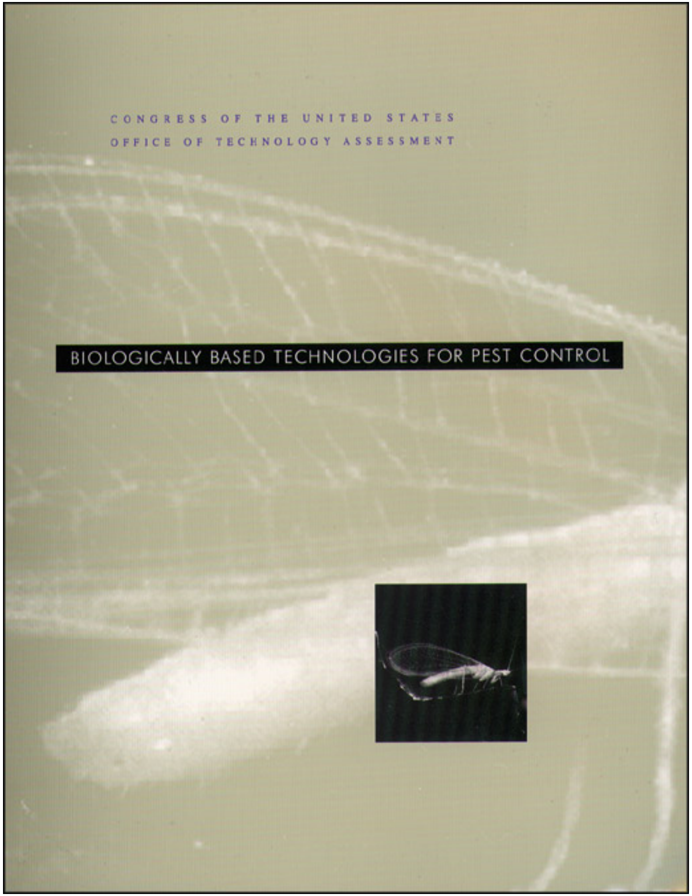
Biologically Based Technologies for Pest Control

September 1995

OTA-ENV-636

GPO stock #052-003-01449-1



Recommended Citation: U.S. Congress, Office of Technology Assessment, *Biologically Based Technologies for Pest Control*, OTA-ENV-636 (Washington, DC: U.S. Government Printing Office, September 1995).

Foreword

The way the nation manages pests is changing because of efforts to reduce the reliance on conventional pesticides. Driving this change is strong public opinion coupled with action by Congress and by federal and state agencies. At the same time, pest control needs are rising. Many important pests are now resistant to formerly effective chemical controls. And new pests continue to enter the country or spread to new locations where they threaten agriculture, native ecosystems, or human health.

The farmers, foresters, ranchers, and others who seek to prevent excessive pest damage are increasingly aware of the shortcomings of conventional pest control approaches. Their need for more pest control options is acute. Current hopes are that integrated pest management (IPM)—which uses alternative tools as well as pesticides—will provide the key to meeting this need while reducing the reliance on conventional pesticides. This assessment examines an array of the biologically based tools that underpin effective IPM.

The report covers technologies ranging from enhanced biological control of pests by their natural predators and parasites to commercial formulations of microbial pesticides. Today, such approaches have joined the mainstream. Biologically based technologies have penetrated most major applications of pest control and are the methods of choice for such widespread pests as the gypsy moth. They could be used more widely to help solve the nation's pressing need for pest control tools. What happens next will depend largely on federal policies and programs.

The federal government's role here is extensive through its involvement in research, technology transfer, plant protection, land management, and pesticide regulation. Annual expenditures for research and implementation of biologically based technologies for pest control exceed $200 million. But the system does not work as well as it might. A better match between national priorities and the portfolio of federally supported research would improve delivery of new pest control tools into the field. An improved regulatory system would streamline the regulatory process while more closely evaluating the occasional high risks. Finally, the relative roles of the private and public sectors warrant rethinking, because the private sector on its own will go only so far in supplying new biologically based tools.

Biologically Based Technologies for Pest Control was requested by three congressional committees: the House Committee on Agriculture; the House Merchant Marine and Fisheries Committee; and the House Committee on Natural Resources, Subcommittee on National Parks, Forests, and Public Lands.

We gratefully acknowledge the contributions of the Advisory Panel, authors of commissioned papers, workshop participants, and the many additional people who reviewed material for the report or provided valuable guidance. Their generous, timely, and in-depth assistance made this study possible. As with all OTA studies, the content of this report is the sole responsibility of OTA.

ROGER C. HERDMAN
Director

Advisory Panel

Katherine Reichelderfer Smith, ***Panel Chair***
Director, Policy Studies Program
Henry A. Wallace Institute for Alternative Agriculture
Greenbelt, MD

Paul A. Backman
Professor and Director
Biological Control Institute
Department of Plant Pathology
Auburn University
Auburn, AL

Ring T. Cardé
Professor
Department of Entomology
University of Massachusetts
Amherst, MA

Willard A. Dickerson
Plant Pest Administrator
North Carolina Department of Agriculture
Raleigh, NC

Roger C. Funk
Vice President of Human and Technical Resources
The Davey Tree Expert Company
Kent, OH

Harry J. Griffiths
Chairman
Entomological Services Inc.
Corona, CA

Judith A. Hansen
Superintendent
Cape May County Mosquito Extermination Commission
Cape May, NJ

Dennis L. Isaacson
Program Director
Noxious Weed Control Section
Oregon Department of Agriculture
Salem, OR

Deborah B. Jensen
Vice President, Conservation Science and Stewardship
The Nature Conservancy
Arlington, VA

Tobi L. Jones
Special Assistant to the Director
Department of Pesticide Regulation
California Environmental Protection Agency
Sacramento, CA

Peter M. Kareiva
Professor
Department of Zoology
University of Washington
Seattle, WA

Allen E. Knutson
Associate Professor and Extension Entomologist
Texas Agricultural Extension Service
Texas A&M University
College Station, TX

James B. Kramer
Family Farmer
Hugoton, KS

David W. Miller
Vice President for Research and Development
EcoScience Corporation
Northborough, MA

Timothy L. Nance
Crop Consultant
Gro Technics Consulting
Naples, FL

David O. TeBeest
Professor
Department of Plant Pathology
University of Arkansas
Fayetteville, AR

Jeffrey K. Waage
Director
International Institute of
Biological Control
Ascot, Berks, UK

Michael E. Wetzstein
Professor
Department of Agricultural and
Applied Economics
University of Georgia
Athens, GA

David M. Whitacre
Vice President, Development
Sandoz Agro, Inc.
Des Plaines, IL

EXECUTIVE BRANCH LIAISONS

Gary H. Johnston
National Park Service
U.S. Department of the Interior
Washington, DC

James Krysan[1]
Agricultural Research Service
U.S. Department of
Agriculture
Washington, DC

Anne E. Lindsay
Office of Pesticide Programs
U.S. Environmental Protection
Agency
Washington, DC

Thomas C. Roberts[2]
Bureau of Land Management
U.S. Department of the Interior
Washington, DC

Sally J. Rockey
Cooperative State Research,
Education, and Extension
Service
U.S. Department of
Agriculture
Washington, DC

Judith St. John[3]
Agricultural Research Service
U.S. Department of
Agriculture
Washington, DC

William S. Wallace
Animal and Plant Health
Inspection Service
U.S. Department of
Agriculture
Washington, DC

Lewis H. Waters[4]
Bureau of Land Management
U.S. Department of the Interior
Washington, DC

[1] Until February 1995.
[2] From April 1995.
[3] From June 1995.
[4] Until March 1995.

Project Staff

Clyde Behney
Assistant Director

Walter E. Parham[1]
Program Director
Food and Renwable Reources

Robert Niblock[2]
Program Director
Environment Program

Elizabeth A. Chornesky
Project Director and Senior Analyst

Cynthia M. Palmer[3]
Analyst

John Longbrake
Research Analyst

Christine Taverna[4]
Research Assistant

CONTRACTORS AND OTHER CONTRIBUTORS

John M. Houghton
Contractor & Workshop Organizer

Priscilla S. Taylor
Editor

Gary Jahn[5]
Analyst

William Westermeyer[6]
Senior Analyst

ADMINISTRATIVE STAFF

N. Ellis Lewis[1]
Office Administrator

Kathleen Beil[2]
Office Administrator

Nellie M. Hammond
Administrative Secretary

Kimberly Holmlund[2]
Administrative Secretary

Sharon Knarvik[2]
Administrative Secretary

Babette Polzer[4]
Contractor

Carolyn M. Swann[1]
PC Specialist

[1] Through February 1994.
[2] From March 1994.
[3] From January 1995.
[4] From May 1995.
[5] April through July 1994.
[6] February through May 1995.

Contents

Summary 1

CONTEXT AND SCOPE

Pest management in the United States is changing. Increasingly, the emphasis is on reducing the reliance on conventional pesticides.[1] Several factors make such change almost inevitable. Increased rigor of pesticide screening, economic forces within the pesticide industry, and continuing widespread public concern about the harmful effects of pesticides are contributing to reductions in the number of available pesticides and their allowed uses. At the same time, pest control needs are rising because of the increasing occurrence of pesticide resistance and newly emerging pest threats. The growing disparity between the available pesticides and the number of pests requiring control will generate needs for more and a greater variety of pest control tools and techniques.

