action under FIFRA misbranding actions, if the product doesn't work, as well as under federal consumer protection laws that prohibit false or misleading advertising.

Another exception to this approach is found under the reduced risk policy. A registrant who wishes prioritization of a new registration may accelerate product review by establishing that the product is safer than current products and demonstrates equal or superior performance. The new product's ability to displace "less safe" older products would be considered. Since the specific advantages of various products are very difficult to determine, each new product presented for EPA review is judged on its risks relative to what is already on the market.

Jodie Green

Thomas V. Myers

Jay Kelley

EPArequirespesticidemanufacturerstoprovetheirproductsareeffectiveagainst termites before allowing them to be sold.

Review of Emergency Exemption Requests

Section 18 of FIFRA, as well as the regulations in 40 CFR Part 166, give EPA emergency authority to permit use of unregistered products or unapproved uses of registered products. An emergency exemption usually is requested when a pest outbreak occurs for which there are no registered pesticide control options. EPA conducts a benefit assessment to determine if the benefits of short-term use outweigh potential risks.

Under certain well-defined conditions of emergency, risk, or quarantine, a state may petition EPA to register a product for temporary use. Growers may petition their state agency to request a Section 18 from EPA to help control special pest outbreaks. Prior to granting an emergency exemption, EPA's Biological and Economic Analysis Division (BEAD) conducts a benefit assessment to help determine whether the condition is an emergency. BEAD determines (1) whether it's an urgent and non-routine pest problem, (2) whether alternative control options are currently available in the marketplace, and (3) whether significant economic losses will occur if a Section 18 is not granted.

Because a Section 18 often is requested at the onset of an emergency, BEAD is required to conduct benefit assessments very quickly. BEAD can provide detailed benefit assessments under stringent time constraints because it maintains or has immediate access to information on cropping systems, pesticide use data (e.g., National Agricultural Statistics Service), and comparative product performance data. In addition to accessing great quantities of data, BEAD scientists often conduct personal interviews with growers or experts from universities, grower groups, and trade associations.

While BEAD is evaluating the emergency and formulating its decision, other EPA personnel are determining whether the use of the product under an emergency exemption would result in adverse effects to humans or the environment.

FIFRA Section 18 gives EPA authority to temporarily exempt a product from the requirements of registration. Such exemptions seldom extend beyond one year and often are limited to the time period during which the specific pest is present.

DuPont Crop Protection

SECTION 18 EMERGENCY EXEMPTION USE DIRECTIONS

For use in connection with an emergency exemption authorized under the provisions of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DUPONT™ CORAGEN® insect control with the active ingredient RYNAXYPYR® insecticide
FOR USE ON SWEET CORN FOR CONTROL OF CORN EARWORM IN THE STATE OF INDIANA

Effective Use Date: 08/05/2008
Expiration Date: 10/15/2008
FILE SYMBOL: 08-IN-03

CORAGEN® insect control is a suspension concentrate.

Contains 1.67 lb. active ingredient per gallon.

All Applicable Directions, Restrictions and Precautions on the Registered Product Label for CORAGEN® (EPA Registration Number 352-729) are to be followed. Any adverse effects resulting from the use of CORAGEN® under this emergency exemption must be immediately reported to the appropriate state lead agricultural agencies.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Crop	Application Method	Target Pest	CORAGEN® RATE		Last Application (Days to Harvest)	REI (Hours)
			Lb. ai per acre	fluid ounces product per acre		
Sweet Corn	Foliar	Corn Earworm	0.045 - 0.068	3.5 - 5.5	1	4 hrs.

Minimum interval between treatments is 1 day.
Do not apply more than 15.4 fl oz CORAGEN® (0.2 lbs a.i.) per acre per crop.

APPLICATION

Apply at the specified rates when insect populations reach locally determined economic thresholds. Consult the cooperative extension service, professional consultants or other qualified authorities to determine appropriate threshold levels for treatment in your area.

Apply follow-up treatments of CORAGEN®, as needed, to keep pest populations within threshold limits. Refer to the Resistance Management section of the federally registered product label for further guidance on follow-up treatments. See individual crop sections of this label for specific minimum spray interval.

Use sufficient water to obtain thorough, uniform coverage. CORAGEN® may be applied by: ground or aerial application equipment. For aerial application use the following directions unless otherwise specified in this label: use a minimum of 5 gallons per acre of water. For all other application methods use the following directions, unless otherwise specified in this label: use a minimum of 10 gal per acre of water for all crops.

Use of Adjuvants: In some situations where coverage is difficult to achieve such as closed canopy, dense foliage, plants with waxy leaf surfaces, or less than optimum application equipment, an adjuvant may improve performance. Use only adjuvant products that are labeled for agricultural use and follow the directions on the manufacturer's label. Always conduct a premix test for compatibility. Use a proven, EPA-approved adjuvant that does not affect foliage and/or fruit finish. Refer to specific crop sections of this label for additional adjuvant guidance.

For ear protection sprays to control corn earworm, begin applications just before or at time of silking. Repeat applications may be applied if economically damaging populations exist.

SPECIFIC EXEMPTION PURSUANT TO SECTION 18 OF FIFRA AS AMENDED.

This labeling must be in possession of the user at the time of pesticide application.

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EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

US Environmental Protection Agency Office of Pesticide Programs

Reregistration Eligibility Decision for Acephate

When EPA concluded the organophosphate (OP) cumulative risk assessment in July 2006, all tolerance reassessment and reregistration eligibility decisions for individual OP pesticides were considered complete. OP Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs. OP tolerance reassessment decisions (TREDs) also are considered completed.

Combined PDF document consists of the following:

- Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006)
- Acephate IRED

Office of Pesticide Programs

EPA's office of Pesticide Programs consists of the following divisions:

- Director's Office
- Antimicrobial Division (AD)
- Biological & Economic analysis Division (BEAD)
- Biopesticides & Pollution Prevention Division (BPPD)
- Environmental Fate & Effects Division (EFED)
- Field & External Affairs Division (FEAD)
- Health Effects Division (HED)
- Information Technology & Resources Management Division (ITRMD)
- Registration Division (RD)
- Special Review & Reregistration Division (SRRD)

Review of Existing Uses of Chemicals

EPA has the regulatory flexibility to reconsider prior registration decisions. EPA also has the discretion to review a pesticide at any time. For example, new evidence may surface, suggesting current uses of a registered pesticide pose unreasonable risks to human health or the environment. Events that may precipitate the review of existing registration include unanticipated or adverse effects on water quality, wildlife, worker safety, or public health, or the occurrence of residues that surpass regulatory trigger points established by law or policy.