This problem's significance has not been lost on national policymakers. Both Congress and the executive branch have responded in recent years with initiatives related to providing pest management tools and expanding the implementation of integrated pest management (IPM).[2] It is in this context that Congress has asked the Office of Technology Assessment (OTA) to examine the current and potential future role of biologically based technologies for pest control (BBTs). These technologies are grounded in an understanding of pest biology and have a relatively low probability of harmful effects on human health or the environment.[3]

The assessment covers the following five technologies:

- *Biological Control*—Suppression of pest populations by *natural enemies* (predators, parasites, competitors, diseases). Humans can exploit biological control by permanently establishing new natural enemies in a region (*classical biological control*), by repeatedly releasing natural enemies to temporarily boost their abundance (*augmentative biological con-*

[1] Conventional pesticides are chemical compounds in wide use that kill pests quickly. These chemicals currently pervade all aspects of pest management in the United States and support annual sales exceeding $8.4 billion.

[2] The term integrated pest management or IPM refers generally to pest management practices that seek to integrate all available tools for pest control—biological, chemical, cultural, and otherwise. See box 2-1 for more detailed discussion of IPM concepts and origins.

[3] Biologically based technologies are not, however, risk free. See text that follows and chapter 4 of the report for more detailed treatment of the potential risk issues.

trol), and by engaging in practices that enhance the survival and impacts of natural enemies, e.g., reducing pesticide use (*conservation of natural enemies*).

- *Microbial Pesticides*—Relatively stable formulations of microorganisms[4] that suppress pests by producing poisons, causing diseases, preventing establishment of other microorganisms, or other mechanisms. Microbial pesticides are designed for large-scale production and application. The most common one in use today is Bt, formulated from the bacterium *Bacillus thuringiensis.*
- *Pest Behavior-Modifying Chemicals*—Exploitation of the chemical cues used by living organisms to evoke specific behaviors from other organisms. Pheromones, chemicals that communicate information between members of a single species, currently are used to disrupt pest mating or to attract pests to pesticides.
- *Genetic Manipulation of Pest Populations*—Release into the pest population of individuals genetically altered to carry genes that interfere with the pest's reproduction or impact. The method in significant use today is release of sterile males in order to reduce pest reproduction.
- *Plant Immunization*—Enhancement of plant resistance to pests by means other than breeding or genetic engineering. Scientists can enhance disease resistance in some plants by exposing them to certain microbes or chemicals. Research is also under way to transfer certain predator- and disease-deterring fungi into plants.

These technologies represent an important segment of the alternatives to conventional pesticides. Federal expenditures on BBT research and implementation exceed $200 million annually. BBTs are a major part of the U.S. Department of Agriculture's (USDA) emphasis in pest control. BBTs also comprise a significant part of the "reduced-risk pesticides," "biopesticides," and "biorational pesticides" that are receiving a good deal of attention from the U.S. Environmental Protection Agency (EPA) and state agencies.[5,6]

CURRENT USE AND FUTURE POTENTIAL OF BBTS

Even though conventional pesticides dominate U.S. pest management practices, BBTs have penetrated most major applications and joined the mainstream. For example, at least 28 state departments of agriculture operate their own biological control programs. The USDA Animal and Plant Health Inspection Service (APHIS) as a matter of policy promotes biological control where possible in its programs. For control of gypsy moth, a major forest defoliator found in more than 11 states, the U.S. Forest Service relies primarily on a combination of microbial pesticides and natural enemies. Numerous farmers adjust pesticide selection or spray schedules in order to minimize harmful impacts on pests' natural enemies. Several major food processing companies, such as the Campbell Soup and Gerber Companies, have set low tolerances for residues of conventional pesticides in their products and are promoting "biointensive" IPM among farmers who supply their produce.[7] And a growing array of microbial pesticides is now available

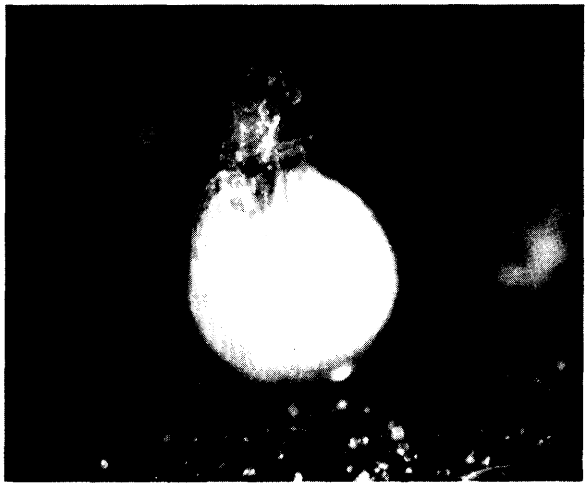
---

[4] Organisms too small to be seen by the naked eye, e.g., viruses, bacteria, fungi, protozoans, and certain nematodes (worm-like animals).

[5] "Reduced-risk," "biopesticide," and "biorational pesticide" have all been used with differing meanings, depending on the source, to encompass various combinations of microbial pesticides, botanical pesticides, chemicals that modify pest behavior or growth, augmentative releases of natural enemies, and conventional pesticides that have new chemistries. OTA will not use these terms because of their ambiguous meanings.

[6] Microbial pesticides and pheromone-based products made up 45 percent of all new pesticide active ingredients registered by EPA in 1994.

[7] "Biointensive" IPM refers to an IPM system that minimizes pesticide inputs and that uses BBTs for pest control in addition to other crop management practices.



Tiny Trichogramma *wasps, about the size of the head of a pin, are one of the most widely sold natural enemies for control of agricultural pests. The wasp shown here is laying its egg in the larger egg of a corn earworm* (Helicoverpa zea).

J. Clark, University of California Statewide IPM Project

to homeowners for control of landscape and household pests.

Current use of BBTs in the United States is patchy, however. The major share of BBT usage targets insect pests of arable agriculture, forestry, and aquatic environments. Use is growing for insect control in urban and suburban settings as new microbial and pheromone bait products become available for turf and household pests. In arable agriculture, BBTs have virtually no role at present for weed control; in contrast, classical biological control has been used to suppress a number of weeds of rangelands, pastures, and waterways. Few BBTs are yet available for control of plant pathogens, although a number of microbial products have been introduced in the past year for seed treatments and other applications.

Adoption of BBTs has occurred most frequently where conventional pesticides are: 1) unavailable because of pest resistance or small market size; 2) unacceptable, such as in environmentally sensitive habitats or where human contact is high; or 3) economically infeasible because the costs of pesticide use are high relative to the economic value of the resource, such as in rangeland management. In these situations the chief advantages of BBTs become significant assets—namely that they reduce reliance on conventional pesticides, are relatively benign in terms of impacts on human health and the environment, and, in the case of classical biological control, provide lasting, widespread, and low-cost suppression of individual pests.

Adoption is less common where effective and acceptable conventional pesticides exist and where numerous pests require simultaneous control. This is largely because BBTs do not usually compare favorably when measured against the performance standards set by conventional pesticides. Most have a narrower target range, act more slowly, provide a less efficient level of pest suppression, and, if sold commercially, have shorter field persistence and briefer shelf life. A biologically based method usually must be integrated with other control methods in order to provide an overall package of pest suppression. Reliance on BBTs thus requires a knowledgeable user and greater planning.

The limited availability of BBTs also contributes to their uneven adoption. At present, considerably more effort is focused on BBT research than on adaptation of the research findings to field use. BBTs are presently unavailable for many pest problems due to a lack of the necessary research on applications, development, or production and delivery technologies. Even when available, certain BBTs remain inaccessible to many end-users who lack sufficient training or appropriate sources of information.

ISSUES AND OPTIONS

Today's national policies on pest management and pesticide use reduction depend on the development of alternatives to conventional pesticides. Some underlying assumptions about the capacity of the public and private sectors to support expansion of BBT use may be overly optimistic. The federal government potentially exerts a significant influence on BBT adoption through its extensive and diverse roles in research, development, implementation, and regulation. Adjustment of federal policies and programs in several areas could greatly enhance the effectiveness of efforts to safely bring BBTs into wider use.

Balancing Risks and Regulations

In looking ahead to expanded BBT use, it is important to ask what risks the technologies will bring. BBTs generally rank favorably from the perspective of public health and environmental safety. Many are relatively host specific and impact primarily the targeted pests. Unlike conventional pesticides, most BBTs lack mammalian toxicity or pathogenicity. Moreover, the development of resistance by weed and insect pests appears significantly slower for most BBTs than for conventional pesticides.

Nevertheless, BBTs are not risk free. Some may pose certain hazards to human health and the environment. Some of these potential impacts are better documented than others. Allergic reactions to fungal pathogens and to insect eggs, scales, and waste in insectaries are the best-understood human health impacts. To scientists who study the ecology of natural systems, the most significant concerns relate to the impacts of biological control and microbial pesticides on native species and the functioning of ecosystems. A lack of monitoring for such effects during past decades means some of the most likely ecological effects, such as declines in native insect populations, have probably gone unnoticed.

The significance of any risk depends on how well the regulatory structure prevents the high impacts from occurring. Past regulatory review of biological control by APHIS has been inconsistent—too lax in some cases and too burdensome in others. The EPA has done a better job in its oversight of pheromones and microbial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act,[8] although the risks posed by upcoming microbial pesticides—some genetically engineered for enhanced target range and lethality—will pose new challenges for the agency. The Food and Drug Administration (FDA) needs to clarify its regulatory responsibilities for certain uses where BBT residues may become a component of food products.

Chapter 4 of the report presents options related to:

- improving APHIS's regulatory structure for biological control;
- strengthening innovations while retaining balance in EPA's regulation of microbial pesticides and pheromones;
- anticipating food safety issues and the expanded role of the FDA that will arise as uses of BBTs on harvested produce and in food preparation areas increase; and
- reducing the likelihood that pests will develop resistance to BBTs, specifically the microbial pesticide Bt.

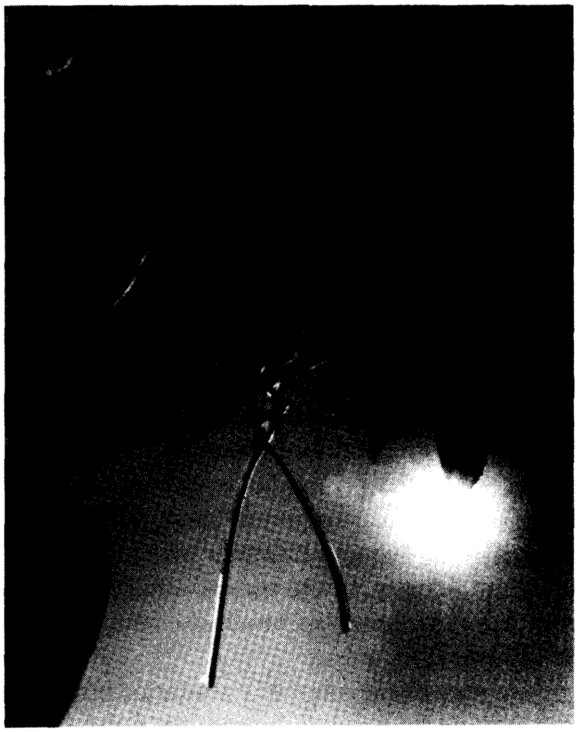
Improving the Pipeline from Research to Implementation

The federal government plays a large role in the research, development, and implementation of BBTs. At least 11 federal agencies are involved, most within the USDA. Despite the size of these efforts, BBTs do not move smoothly from research into on-the-ground solutions to pest problems.

Adjusting the Research Agenda

The gap between BBT research and its use—referred to by some long-time observers as the "valley of death"—was the single most prominent problem identified during the OTA assessment. It results, in part, from a lack of institutional coordination at several levels within and among federal departments. Ad hoc interactions among scientists working on BBTs from various government agencies and universities have generally been quite good. In contrast, problems frequently arise when cooperation between institutions is required. The results have included: a poor match between federally supported research and national priorities; abundant research that never makes it into the field; and

[8] Federal Insecticide, Fungicide, and Rodenticide Act (1947), as amended (7 U.S.C.A. 136, *et seq.*).



Pheromone dispensers are widely used in California peach orchards to suppress the oriental fruit moth (Grapholita molesta) *by disrupting the pest mating.*

J Clark, University of California Statewide IPM Project

national programs to control emerging pest threats that are beset by delays in the development of appropriate management tools.

The diffuse decision-making structures within the USDA research agencies (the Agricultural Research Service and Cooperative State Research, Education, and Extension Service) often fail to effectively focus research onto nationally identified needs. For example, although herbicides make up the single largest category (57 percent) of pesticide use in the United States today, only 15 percent of federal BBT research is directed toward control of weeds. The scattered portfolio of BBT research rarely addresses all of the research components necessary to enable the practical uses of a given BBT. No agency has consistently taken responsibility for conducting or funding the essential research to translate the work of scientists on BBTs into practicable applications for farmers and other users.

Educating and Influencing Users

Few farmers will readily embrace technologies that involve unfamiliar procedures and uncertain consequences. Many BBTs require a significant level of information to use properly, and farmers often lack clear-cut instructions or authoritative sources of advice on how to apply them.

The Cooperative Extension Service is the principal governmental provider of direct, hands-on services to growers and historically played a key role in farmers' pest control decisions. In most states, however, extension plays only a minimal role in educating farmers about BBTs; most extension agents have had little if any formal exposure to biologically based approaches. Moreover, the Cooperative Extension Service's role in shaping pest management practices is now secondary to that of the far more numerous private consultants in most regions (crop advisors, pest control advisors, and pesticide dealers and applicators). However, like extension agents, many private advisors are not well versed in BBTs or 1PM. Many are associated with conventional pesticide manufacturers or suppliers and are thus inclined to recommend chemically based technologies. According to representatives of major pesticide companies that also produce BBTs, even their own sales representatives do not adequately promote Bt or other biologically based products.

A number of other factors are thought to indirectly influence the pest control decisions of some users, although most lack adequate documentation. Produce standards set by USDA and our international trading partners, for example, sometimes require minimal pest damage, and may provide strong incentives for more frequent pesticide application. Certain production contracts and other arrangements with food processing companies may direct growers to use specific pest management practices.

Chapter 5 of the report presents specific options designed to address the shortcomings of the federal research system and the indirect influences of the federal government on the pest control decisions of farmers, These options include:

- better coordinating the USDA research agenda with national pest management needs identified by EPA and the land management agencies;
- modifying mechanisms of funding BBT research to better ensure the research makes it into field applications;
- providing an institutional structure for coordinating biological control activities at a national level in order to increase the potential for success and decrease the risks;
- addressing currently unmet research needs related to weeds and monitoring of BBT impacts and effectiveness;
- maintaining the necessary levels of technical expertise in IPM and taxonomy; and
- improving the flow of BBT information to users.

Commercial Considerations

Certain BBTs lend themselves to commercial production—specifically, natural enemies for augmentative release, microbial pesticides, and pheromone-based traps and mating disrupters. Almost all of the biologically based products sold to date have been for control of insect pests. Over the near term, BBTs are thus unlikely to capture a significant proportion of the conventional pesticide market, only about 29 percent of which is aimed at insect control.

Nevertheless, BBTs represent one of the fastest growing sectors of the pesticide industry. Biologically based products now comprise around 2 percent of the U.S. pest control market and 1 percent of the international market (approximately $120 million and $214 million in annual sales, respectively). The companies involved are diverse, ranging from small owner-operated companies to large multinational corporations. Almost all of the major agrochemical companies, such as Ciba-Geigy, have invested to some degree in BBTs, mostly microbial pesticides, although this involvement is somewhat tentative.

In general, these are financially troubled times for many of the companies specializing in the development or marketing of BBT products. Numerous small companies operate at a low profit margin, are vulnerable to unstable markets, and have difficulty investing in product discovery or formulation and production technologies. An important obstacle to wider use is that BBTs do not move easily through the extensive entrenched infrastructure currently in place for the research, development, and marketing of conventional pesticides.

According to a workshop of private sector experts convened by OTA, in the absence of any change to federal policies and programs, BBTs are likely to experience slow gains and will remain restricted primarily to high-value crops (e.g., fruits and vegetables) and other niche areas. Due to economic factors within the agrochemical industry, future conventional pesticides will tend to be broad-spectrum chemicals that fit poorly into IPM.

Congress could alter this scenario, however, by adjusting the many influences the federal government presently exerts on the BBT industry.

Options set out in chapter 6 of the report address:

- fashioning public-private partnerships in research;
- supporting development of voluntary product standards and the registration of BBTs; and
- enhancing market opportunities for BBTs.

RETHINKING PUBLIC AND PRIVATE SECTOR RESPONSIBILITIES

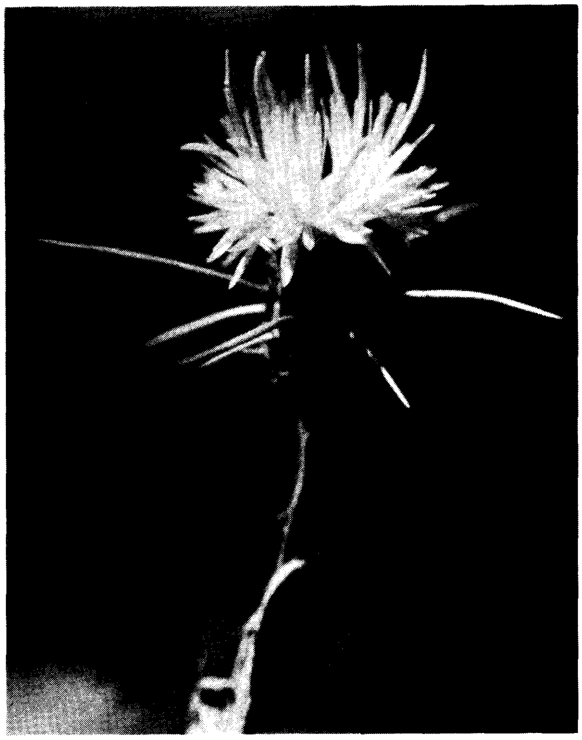
As Congress looks ahead to the future of pest management in the United States, two things are clear. First, the status quo cannot continue. Future approaches to pest management will require a greater diversity of tools and techniques. Over the near term, conventional pesticides will continue to play a key role, but the chemicals will need to be used more strategically in order to enhance natural control of pests and minimize the potential for pest resistance and other harmful impacts.