EPA's Special Review and Reregistration Division reviews conventional pesticides. Each active ingredient under review is assigned to a chemical review manager who directs the various aspects of the risk and benefits assessments. EPA produces Reregistration Eligibility Decisions (REDs, page 19) once a complete set of data on a chemical has been reviewed. These REDs are comprised of product risk characterizations and risk mitigation options for reregistration. REDs are decision documents that describe EPA reregistration determination for active ingredients. REDs' risk management decisions, including label changes and additional studies or data requirements necessary to support continued registration, are a means of transparency among EPA, the manufacturer, and the public.

The reregistration process begins with a review of the data on human health risks by the Health Effects Division (HED); the Environmental Fate and Effects Division (EFED) reviews any risks posed by the pesticide to aquatic systems and wildlife. BEAD is asked to conduct a benefits assessment when the risks approach EPA's trigger levels.

Most benefits assessments involve crops for which a large percentage of the total acreage is treated with the active ingredient; crops for which only a small percentage of acreage is treated are not included unless the pesticide plays a critical role in protecting them. BEAD often solicits input from pesticide users to help assess the importance of a specific compound.

BEAD officials review the use of pesticides in a commercial greenhouse.

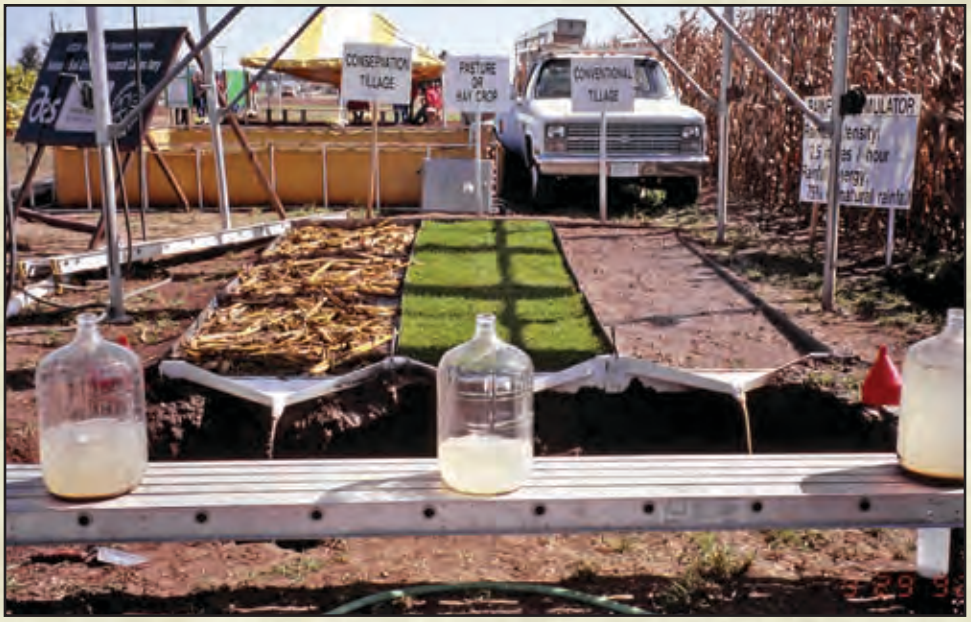
Photo courtesy of U.S. EPA.

EPA analysts consult with USDA on the benefits of compounds under review to determine whether marginal uses have any compelling benefits; e.g., maybe a regional group of farmers growing a particular crop has a very unique pest problem. This data collection is conducted under the auspices of USDA's Office of Pest Management Policy (OPMP), which contacts farmers, universities, and grower groups. They gather information to determine if important uses for the active ingredient exist in crops for which only small amounts are used. If there are compelling reasons to retain the use of the product on small acreage crops, these uses are subjected to a more detailed assessment. OPMP personnel develop pesticide data for the assessments under a Memorandum of Understanding (MOU) between EPA and USDA.

An EPA product review team meets frequently to discuss risks and benefits associated with the pesticide under review, ultimately formulating a series of recommendations describing various options and their associated cost or impact. The public is provided an opportunity to offer comment on the assessment and potential mitigation approaches when risks or concerns are identified. The purpose of such comment is to correct errors, bring in new data, or offer additional points of view; sound, factual information influences EPA's assessment and proposed risk mitigation.

Although this process takes time, ultimately the uncertainties are reduced and better decisions result. The process has evolved over the years, but essentially it focuses on reducing the risk while minimizing economic impact. When risks are identified, attempts are made to determine whether restrictions are feasible. EPA considers its various options to change the product label (e.g., extend the reentry period, require additional personal protective equipment, require grass buffer strips along waterways) to reduce risk potential. However, in some cases, the only way to effectively reduce the risk is cancellation of the product's registration for some or all uses.

Decisions to mitigate one risk might lead to severe consequences by increasing other risks. For example, eliminating or greatly limiting how a herbicide is used might result in increased tillage to control weeds; and although increased tillage can be used successfully to control weeds, it increases emissions from greater use of fossil fuels and contributes to additional topsoil erosion from farmland. Topsoil eroding into streams results in



Nonchemicalpestcontroltacticscanalsohaveunintendedconsequences.Afieldwithside-by-sideconventionaltillageandno-till(below).Riskmitigationoptionsthatpromotetillageofthesoiltosuppressweedscanadverselyimpactfishhabitat,increasesoilerosion(above,farright),reduce water quality, and increase local flooding when sediments fill ditches and creeks.

sedimentation of water bodies, which is harmful to aquatic life (e.g., fish spawning beds and eggs are smothered by soil). In addition to environmental harm, the more topsoil that is lost, the less sustainable the land becomes to produce food and fiber for future generations. Overall, an understanding of the benefits of pesticide use is critical in comprehending the full impact of EPA risk mitigation decisions.