Second, adjustment of today's dominant paradigm based primarily on conventional pesticides will not come easily. Alternative technologies do not exist for certain pest problems. Many of those that do exist require a change in the way farmers and other users think about pest control and its goals and methods.

In the past, the federal government has shouldered a significant part of the research and development of BBTs. The investment is appropriate because the costs of *not* planning for the future will fall on the public at large; for example, in reduced agricultural productivity or degradation of native ecosystems because certain pests are uncontrollable, or in health and environmental impacts because more harmful pesticides are kept on the market. Moreover, the private sector cannot or is unlikely to become involved in certain key areas because no marketable product is involved (e.g., classical biological control and conservation of natural enemies).

Consideration of the current division of public and private responsibilities suggests some reapportioning is warranted, however. Most new biologically based products will address control of insect pests, with several other new products coming on line for plant pathogens. Weeds have been largely ignored by both the private and public sectors. Increased public investment might ensure that technical successes in weed control remain available to farmers, even if the profit margin is too low to sustain commercial interest.[9] Conversely, private sector innovations in the rearing of natural enemies would be more likely to occur if markets for these products were expanded and stabilized; for example, by contracting out production of natural enemies and sterile insects for the federal government's pest control programs.

The effectiveness of federal efforts to bring BBTs into widespread use could be improved. Better mechanisms are needed to ensure that the federal government's annual investment of more than $135 million into BBT research delivers solutions to national priorities. And certain goals and approaches of Cooperative Extension merit adjustment to ensure the greatest impact of the system's limited resources.



Many land managers expect biological control to be an important part of the solution to widespread pests on low-value lands—such as this yellow starthistle (Centaurea solstitialis), a noxious weed that is now spreading across western rangelands.

J. Asher, Bureau of Land Management

Scientists have been warning for years that meeting the nation's future needs in pest management will require new tools and techniques. While BBTs won't fulfill all of these needs, they could play a significant role. Safely bringing biologically based tools into the hands of farmers and other users will require certain changes in the operation of various federal agencies. The report that follows focuses on the underlying technical and institutional issues and identifies potential solutions.

[9] A good example is Collego, a very effective microbial pesticide for weed control that became a commercial failure because it could not sustain a large enough market,

The Context 2

The way pests are managed in the United States is changing. A growing emphasis is on reducing the reliance on conventional pesticides. Strong public opinion coupled with legislative and executive actions by state and federal governments is driving this change. Farmers, foresters, ranchers, homeowners, and others who seek to prevent excessive pest damage are increasingly aware of the shortcomings of many conventional approaches to pest control. Yet their need for effective methods is acute. Meeting this need with a diversity of pest control tools and techniques poses a significant challenge. It is in this context that Congress has asked the Office of Technology Assessment (OTA) to examine the current and potential future role of biologically based technologies (BBTs) in the nation's pest management practices.

The OTA assessment covers a group of technologies that are grounded in an understanding of pest biology and generally have the following characteristics that differentiate them from most conventional pesticides:[1]

- narrow spectrum of action, that is, affecting only one or a narrowly defined class of organisms;
- relatively low probability of harmful environmental impacts; and
- general lack of significant adverse impacts on human health.[2]

These BBTs for pest management are biological control, microbial pesticides, pest behavior-modifying chemicals, genetic manipulation of pest populations, and plant immunization (box 2-1). The tools raise a unified set of technical and policy issues. BBTs comprise a significant part of the "reduced-risk pesticides," "biopesticides," and "biorational pesticides" that are receiving a good deal of attention in federal and state policy initiatives.[3]

OTA's assessment takes a critical look at these BBTs. This chapter describes past, current,

[1] Conventional pesticides are chemical compounds in wide use that kill pests quickly (267).

[2] The technologies are not, however, risk free. See chapter 4 for a detailed analysis of the major risk issues.

[3] "Reduced-risk," "biopesticide," and "biorational pesticide" have all been used with differing meanings, depending on the source, to encompass various combinations of microbial pesticides, botanical pesticides, chemicals that modify pest behavior or growth, augmentative releases of natural enemies, and conventional pesticides having new chemistries. This report does not use these terms because of this ambiguity.

CHAPTER 2 FINDINGS

- The need for new pest control methods and systems will grow in the future. The number of available conventional pesticides is declining, especially for minor uses, because of regulatory constraints, economic forces, and continuing public concern. At the same time, the number of pests requiring new control methods is increasing as more pests become resistant to pesticides and new pest threats emerge.
- Congress and the executive branch have sought to address the need for pest control in the future by pressing to diversify available pest control technologies and to expand the use of integrated pest management. Biologically based technologies underpin many of these efforts. An assessment of these technologies provides a "bottom-up" view of whether and how effectively the national infrastructure for research, development, and implementation can deliver on this agenda.

and potential future trends in U.S. pest management. Chapter 3 examines the effectiveness of BBTs and their future potential. The remainder of the report identifies the many activities of the federal government that affect the availability and use of BBTs (table 2-1). The potential risks of BBTs and how these are addressed through federal regulation are covered in chapter 4. Chapter 5 focuses on the public-sector roles in the research, development, and implementation of BBTs. And chapter 6 looks at BBTs from the vantage of private-sector companies involved in the production of pest control products.

AN INTRODUCTION TO PEST MANAGEMENT

Throughout history, humans have sought to eliminate or reduce the abundance of living organisms that cause problems. The "pests" include animals, plants, insects, and microbes[4] that reduce agricultural productivity, damage forests and gardens, infest human dwellings, spread disease, foul waterways, and have numerous other deleterious effects. Left unimpeded, their economic impacts in the United States would amount to billions of dollars annually. The Weed Science Society of America has estimated that annual U.S. losses to agriculture if weeds were uncontrolled would exceed $19.6 billion—almost five times the costs under current control regimes (32). The environmental impact of pests can be equally profound: European gypsy moth (*Lymantria dispar*) now infests some 255 million acres in the United States; if the pest was left untreated, its annual defoliation of trees could fundamentally change the composition of hardwood forests (385).

Although what constitutes a "pest" is highly subjective, needs for pest control identified by U.S. consumers, agribusiness, and industry now support a multibillion-dollar infrastructure of pesticide production, pest control companies, and consultants on pest control methods. U.S. expenditures for pesticides exceeded $8.4 billion in 1993, approximately one-third of the world market (table 2-2) (399)

Pest control is quite literally a science of the specific. In agriculture, each pest and crop combination represents a different problem that can further vary with the specific location and time of year. There are literally thousands of (crop × pest × site) combinations, each differing in its potential impact and in the way that it is most successfully and appropriately controlled. Pests in other environments, such as parks, suburban landscapes, and urban dwellings, pose a similarly complex array of management needs.

[4] Microbes include viruses, bacteria, and other organisms that are too small to be seen by the human eye. Many microbes that are pests cause animal or plant diseases.

BOX 2-1: Scope of the OTA Assessment

Pest Control Technologies Within the Scope of the OTA Assessment

- *Biological Control:* the use of living organisms to control pests (includes predators, parasites, competitors, pathogens,[1] and genetic engineering applied to this approach)
- *Microbial Pesticides:* formulations of live or killed bacteria, viruses, fungi, and other microbes that are repeatedly applied to suppress pest populations (includes Bt formulated from *Bacillus thuringiensis*, nuclear polyhedrosis viruses (NPVs), and genetic engineering applied to this approach)
- *Pest Behavior-Modifying Chemicals:* the use of chemicals to trap pests or to suppress pest mating (includes pheromones)
- *Genetic Manipulations of Pest Populations:* genetic modification of pests to suppress their reproduction or impacts (includes releases of sterile insects)
- *Plant Immunization:* non-genetic changes to crop or landscape plants that deter insect pests or reduce susceptibility to diseases (includes induced immunity and endophytes)

Pest Control Technologies Outside the Scope of the OTA Assessment

- *Chemical Pesticides:* chemicals that kill pests (inorganic substances like arsenic-containing salts; synthetic organic compounds like organophosphates, carbamates, and triazines; insect growth regulators that mimic insect hormones; and synthesized and naturally occurring botanical pesticides)
- *Physical, Mechanical, and Cultural Controls:* nonchemical pest control by methods such as crop rotation, tillage, mechanical removal of pests (e.g., by hand or vacuums), and heat treatment
- *Plant Breeding and Enhanced Resistance to Pests:* development of plant cultivars that are less susceptible to pest damage either through plant breeding or genetic engineering

[1] Pathogens can be used as biological control agents if they are released and then spread on their own. They can also be formulated into microbial pesticides that are applied repeatedly.

NOTE: Box 2-5 at the end of this chapter describes in detail certain subcategories of the technologies outside the scope of this assessment that are receiving increased attention for the same reasons as BBTs.

SOURCE: Office of Technology Assessment, 1995.

The Role of Conventional Pesticides

Conventional pesticides greatly simplify control of these diverse problems. Most conventional pesticides are broad spectrum—providing control for numerous pests simultaneously. They are relatively easy to use, because most chemicals are applied with similar methods and allow a fair margin of error in application technique. Perhaps most important, conventional pesticides are effective at killing pests and are relatively inexpensive.