By understanding the risks and benefits of pesticides, we can use concepts such as integrated pest management, reduced exposure programs, and finely tuned pesticide product selection to minimize negative impacts to humans and the environment while benefiting pesticide users and the public. Although it may be difficult to convey to the public a sense of balance among pesticide risks and benefits, this issue is central to America's discourse on the continued use of pesticides.

How EPA Determines Pesticide Benefits

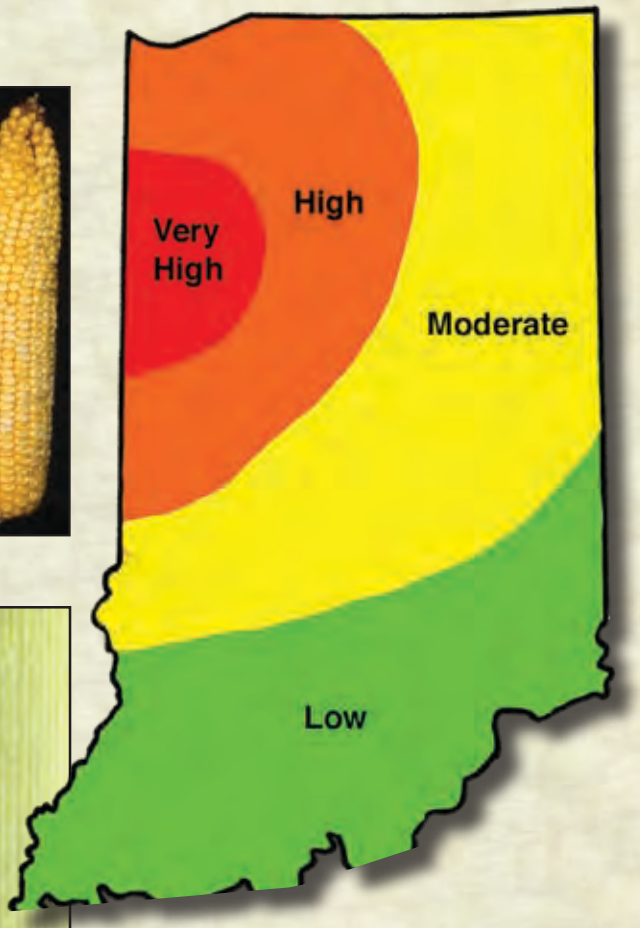
Every EPA action to manage pesticide risk affects the user and the public. It is up to BEAD to determine the ultimate impact. BEAD agricultural scientists and economists collect pesticide use information that accomplishes the following:

- Identifies crops on which the pesticide is used.
- Indicates how the pesticide is used.
- Suggests alternative pest control practices.
- Determines crop yield and quality differences between crops treated with the reviewed pesticide and those treated with alternative products or methods.
- Quantifies potential impact on users and the public.

BEAD develops benefit assessments when risk mitigation measures are being proposed (e.g., cancellation, rate reduction, extension of worker reentry intervals, limitation of the time

period during which the material can be applied). BEAD analyzes the impacts of the proposed risk reduction measures to determine which measures would have the least impact on growers and consumers. Analysts also consider alternative pest control methods that could be legally and effectively substituted for the pesticide in question, and the resulting economic impact of alternative control methods on pesticide users. In conducting these benefit assessments, BEAD considers real world conditions, uses input from a wide variety of sources, and characterizes conditions under which users make pest control choices.

Photos and illustration courtesy of
Purdue University Extension Entomology.



The western corn rootworm has been one of the most serious pests of corn in the Midwest. Adult beetles feed on silks (left), which prevents pollination of kernels (top left). A major control tactic was to alternate corn and soybeans, but the corn rootworm has adapted to that strategy by laying its eggs in soybean fields. The eggs overwinter there and wait for corn to be planted the following spring. The ability of the insect to circumvent crop rotation has resulted in greater use of soil insecticides and plant-incorporated insecticides in high risk areas where crop rotation is failing to control this insect pest.

Corn rootworm eggs hatch in late May or early June, and the larvae feed solely on corn roots. The higher the population of larvae, the more roots consumed and the lower the crop yield. Also, compromised roots leave the crop vulnerable to strong wind which can lay it over and make harvesting difficult.

Corn rootworm larva feeding on a corn root.

Corn roots damaged by corn rootworm.

Thinning of roots caused by corn rootworm larvae.

Corn rootworm-damaged corn.

Corn rootworm damaged roots let corn go down in wind.

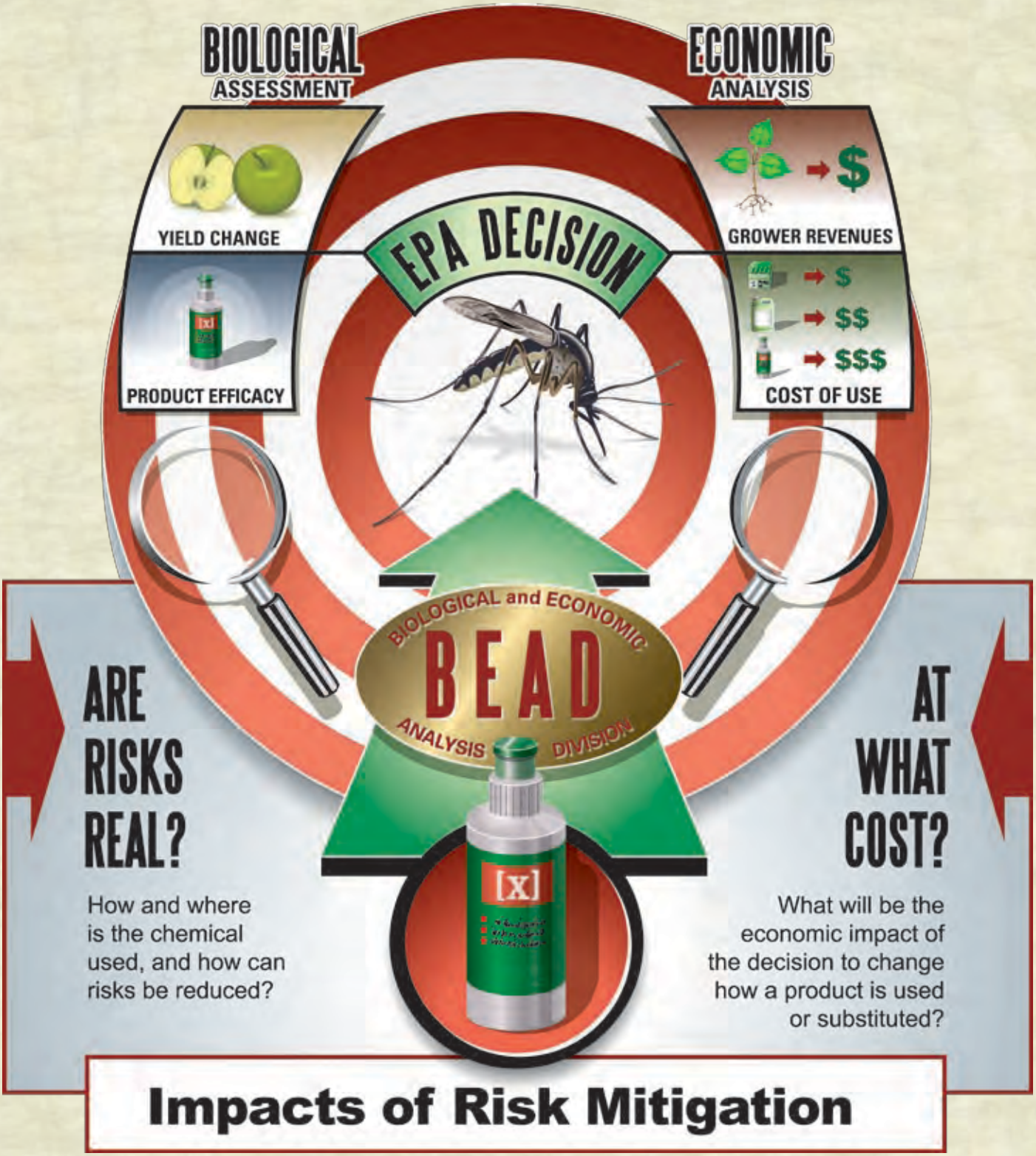
All photos on pages 26–27 are courtesy of Purdue University Extension Entomology.

The amount of yield loss can be realized as a price per bushel of corn. Subtract the cost of the insecticide and any application costs can provide BEAD a net return from the use of the insecticide.

Monitoring for the presence of adult corn rootworms in soybeans helps scientists determine the risk of corn rootworm damage to corn the following season. When the risk of significant yield loss is high, an insecticide is considered necessary to protect the yield.

BEAD analyzes benefit assessment data by assigning an economic value to the subject pesticide, relative to alternative control measures. The assessment group assigns a dollar value to each risk mitigation option considered; these values estimate the cost of the measure for individual farmers as well as state, regional, and national growers. Ultimately, the pesticide use information and the economic analysis are reviewed along with the human health and environment risk assessments to formulate and finalize decisions on managing the risk.

A benefit assessment can be conceptually divided into two separate analyses: a biological review analysis and an economic impact analysis.


BIOLOGICAL
ASSESSMENT
ECONOMIC
ANALYSIS
YIELD CHANGE
GROWER REVENUES
$
EPA DECISION
PRODUCT EFFICACY
$
$$
$$$
COST OF USE
BIOLOGICAL and ECONOMIC
BEAD
ANALYSIS
DIVISION
ARE RISKS REAL?
How and where is the chemical used, and how can risks be reduced?
AT WHAT COST?
What will be the economic impact of the decision to change how a product is used or substituted?
[X]
Impacts of Risk Mitigation

Biological Assessment

A biological review analysis describes in detail the following items:

- General information on each crop (e.g., total acreage, total production, yield per acre, regional yield differences).
- Pests (e.g., crabgrass, foxtail, soybean rust, soybean aphid) targeted by the pesticide for each crop.
- States or regions where the pesticide is used most.
- Timing of pesticide application relative to cropping pattern (e.g., winter weed control, pre-plant).
- Method, frequency, and rate of application.
- Evaluation of alternative pesticides and practices (e.g., tillage, incorporation of pesticide).
- Product performance data (e.g., yield increase or product quality protection relative to alternative pesticides or practices).

The biological review analysis is critical because it explains to the decision-makers how the crop is grown, its relative regional or national importance, and how and why the pesticide is used. Ultimately, the information is summarized and distilled into tables showing the expected yield and quality changes that would result from the loss of one product compared to the use of alternative products and practices. This type of analysis often requires the examination of studies that indicate how well the product works to control the pests as well as studies that show yields from areas treated with the pesticide compared to its alternatives.

Sometimes the data needed to complete a biological assessment are unavailable or outdated. In these situations, BEAD relies on mathematical calculations, economic models, expert opinion, or information from contract vendors. These and other sources of data are identified in the biological analysis review.

Taken as a package, the biological review provides a brief but detailed analysis of production and production time-lines. Once yield differences are calculated for all viable options, the biological review analysis assessment is complete.

A research entomologist studies the yield and quality of apple production under organic growing conditions (above) and in a conventional orchard (below).

Photos above and below courtesy of Purdue University Extension Entomology.
All others on pages 30–31 courtesy of Janna Beckerman.

Economic Impact Analysis

The economic impact analysis examines the costs and returns associated with producing the crops affected by the proposed pesticide restrictions. Costs evaluated by the economists include those associated with the next best alternatives:

- Are application costs higher?
- Is special equipment needed to apply this material?
- Does the chemical cost more per acre?
- Does it need to be applied more often (resulting in an increase in cost per acre)?
- What are the costs of any yield loss due to use of a less efficacious product or practice?
- What are the costs of nonchemical approaches?
- What is the impact on gross revenue and net profit from any increased production costs or decrease in crop yields?