Widespread use of conventional pesticides, however, is a recent development. Prior to the 1940s, U.S. farmers relied primarily on nonchemical methods such as crop rotation, tillage, and hand removal to minimize pest impacts (433). A number of inorganic salts (e.g., copper sulfate, lime sulfur, and lead arsenate) and botanically derived compounds (e.g., pyrethroids and rotenone) had come into use in the late 1800s and early 1900s. But chemical pest control did not truly burgeon until after World War II, with the increasing availability and use of DDT and other chlorinated hydrocarbon, organophosphate, and carbamate pesticides. From the 1950s to the 1980s, use of conventional pesticides in the United States grew dramatically, doubling between 1964 and 1978 (figure 2-1) (399). The increased use paralleled a growing mechanization of farming practices and a drop in the number of people engaged in farming. An example of how great the change has been can be seen in the

TABLE 2-1: Roles of Federal Agencies Related to Biologically Based Pest Control and Location of Discussion in This Report

Agency	Regulates production or use of BBTs	Conducts research	Funds outside research	Implements technology in pest control programs	Educates end users	Transfers technology to the private sector
	(Chapter 4)	(Chapter 5)	(Chapter 5)	(Chapter 5)	(Chapter 5)	(Chapter 6)
USDA Agricultural Research Service (ARS)		X				X
USDA Cooperative State Research, Education, and Extension Service (CSREES)[a]		X	X		X	
USDA Forest Service		X		X		
USDA Animal and Plant Health Inspection Service (APHIS)	X	X[b]	X	X[c]	X[c]	
U.S. Environmental Protection Agency (EPA)	X	X	X		X	
Food and Drug Administration (FDA)	X					
Management agencies of the U.S. Department of the Interior (DoI)[d]		X	X[e]	X		

[a] CSREES is a newly formed agency that incorporates prior functions of the Extension Service and the Cooperative State Research Service

[b] APHIS conducts "methods development" research, which translates the findings from more fundamental research into on-the-ground applications.

[c] The National Biological Control Institute produces a variety of public education materials and has provided about $1.5 million in grants for education and implementation of biological control over the past four years.

[d] The National Park Service, the Bureau of Land Management, the Bureau of Reclamation, and the U.S. Fish and Wildlife Service.

[e] Mostly via "pass-through" funds to the ARS for research on biological control of rangeland and other weeds.

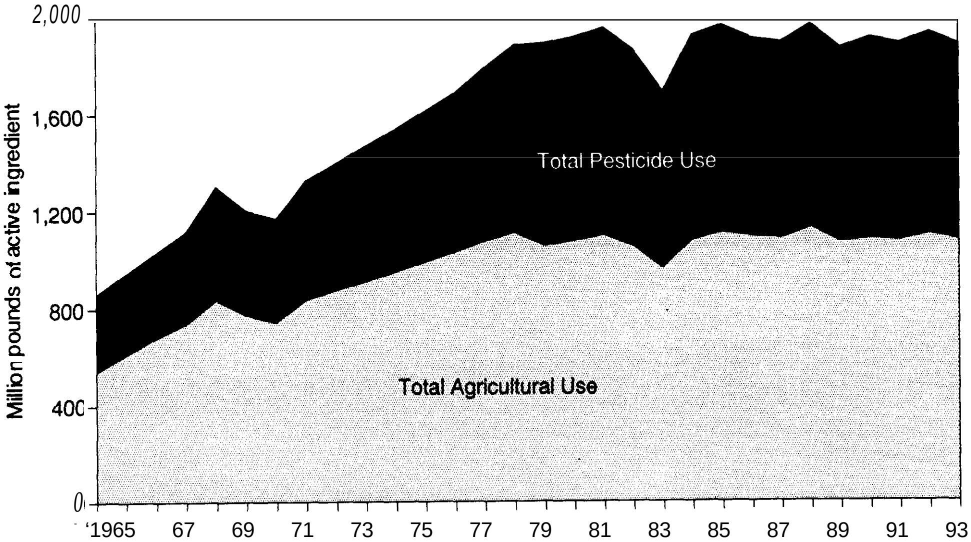
SOURCE: U.S. Congress, Office of Technology Assessment, 1995.

TABLE 2-2: User Expenditures for Pesticides in the U.S. by Sector, 1993

Sector	Total in millions $	Percentage
Agriculture	6,130	72.2
Individuals/Communities/Government	1,136	13.4
Home and Garden	1,218	14.4
Total	$8,484	100.0%

SOURCE: U.S. Environmental Protection Agency, *Pesticide Industry Sales and Usage: 1992 and 1993 Market Estimates,* A.L. Aspelin, 733-K-94-001 (Washington, DC: June 1994).

FIGURE 2-1: Growth in U.S. Conventional Pesticide Use, 1964 to 1993



SOURCE: U.S. Environmental Protection Agency, *Pesticide Industry Sales and Usage: 1992 and 1993 Market Estimates*, A.L. Aspelin, 733-K-94-001 (Washington, DC: June 1994).

NOTE: Usage level is reported in millions of pounds of "active ingredient." The active ingredient is the component of a commercial product that has pesticidal properties. Newer pesticides tend to have active ingredients that are more potent and can be applied at a lower dosage level. Consequently, the leveling-off in the 1980s in the figure does not necessarily translate into a stabilization of pesticide use according to numbers of acres treated, numbers of products applied, frequency of pesticide application, or other relevant measures.

figures for cultivation of corn, cotton, and wheat: herbicides were applied to only 10 percent of acreage in 1952, but climbed to 90 to 95 percent of acreage by 1980 (378).

Conventional pesticides now pervade all aspects of pest management in the United States. More than 900,000 U.S. farms use pesticides (399). In 1993, pesticides were applied to more than 80 percent of the acreage planted in corn, cotton, soybeans, and potatoes (377). Between 35,000 and 40,000 commercial pest control companies and 351,600 certified commercial applicators apply pesticides to building, home, and landscape pests (399). Each year such commercial operations treat an estimated 20 percent of the 6.1 million U.S. households for indoor pests such as cockroaches (424). Most of these homes (85 percent) also contain pesticidal products, the majority of which (70 percent) had been used within the past year, according to the 1990 National Home and Garden Pesticide Use Survey commissioned by the Environmental Protection Agency (EPA) (424).[5]

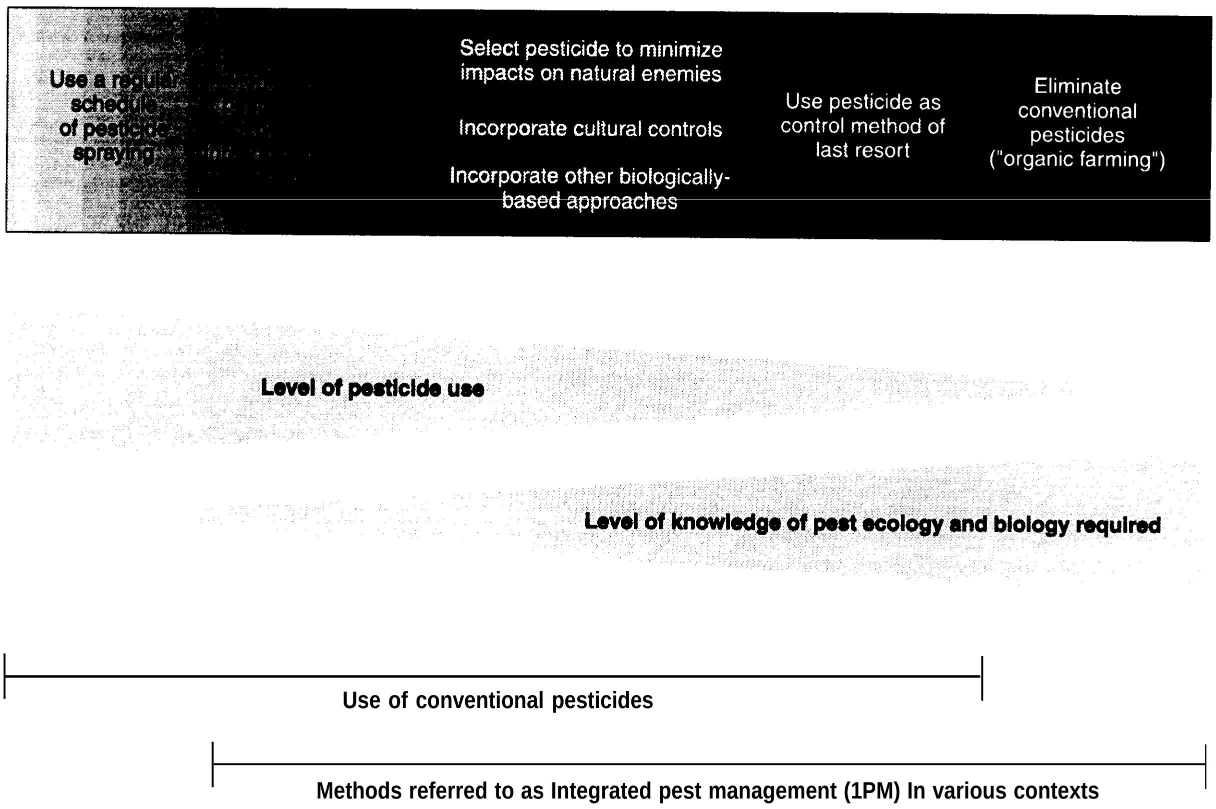
■ The Spectrum of Approaches to Pest Control in Practice Today

Today, the extent to which people seeking to control pests rely on conventional pesticides varies (figure 2-2). Some depend on a number of other pest control tools as well, including cultural practices, use of pest-resistant crop cultivars, and the BBTs that are the subject of this assessment.