Suppose that under a worst-case scenario EPA considers canceling a fungicide for which there is no viable alternative product. Current research indicates that growers would experience a 20 percent decrease in yields by not treating the crop. Revenue reduction associated with decreased yield could be expressed as a gross loss; i.e., a 20 percent loss in yield (say from 500 bushels to 400 bushels), or as a net loss to the grower, which is based on profit (wherein 20 percent yield loss could easily translate to elimination of all profit). Often, the narrow profit margin and high fixed costs of most food production enterprises in the United States leave little room for unexpected expenses. Thus, 20 percent takes on a different meaning when examining the gross loss versus net loss to the grower. This is why most economic impact analyses present the pesticide benefits and the cost of regulation in both formats.

Dan Egel

Muskmelon attacked by the disease Alternaria leaf blight in the row labeled "TRT 1" (right side of photo above). The row on the left, labeled "TRT 2," has been protected by a fungicide.

Untreated tomato plants right of the green flag show early blight damage. The healthy plants left of the flag were treated with a fungicide.

Dan Egel

Sources of Pesticide Data Used in Assessing Benefits

EPA seeks pesticide use and economic information from a wide array of sources, each with its own strengths and weaknesses.

Pesticide Labels

The pesticide label is the primary legal authority governing the sites on which the product can be used (e.g., crops, livestock, home) and how the pesticide must be used (e.g., rates, number of applications, size of weed or crop, insect growth stage, preharvest intervals, reentry periods). Labels of products that contain the pesticide under review provide a list of crops, use rates, etc., that become the basic elements of a biological review analysis. EPA can create customized reports for this analysis by accessing their internal electronic database of product labels, the Label Use Information System (LUIS). Label summaries are normally provided as part of the use profile written in the Reregistration Eligibility Decision (RED) document.

EPA officials review the processofmakinganaquatic herbicide application.

By using a summary of pesticide labels, all legal uses (sites, rates, etc.), and user groups that might be impacted by a restriction of the pesticide under review are identified. However, product labels do not provide information on how the product was actually used, which crops were treated, the number of acres treated, the actual application rates, the number of applications used per season, etc. That real world information must come from other sources.

Survey Data

Pesticide use surveys form the foundation of most benefit assessments. The originators of these surveys differ but are typically compiled by private marketing consultant companies, grower groups, land grant universities, state departments of agriculture, or the federal government (USDA National Agricultural Statistics Service). Survey data is a good source of pesticide use information because it is collected directly from the user of the product.

One of the most reliable sources of pesticide use and crop production information is USDA's National Agricultural Statistics Service (NASS). Although their principal emphasis has been on collecting information on major field crops (e.g., corn, cotton, vegetables, and fruits), NASS has also cooperated with state land grant universities to collect data on less widely grown crops. Examples of NASS surveys are found at http://www.nass.usda.gov/Publications/innex.asp.

USDA National Agricultural Statistics Service enumerators collect information on acres planted, yields expected, and pesticides used.

Photos courtesy of USDA National Agricultural Statistics Service, Indiana Field Office.

EPA analyzed the potential risks that pesticides pose to field workers. The mitigation steps to protect field workers from risk was assessed against the cost of such actions. Overall, field worker training, field warning signs, and the posting of emergency numbers were considered important steps in protecting field workers' health. The costs associated with implementing the EPA Worker Protection Standard were viewed as reasonable relative to the benefits provided to field workers.

Survey data can be very useful in a benefit assessment. Probably most helpful is the information it provides on how the pesticide is used by the grower and what alternatives are also used to control the same pests. Disadvantages include the expense and time it takes to develop and conduct the survey and to analyze and report the findings; the prohibitive cost of surveys limits their use to major crops with only periodic application to minor crops.

Efficacy and Product Performance Testing

EPA must have access to efficacy and product performance information to predict changes in product use that might result from restrictions imposed by regulatory action.

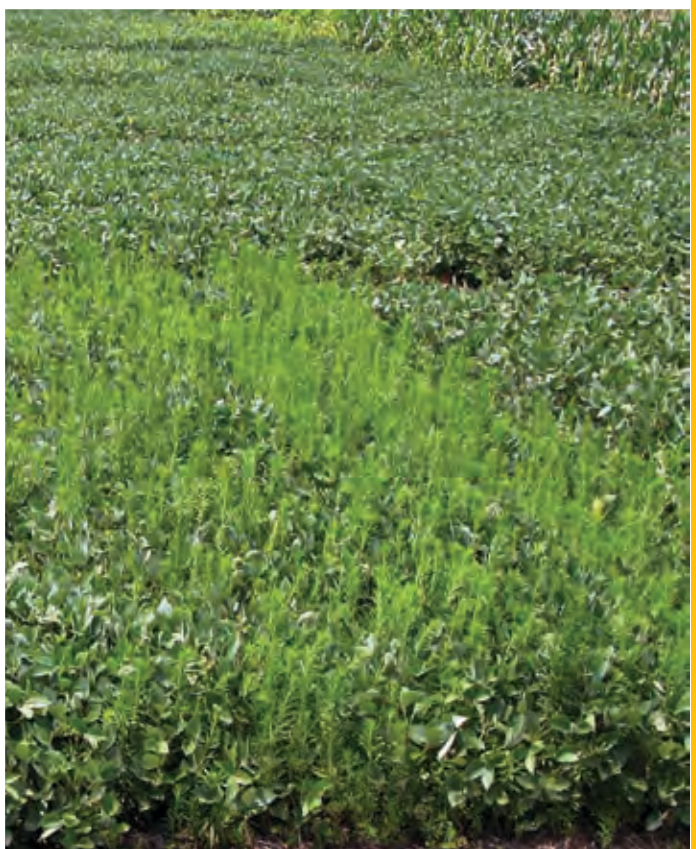
Sources of product efficacy (e.g., how well a product controls pests) and performance data (how control translates into better yields or quality) are found in scientific journals, university experiment station reports, grower association proceedings, and unpublished research reports. EPA locates and reviews as much information as possible when preparing a benefit assessment. Ultimately, differences in yield and/or quality determine the economic impact of regulatory action. Therefore, the more precise and refined the data, the more accurate the benefit assessment in forecasting economic effects.