At one end of the spectrum are those who use only conventional pesticides, often applying them as a prophylactic measure according to some regular, predetermined spray schedule. At the other end are those who control pests by a combination of numerous non-chemical tools, and use conventional pesticides either as the last method of choice or not at all.

5 A total of 2,078 households in 29 states were surveyed, with results statistically extrapolated to a target population of 84,573 households.

FIGURE 2-2: Approaches to Pest Control in Practice Today



SOURCE: Office of Technology Assessment, 1995,

The gradation from one end of the spectrum to the other entails increased targeting of pesticide application and incorporation of a greater number of pest control tools and techniques. Diversification of pest control approaches beyond the regularly scheduled use of conventional pesticides requires planning as well as a greater understanding of pest biology and ecology and the specific effects of each control technology. This thoughtful incorporation of various control methods into an overall pest suppression plan has generally been referred to as integrated pest management (IPM)[6] (box 2-2). Note that a diverse range of approaches have all been referred to as 1PM by various sources (figure 2-2).

Most users currently fall toward the left and center of figure 2-2. For example, according to a 1993 survey of pest control professionals commissioned by Sandoz Agro and conducted by the Gallup Organization? only 32 percent reported having ever used 1PM, with rates being highest among pest control operators (85 percent) and lowest among farmers (19 percent) (302).[7] A more precise survey by the Economic Research Service of the U.S. Department of Agriculture (USDA) showed that acreage under 1PM varied

6 The term IPM has been used with a good deal more precision in the scientific and technical literature on pest management, although various authors use it to mean different things, For a thoughtful analysis of how 1PM concepts and definitions have evolved since the 1950s, see ref. 44.

7 Survey was of 2,361 professional lawn care operators, golf course managers, pest control operators, mosquito district managers, roadside vegetation managers, small-animal veterinarians, and farmers, Note that the meaning of 1PM was not specified in the survey. Results thus indicate respondents' perceptions of whether they have ever used IPM, Some using varied techniques or monitoring pest levels may not refer to their management practices as 1PM.

BOX 2-2: What Is Integrated Pest Management?

The concept of integrated pest management (IPM) originated in the late 1950s and 1960s, when entomologists at the University of California began to detect failures of pest control as a result of overuse of insecticides. Some pests became difficult to control because they developed resistance to formerly effective chemicals. And populations of certain other insects that had previously not been considered pests surged to outbreak levels. These "secondary pest outbreaks" were attributed to the harmful effects of pesticides on natural enemies—the insect predators and parasites that occurred naturally in fields and otherwise kept secondary pests in check through biological control.

IPM developed as a way to avoid the problems of insecticide resistance and secondary pest outbreaks by integrating biological and chemical control. Its cornerstones were:

- "Natural" control should be maximized, enhanced, and relied on whenever possible. Natural control results from factors both within (i.e., biological control) and outside (i.e., weather) human influence;
- Pesticides should be used only when the abundance of a pest reaches a threshold level that causes economically significant damage. Such restraint minimizes the harmful effects of pesticides on natural enemies.

Since the 1960s, ideas about IPM have expanded and changed. Additional pest management tools have come into wider use, and IPM concepts have been applied to other types of pests with a resulting proliferation of related terms like "integrated weed management" and "integrated disease management."

Practitioners now often use IPM to refer more generally to an approach that integrates all available tools for pest control—biological, chemical, cultural, and others. The idea that chemicals should be applied only when a pest is detected at an (economically or aesthetically) significant level of abundance has been retained. What is lost in many current applications, however, is the concept that biological control should form one of the foundations of IPM. One consequence, according to some critics, is that IPM as practiced today too often becomes integrated *pesticide* management instead.

Right now the difference between these interpretations of IPM may make very little difference in practice. Many users would be hard pressed to base a pest control system on natural control because they have access to little of the necessary information and relatively few alternatives to conventional pesticides.

The distinction does, however, make a great deal of difference in another regard. The two interpretations lead to very different conclusions regarding the types of research that must underpin IPM. A core reliance on natural control requires emphasizing research into the ecology of pest systems. It also requires giving greater weight to pest control methods that are compatible with biological control.

SOURCES: Office of Technology Assessment, 1995, and J.R. Cate and M.K. Hinckle, *Integrated Pest Management: The Path of a Paradigm,* National Audubon Society (Alexandria, VA: Weldon Printing Inc., July 1994).

TABLE 2-3: Use of Integrated Pest Management on U.S. Crops

	Do not use IPM	Monitor levels of pests and use pesticides when levels exceed set thresholds, but use no additional pest control tactics	Use additional pest control tactics in an IPM program	Do not use pesticides
		Percent of acres		
Fruits and nuts	42	6	44	8
Vegetables				
Insect control	38	9	43	10
Weed control	60	2	33	6
Disease control	29	12	29	30
Corn				
Insect control	15	52	22	11
Weed control	45	2	51	2
Soybean				
Weed control	39	2	57	2
Fall Potatoes				
Insect control	25	3	69	3
Weed control	30	1	65	5
Disease control	14	5	58	22

SOURCE: Adapted from U.S. Department of Agriculture, Economic Research Service, *Adoption of Integrated Pest Management in U.S. Agriculture,* prepared by A. Vandeman et al., AIB-707 (Washington, DC: September 1994).
NOTE: Survey was conducted during 1991 and 1992 and covered from 70 to 100 percent of total acreage per crop in the United States.

with type of crop and pest, but that an absence of pesticide use is rare (table 2-3) (377).

FORCES SHAPING THE FUTURE OF U.S. PEST MANAGEMENT

Because conventional pesticides are easy to use and effective, they are the sole or primary tool used by most practitioners today to control the number and impact of pests. But constraints are being imposed on the nation's pest management practices. Some—such as the increased rigor of pesticide screening prior to registration, economic forces within the industry, and continuing widespread public concern—will tend to limit growth in the number of available pesticides (especially insecticides and fungicides) and their use. At the same time, increasing resistance to pesticides and newly emerging pest threats will cause the need for pest control to rise. The resulting gap between pests requiring control and available pesticides will generate the need for more and a greater variety of pest control tools and techniques—essentially a centerward shift of those toward the left end of the spectrum in figure 2-2.

That such needs already exist is evident from EPA data on exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the authorizing statute under which EPA regulates registration and use of pesticides.[8] These exemptions are granted under emergency circumstances to allow use of a pesticide without the normal registration requirements that ensure safety to human health and the environment. According to EPA, at least 200 exemptions are being approved each year (164,19). Resistance to pesticides, cancellation of a pesticide previously in use, and emergence of new pests are the most

[8] Such exemptions are authorized under section 18 of FIFRA (1947) as amended (7 U.S.C.A. 136, *et seq.*) (105).

common reasons for exemptions. The level of use of these exempted chemicals is uncertain. Nevertheless, one consequence of the growing backlog of pest control needs is circumvention of the standard criteria that ensure safe pesticide use.

Regulation of Conventional Pesticides

More rigorous federal regulation of conventional pesticides is directly and indirectly causing certain pesticides to be withdrawn from U.S. markets. These losses are unlikely to be completely offset by the new chemicals coming on line.

Over the past few decades, the Congress has set a clear national policy, through amendments in 1972 and 1988 to FIFRA, to phase out conventional pesticides that are harmful to human health or the environment. These amendments required reevaluation and reregistration of pesticides already on the market to bring them into line with current testing requirements.

A significant number of pesticides are expected to disappear from U.S. markets as a result of the reregistration requirements. In the early 1990s, companies elected not to reregister an estimated 25,000 of the 45,000 products on the market (401). The total number that will ultimately disappear is unknown, as are the specific reasons why companies decide not to reregister each product. According to EPA, 19,000 of the dropped registrations were for older products that had not been produced in the three previous years (401). With respect to the remaining 6,000 products, companies may not have sought the reregistration of some that would not meet the more scrupulous registration criteria. But a more common reason may be that manufacturers have determined that the potential market size for certain products does not justify the costs of reregistration.

Experts expect that many pesticides falling into the last category are those that serve relatively small markets, the "minor use" pesticides, for use in crops like fruits, vegetables, and nuts where the potential market size per registration is quite small, especially when compared with markets for major crops like corn, wheat, soy, and cotton. Corn, for example, was grown on about 79 million U.S. acres in 1992; in contrast, the acres devoted to all vegetables combined amounted to only 4.6 million (379). Industry experts now anticipate that manufacturers will drop the registrations on 4,000 pesticides currently labeled for only minor uses; about 1,000 of these have significant uses (335).

Congress has sought to redress these economic disincentives for registration of minor use pesticides in a number of ways. The IR-4 program,[9] administered by USDA through the Cooperative State Research, Education, and Extension Service (CSREES) and funded at $5.7 million in fiscal year 1995, supports the development of data for minor use registrations. IR-4 works in conjunction with the Agricultural Research Service (ARS) minor use program, funded at $2.1 million for 1995. A number of bills have been introduced with strong bipartisan support in the 103d and 104th Congresses[10] to reduce the costs of minor use registrations—most recently in H.R. 1627 introduced May 12, 1995.

Removal of the economic constraints will not completely counter the effects of reregistration on the number of available pesticide products. The active ingredients and products that have been reregistered first are those that require the least new data on environmental and health risks. Older chemicals long on the market generally require more data to support reregistration and will be the last to be reregistered. Far less is known about the potential risks of these chemicals. As the chemicals come under review, additional products may have uses restricted or be removed from the market due to risk considerations, not economic forces.

Costs of pesticide research and development have risen steadily in the recent past. These

[9] The Interregional Research Project, No. 4 was begun in 1963 by directors of the State Agricultural Experiment Stations.
[10] Related bills include H.R. 967 and S. 985 in the 103d Congress and H.R. 1352, H.R. 1627, and S. 794 in the 104th Congress.

costs, coupled with the more careful scrutiny of potential impacts, have slowed the rate at which new pesticide products have been marketed (150) (see chapter 6). Moreover, companies are increasingly seeking to position new products in major, not minor markets. The effects of this trend on the number of pesticides available in the United States are uncertain, but the development of new pesticides is unlikely to compensate for the losses of current pesticides through the reregistration process, especially of those for minor use markets.

Development of pesticide replacements may also be impeded by the rate of the pesticide reregistration process. EPA has been widely criticized for its slow action on reregistration, prompting repeated prodding by Congress through oversight hearings (336). The delays allow continued marketing of older pesticides, potentially creating a deterrent to the development of new, lower-risk alternatives (190).

Public Concern

Assessment of the benefits and risks of conventional pesticides is beyond the scope of this report. The use of pesticides in the United States over the past several decades has obviously had considerable benefits to agriculture and public health, but has also caused harm. The body of information addressing pesticide impacts on human health and the environment is complex and large (202). Certainly, humans and wildlife exposed to certain pesticides under specific conditions have shown short- and long-term adverse impacts ranging from poisoning to sterility and cancer (55,202). The thousands of chemical formulations in use today vary greatly in their modes of action, toxicological profiles, and other significant features. Effects of any given pesticide depend not only on such specific characteristics, but also on the ways in which it is used, the environment into which it is released, and the duration and level of exposure of humans and other living organisms.

Despite this complexity, it is clear that the public now has substantial concern about exposure to pesticides. This concern is driven as much by perceptions about how much we don't know about pesticide impacts as by what we do. It is compounded by the frequent reports of unanticipated exposure from groundwater contamination, food residues, and improper pesticide use and storage. The resulting public sentiment can be powerful, especially if the level of uncertainty is great, even in the absence of technical evidence that an unambiguous risk to public health or the environment exists (e.g., box 2-3).

The level of media coverage suggests that public interest is constant and intense. OTA's search of six major newspapers across the country showed that they run, on average, more than three related articles a week, providing a constant chronicle of public exposure, health impacts, and unintended contamination of food and the environment.[11] Not surprisingly, the media focus on events of greatest public interest, such as recently reported widespread contamination of tap water by agricultural herbicides in the Midwest (199) and the potential effects of pesticides on reproduction in humans and wildlife (323).

Recent surveys consistently show that the public is genuinely concerned about pesticide residues in food (421). For example, a 1990 survey of 1,900 U.S. households by researchers from the USDA Economic Research Service showed that the majority were concerned about pesticide safety and food residues (206). More than half of the respondents expressed the belief that foods were unsafe when grown using pesticides at approved levels. The majority also did not believe that the health risks of pesticide use are well understood and agreed that pesticides should not be used on food crops because the risks exceed the benefits (206).

---

[11] OTA's search covered the years 1992, 1993, and 1994 for the following newspapers: *New York Times, St. Louis Post-Dispatch, Washington Post, Chicago Tribune, Houston Post,* and *Los Angeles Times*. Search criteria covered various types of pesticides and health or environmental impacts.

BOX 2-3: Alar: A Case Study on the Influence of Public Opinion

In early 1989, the television show *60 Minutes* and other media sources focused public attention on a report from the Natural Resources Defense Council (NRDC) charging that children were particularly at risk from exposure to residues of cancer-causing agents in their food. The NRDC report identified as an example Alar, a chemical widely used in apple production to enhance fruit color and to keep fruit from falling off trees. Demand for fresh apples plummeted and concern about the presence of other chemical residues on produce increased. Losses to apple growers caused by diminished sales exceeded $100 million that spring.

The NRDC report stated that Alar is a potent carcinogen and that children face particular risk. The scientific information underlying this assertion was inconclusive, however. In 1973, scientists in Omaha, Nebraska, had found evidence that unsymmetrical dimethyl hydrazine (UDMH), a chemical comprising 1 percent of Alar, was carcinogenic to mice at very high doses. EPA declared these results “unscientific” because the mice received excessively high doses of the chemical. Subsequent tests found effects on mice only at extremely high doses and no effects on rats at any level of exposure. Neither U.S. nor British regulators found sufficient justification in the research to ban the use of Alar.

Alar, like other plant growth regulators, is regulated as a pesticide by EPA. The strong public outcry against Alar following the media coverage forced EPA to reassess its findings. The agency subsequently determined that the risks of Alar were too high and pulled the chemical from the market.

Uncertainty was the real issue underlying the debate about Alar. Because there was no proven risk, government regulators and industry assumed that the chemical was safe. In contrast, the possibility that Alar might cause cancer led NRDC and parent groups to call for the chemical’s prohibition—especially in light of the high consumption of apples and apple products by infants and children and the uncertainties regarding long-term effects of exposure to carcinogens early in life.

SOURCES: E. Marshall, “A is for Apple, Alar, and . . . Alarmist?” *Science* 254(5028):20–4, Oct. 4, 1991; J.D. Rosen, “Much Ado About Alar,” *Issues in Science and Technology* 6:85, Fall 1990; D. Warner, “The Food Industry Takes the Offensive,” *Nation’s Business* 79(7):42–45, July 1991; and F.E. Young, “Weighing Food Safety Risks,” *FDA Consumer* 23(7):8–14, September 1989.

Concern about pesticide food safety issues gained new impetus in 1993 with the release of the National Research Council’s highly publicized report on “Pesticides in the Diets of Infants and Children.” The study concluded that children and infants may be uniquely susceptible to the toxic effects of pesticides and are at greater risk than adults from some chemicals. Past risk assessments may not always have adequately protected infants and children because they did not explicitly account for these differing impacts, as well as for differences between adults and children in diet and other factors—and hence in pesticide exposure levels (241).

Consumer worries about food safety have fueled a 20 percent annual growth in the market for organically grown products since 1989. Sales by U.S. companies amounted to $2.3 billion in 1994 (226). Pest control professionals also report growing public concern. In the 1993 Sandoz survey of pest control professionals, 76 percent reported greater public concern about the environmental impacts of pest control than five years previously (302). One response to this growing concern has been a reduction in pesticide use. In a 15-state survey of 9,754 farmers conducted in 1994, 82 percent reported using less or the same amount of pesticides than five years ago, compared with only 6 percent reporting an increase in pesticide use (131).

Pesticide Resistance

An increasing number of pests—insects, weeds, and plant diseases—have become resistant to pesticides that formerly were effective in controlling them. Alternative control technologies may provide the solutions to management of some resistant pests. They also will become integral components of strategies to slow the rate at which resistance develops (77,111). Abundant evidence exists that the use of multiple tactics to control a pest slows the rate at which the pest develops resistance to any single tactic in the arsenal (125).

A pest becomes resistant to a formerly effective pesticide when the chemical ceases to provide adequate control. Resistance develops because repeated exposure to the pesticide causes the selective survival of pest strains that can tolerate the chemical. Farmers and other users often find themselves applying the pesticide at an ever-increasing rate to achieve the same level of pest control. Eventually, the pesticide may cease to have any effect on the pest whatsoever.

Evidence of pesticide resistance was observed as early as the 1950s. As of 1992, the numbers of resistant species worldwide were estimated at 504 arthropods (including insects and arachnids, such as mites), 87 weeds, and 100 plant pathogens (68).

As of 1988, at least 18 herbicide-resistant weed species had been reported from 31 states (198). Twelve of these species have shown resistance to triazines, the most widely used category of herbicides. More than three million acres in the United States are now infested with resistant weeds (198). They include such well known weeds as cheatgrass (*Bromus tectorum*), a common seed contaminant and cause of fire hazards on western rangelands, and black nightshade (*Solanum nigrum*), a common crop weed whose toxic berries can contaminate harvests of peas and beans (425).

Today in the United States at least 183 insect and arachnid pests are resistant to one or more insecticides; 62 of these have developed resistance to synthetic insecticides within at least two of the three major categories of these products now in use (organophosphates, carbamates, pyrethroids) (112). California scientists believe that almost every arthropod pest in the state is resistant to at least one insecticide, and some populations of such important pests as the tobacco budworm (*Heliothis virescens*) in cotton and leafminers in certain vegetable crops (*Liriomyza sativae*) cannot be effectively controlled by any chemical now available (410). Table 2-4 shows the most critical cases today of multiple resistance among arthropod pests in the United States. George Georghiou, a renowned world expert on insecticide resistance, predicts that new instances of pest resistance to specific insecticides will pose a continuing impediment to effective control through conventional pesticides (112).