But comparison among alternatives is not always easy. One difficulty in measuring performance is that the measurements need to be made in side-by-side comparative trials to account for environmental variables (e.g., climate, soil type, pest pressure) that affect product performance and yield. This can be particularly difficult when determining differences between pesticides and non-chemical alternatives because products and alternatives are seldom tested side-by-side; various experiments from different locations must be incorporated into a single analysis.

The limited geographic regions from which some studies are drawn makes extrapolation of the results to a national level

BEAD anaylses require an understanding of the relationship between insects, diseases, and weeds as it relates to yield losses and pesticide use.

Photos courtesy of Purdue University Extension Entomology and the Department of Botany and Plant Pathology.



difficult or suspect. This is especially true where the types and density of targeted weeds, insects, and diseases vary by region.

Cost

Part of the benefit assessment involves determining the cost of pesticides and nonchemical alternatives. BEAD solicits information on the cost of different product formulations from use surveys, USDA, pesticide dealers, and professional journals. This information, along with common use rates and knowledge of the acreage treated annually, is used to estimate the cost of various product uses. If there are significant regional differences in the cost of a product, this also must be factored into the calculations.

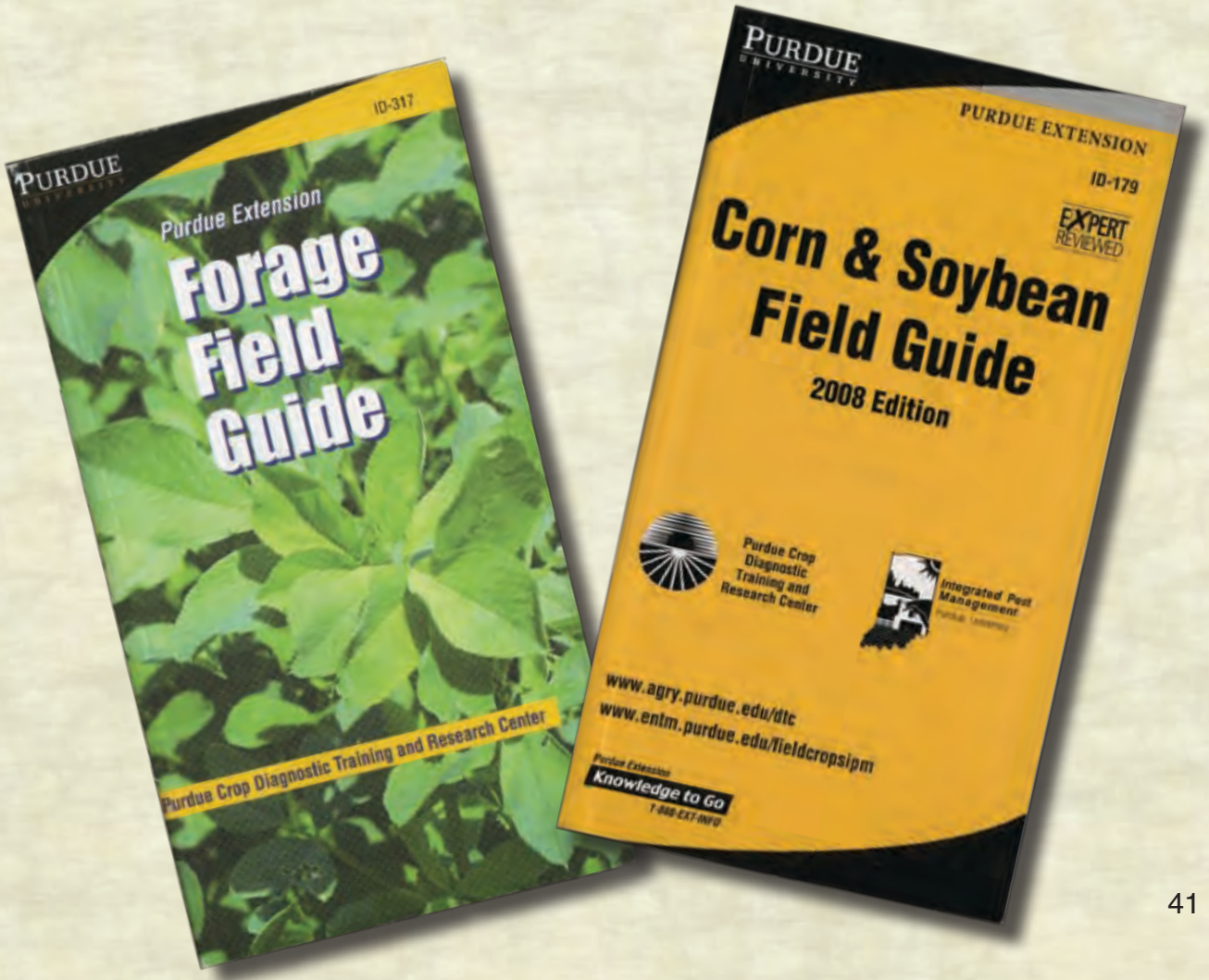
Typically, university specialists are interviewed by BEAD to determine the cost of nonchemical alternatives such as the selection of resistant hybrids or varieties and the use of mechanical pest control. University specialists base their estimations on the cost of equipment, cost of operators' time, fuel costs, and other costs incidental to each specific practice or tactic. When the analysts calculate the cost of alternatives, each is factored in proportion to the expected substitution for the product being restricted or removed. The resultant calculations estimate the cost associated with the proposed restrictions.

Source unknown.

Expert Opinion

The opinions of extension and research specialists, commodity group experts, and consultants often are solicited to provide "ground truthed" information. These data are necessary to establish a thorough assessment of pesticide benefits. Experts provide the best estimates when hard data needed by EPA is nonexistent. Information they provide can include the following:

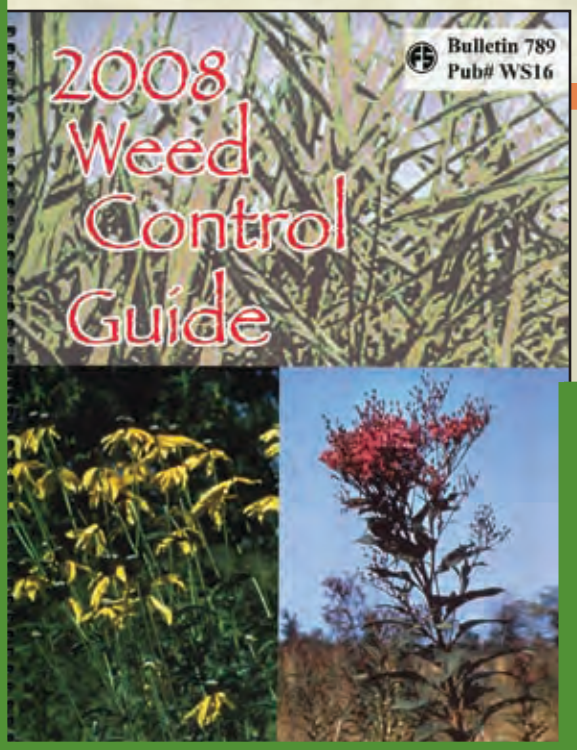
- Practices growers employ to produce a crop.
- Pests that significantly impact the production of the crop.
- Integrated pest management practices currently being used.
- Problems growers face with pest resistance to chemical and nonchemical control tactics.
- Secondary pest outbreaks (e.g., mites) occurring as a result of substituting alternative pesticides.



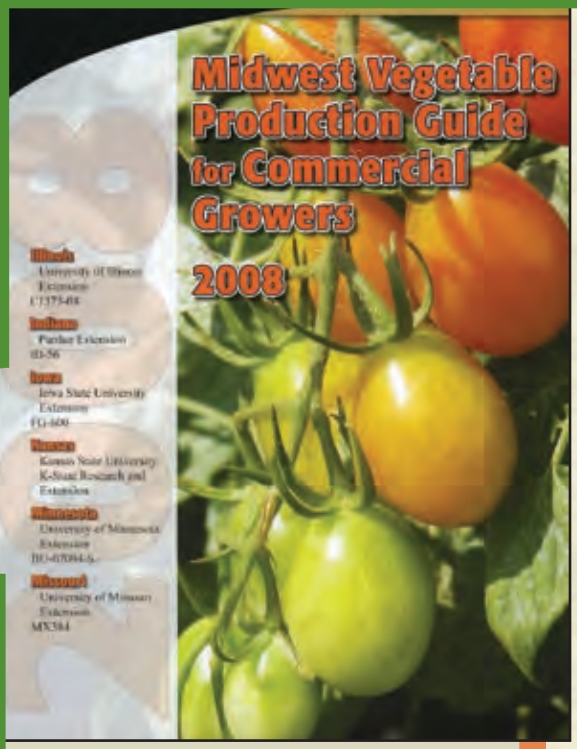
One source of expert opinion used routinely by EPA is USDA Crop Profiles. Hundreds of crop profiles have been developed for many U.S. commodities (http://www.ipmcenters.org). These documents are a compilation of expert opinions, published reports, unpublished data, and sometimes summaries from obscure data sources. EPA uses this information to help formulate decisions on cancellations, risk mitigation measures, and product label restrictions.

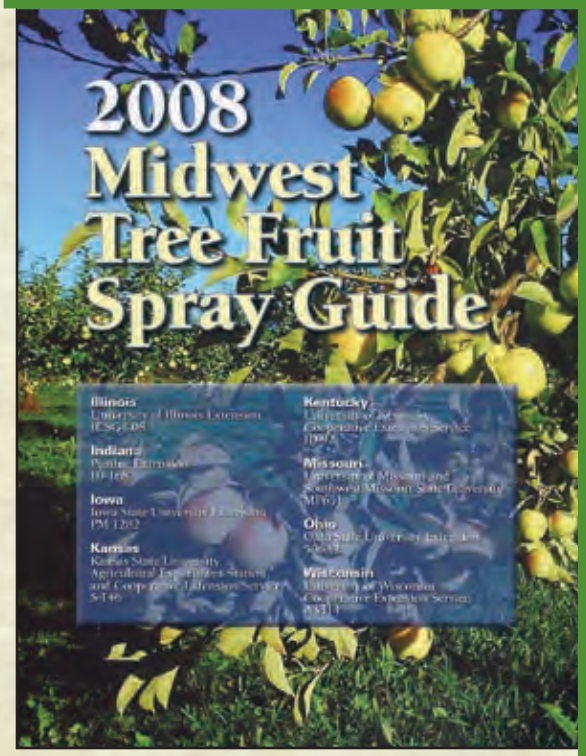
Other sources of expert opinion are published pest management recommendations for crops and livestock written by specialists at land grant universities. Extension and research specialists regularly interact with growers and have good secondhand knowledge of the pest problems most producers face. University scientists also test the various products in university field trials to become familiar with various pest management options. It is this experience that endows these specialists with useful knowledge and credibility. Their published recommendations inform EPA how state and regional recommendations differ.

The advantage of using information from experts is that EPA can gain practical knowledge about the grower, the crop, and pest management options. The experts provide a wealth of information — found nowhere else — on how a proposed risk mitigation might impact production practices.



Land grant university researchers and extension specialists provide valuable information to BEAD on recommended products,applicationtiming,andeffective chemical and nonchemical controls.





Go to http://www.btny.purdue.edu/PPP/ to read an example of a benefits assessment entitled *Elements of a Benefits Assessment Illustrated with Atrazine Use on Sorghum.*

Transmission lines pass through a federally protected area, providing power to millions of customers (bottom). Brush and trees must be kept clear of the lines to assure that service is not disrupted. BEAD must understand the various methods of clearing the right-of-way: manual removal of limbs (right), backpack application of herbicides (middle left), and herbicide applications with a helicopter (middle right). If a product is deemed to be a risk to wildlife, BEAD calculates the respective costs associated with various chemical and nonchemical control options to help guide EPA in selecting mitigation steps to protect wildlife but also protect the availability of electricity to consumers.

Conclusion

The Federal Insecticide, Fungicide, and Rodenticide Act requires that EPA consider both the risks posed by chemicals used and the benefits from their use in making pesticide registration decisions. EPA, in meeting this requirement, undergoes a deliberate and thoughtful process when assessing risks, including the following steps:

- Quantifying the risk.
- Determining whether the risk exceeds government established standards or policies.
- Proposing specific risk mitigation measures (e.g., product cancellation, rate reductions, elimination of use site) that could be used to reduce the risk to a manageable level.
- Calculating the cost and outcome of each risk mitigation option (benefit assessment).
- Discussing risk mitigation options with pesticide manufacturers, the user community, environmental and safety advocates, and the public, and deciding which risk mitigation option(s) to recommend.
- Publishing (in the Federal Register) the risks that EPA is concerned about and the actions they propose for alleviating or eliminating those risks.
- Finalizing the details of EPA decisions based on public comment.

Every technology, including pesticides, comes with some level of risk — small or large, measured or predicted. If the risks can be managed, EPA does so in a manner that is least disruptive to those who use pesticides in their homes, on their lawns, in their businesses, or on their farms.

The public can be informed about the benefits of pesticides and understand that their regulation by government is based on sound science. The entire spectrum of risks and benefits must be quantified and weighed objectively by all parties. Then — and only then — can informed pesticide use decisions be made.

EPA must understand how its actions might impact user groups and consumers. For instance, restricting a product (bottom) means that an applicator has to become certified to purchase it (above) and that growers must attend educational workshops as a prerequisite to maintaining their certification (below). EPA officials review an ag dealer's records of restricted-use pesticide sales (top right). All of these mitigation actions have costs which must be evaluated against the risk mitigation options being offered to solve a pesticide problem.

All photos on this page courtesy of Liz Maynard.

No-till pumpkins, Strategy herbicide applied after planting, hand weeded once.

No-till pumpkins, Strategy herbicide applied after planging, no hand weeding.

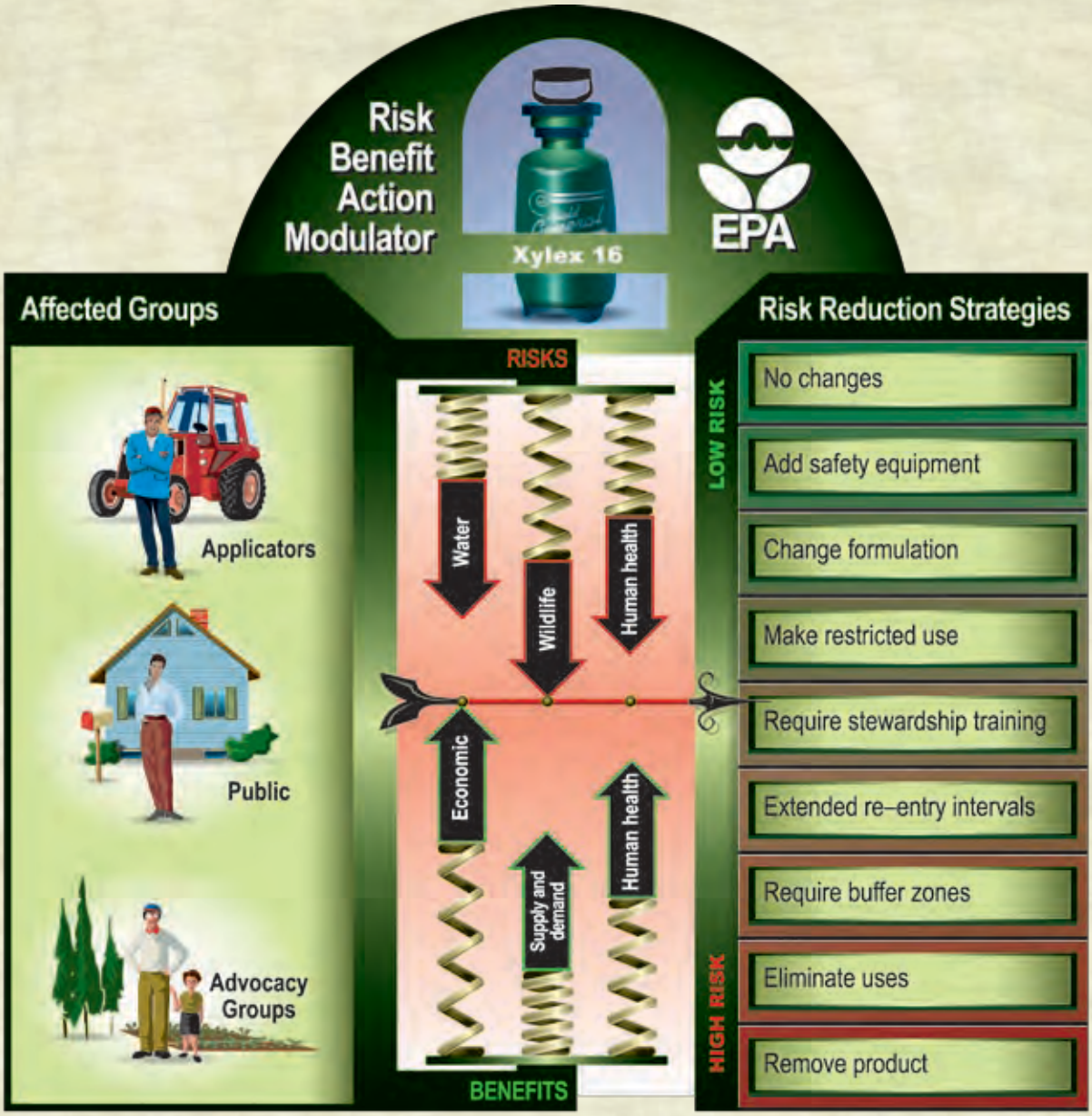
No-till pumpkins, Strategy herbicide applied after planting and Glyphosate applied between rows via hooded sprayers.

No-till pumpkins with Strategy applied after planting and Sandea herbicide applied two weeks later.

Conventional tillage pumpkins treated with the herbicide Strategy after planting, cultivated once.

No-till pumpkins grown without herbicides after planting, cultivation, or hand weeding.

As part of EPA's benefits assessment, BEAD officials examine a wide source of data and production practices to measure how a risk mitigation option can impact yield.



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Purdue Pesticide Programs has published several publications relating to pesticides. Go to http://www.btny.purdue.edu/PPP/ to view or order them.

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