TABLE 2-4: Critical Cases of Multiple Insecticide Resistance in the U.S. Today

Pest	Major impacts	Resistant to			
		OP*	C	P	Oth
Two-spotted spider mite (*Tetranychus urticae*)	Attacks most greenhouse-grown plants; also damages grapes, vegetables, and field and orchard crops	X	X	X	X
Colorado potato beetle (*Leptinotarsa decemlineata*)	Attacks potato, tomato, eggplant, tobacco, and other crops; found throughout most of the United States	X	X	X	
Southern house mosquito (*Culex quinquefasciatus*)	Bites humans and can transfer encephalitis	X	X	X	X
House fly (*Musca domestica*)	Most abundant fly in human dwellings; causes annoyance, spreads filth, and is the suspected vector of numerous human diseases; distributed worldwide	X	X	X	X
Little house fly (*Fannia canicularis*)	Occasional parasite of the human urinary tract and intestines	X		X	X

(continued)

TABLE 2-4: Critical Cases of Multiple Insecticide Resistance in the U.S. Today (Cont'd.)

Pest	Major impacts	Resistant to			
		OP*	C	P	Oth
Sweetpotato whitefly (*Bemisia tabaci*)	Destructive pest of irrigated cotton and vegetables; has caused annual losses in excess of $100 million to California agriculture during severe outbreaks; damages greenhouse crops	X	X	X	
Silverleaf whitefly (*Bemisia argentifolii*)	Attacks over 600 plants including melons, squash, tomatoes, lettuce, cotton, and poinsettias; has caused over $500 million in damage in California, Arizona, Florida, and Texas	X			X
Greenhouse whitefly (*Trialeurodes vaporariorum)*	Attacks cucumber, tomato, lettuce, geranium, and many other plants	X	X	X	
Cotton aphid (*Aphis gossypii*)	Important aphid pest of agriculture, affecting cotton, melons, citrus, and other crops; distributed throughout the United States; most destructive in the South and Southwest	X	X	X	
Pear psylla (*Cacopsylla pyricola*)	One of the most important pear pests where established; transmits pear disease; distributed throughout eastern states and pear-growing regions of Pacific Coast	X	X	X	
Tobacco budworm (*Heliothis virescens*)	Attacks tobacco, cotton, and other plants; key secondary pest of cotton; occurs from Missouri, Ohio, and Connecticut southward; most injurious in Gulf states	X	X	X	
Soybean looper (*Pseudoplusia includens*)	Major defoliator of soybean; also attacks peanut, cotton, tobacco, and other crops; occurs in southern Atlantic and Delta regions of the United States	X	X	X	
Beet armyworm (*Spodoptera exigua*)	Attacks beet, alfalfa, cotton, asparagus, and other root and vegetable crops; distributed from the Gulf states north to Kansas and Nebraska and west to the Pacific Coast	X	X	X	
Fall armyworm (*Spodoptera frugiperda*)	Attacks corn, sorghums, and other grass-type plants; occurs throughout Gulf states; sometimes migrates north as far as Montana or New Hampshire, but cannot survive winter	X	X	X	
Diamondback moth (*Plutella xylostella*)	Attacks cabbage, and ornamental and greenhouse plants; occurs wherever its host plants are grown	X	X	X	X
German cockroach (*Blattella germanica*)	Most common household roach; spreads filth; damages household items; is suspected vector of human diseases; distributed worldwide	X	X	X	X
Cat flea (*Ctenocephalides felis*)	Worldwide pest of cats; common indoors in eastern United States; can carry the bacteria that causes bubonic plague	X	X	X	X
Citrus thrips (*Scirtothrips citri*)	One of the most important citrus pests in California and Arizona	X	X	X	

* OP = organophosphates; C = carbamates; P = pyrethroids; Oth = other smaller categories of pesticides, including microbial pesticides.

SOURCES: Resistance data from G.P. Georghiou, University of California, Riverside, CA, "Insecticide Resistance in the United States," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, April 1995; and data on pest impact from R.L. Metcalf and R.A. Metcalf, *Destructive and Useful Insects: Their Habits and Control,* 5th Ed. (New York, NY: McGraw Hill, 1993).

NOTE: Data in table indicate where resistance has been documented in one or more locations in the United States.

Newly Emerging Pest Threats

The number of pests in the United States is constantly growing. The 1993 OTA assessment of *Harmful Non-Indigenous Species in the United States* showed that new species continuously flow into the country, but few previous immigrant (or nonindigenous) pests, such as the bollworm *(Helicoverpa zea)* or the European gypsy moth, are ever eradicated (338). Newly arrived pests just since 1980 include:

- the Russian wheat aphid *(Diuraphis noxia)*, which has caused more than $850 million in crop losses;
- the zebra mussel *(Dreissena* spp.), which spread to more than 17 states in less than a decade, imperiling native mussels, fouling water intake systems, and causing losses to the power industry that are expected to exceed several billion dollars; and
- the Asian tiger mosquito *(Aedes albopictus)*, which is now found in more than 22 states and is an effective vector of several serious human diseases such as dengue fever (338).

OTA estimated that more than 205 species were newly detected or introduced into the United States from 1980 through 1993, with at least 59 having the potential to become pests. Moreover, this rate of pest entry is expected to rise with the increasing globalization of trade and advent of more rapid methods of transportation (338). Global warming is similarly expected to increase rates of pest entry to the United States, as species usually restricted to lower latitudes migrate northward (338).

In addition, public authorities are now attacking some old pests with new vigor. Specifically, changing public values have caused increased emphasis on the conservation of indigenous biodiversity —the nation's biological heritage. In numerous parks and nature reserves, this biodiversity is now imperiled by nonindigenous weeds, insect pests, and plant diseases that parasitize, kill, consume, compete with, or destroy the habitats of native plants and animals.

In the late 1980s, the silverleaf whitefly (Bemisia argentifolii) emerged as a new pest in the southwestern United States, causing hundreds of millions of dollars in crop damage.

Agricultural Research Service, USDA

National Park Service managers, for example, now rank nonindigenous species as one of the top threats to park natural resources (338). Stewards of Nature Conservancy lands in 46 states report problems with pest plants, and 59 percent of all stewards rank pest plants as one of their top 10 conservation concerns (284).

Managers of natural areas are increasingly seeking methods to suppress these pests while leaving the native flora and fauna unharmed. Scientists are similarly directing increased attention toward dealing with introduced pests in aquatic systems—rivers, lakes, streams, and oceans (191). The need is for effective, but highly specific, pest control methods that can be used in environmentally sensitive habitats-criteria met by few conventional pesticides.

Nonindigenous weeds also degrade western rangelands. A number provide only low-value forage for cattle, and some, like leafy spurge

Some pests can have profound environmental impacts. These leafless trees in midsummer result from the European gypsy moth's (Lymantria dispar) *voracious appetite.*

Agricultural Research Service, USDA

(*Euphorbia esula*), are toxic (425). These harmful plants are spreading rapidly across federal lands and now infest around 17 million acres. Indeed, the threats from certain nonindigenous weeds—called noxious weeds[12]—were deemed significant enough to merit special mention in the 1990 Farm Bill,[13] which amended the Federal Noxious Weed Act to require the development of weed management plans on all federal lands. The Secretary of the U.S. Department of the Interior (DoI) recently set up an agency-wide task force to aid in addressing this requirement (290). In addition, a number of DoI and USDA agencies have signed onto a Memorandum of Understanding to coordinate the prevention and control of noxious weeds (see also chapter 5).

RESPONSES BY CONGRESS AND THE EXECUTIVE BRANCH

The significance of pesticide losses, pest resistance, and emerging pest threats has not been lost on national policymakers. Congress responded directly to a number of these in the 1990 Farm Bill in provisions related to use and registration of pesticides, identification of pest control tools, and control of exotic pests (box 2-4). Pesticide issues have generally remained high on the congressional agenda: between 45 and 152 bills directly or indirectly addressing pesticide issues have been introduced into each Congress since the 98th Congress convened in 1985.[14] In the 103d Congress alone (January 1993 to January 1995), 33 bills dealt directly with pesticide-related issues. Of these, 19 addressed the health and environmental impacts of pesticides, and at least three dealt with future need for effective pest control methods and approaches. This interest continues in the 104th Congress, where eight pesticide-related bills had been introduced as of May 24, 1995. Two dealt with pesticide impacts on health and the environment, and five with meeting future pest control needs.

The most notable related action in the executive branch of government is the Clinton Administration's June 1993 announcement of its intent to reduce the use and risks of pesticides (see also box 5-1 in chapter 5). A major mechanism for achieving this goal is the Administration's stated commitment to develop and implement IPM practices on 75 percent of U.S. crop acreage by the year 2000 through the actions of three federal agencies—USDA, EPA, and the Food and Drug Administration (FDA).[15] The Administration has

[12] A "noxious weed" under the Federal Noxious Weed Act, as amended (7 U.S.C.A. 2814), is "of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure crops, other useful plants, livestock, or poultry, or other interests of agriculture, including irrigation, or navigation or the fish or wildlife resources of the United States or the public health." A total of 93 species have been designated federal noxious weeds by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. Weed experts believe that hundreds of other species also deserve this designation (338).

[13] The Food, Agriculture, Conservation, and Trade Act of 1990.

[14] Data derived from OTA's search of the Legislate and Scorpio databases.

[15] Note that this is the third administration to develop an IPM initiative (44). Under President Nixon, the Council on Environmental Quality issued an IPM policy document in 1972 and $12.5 million were allocated to the "Huffaker Project"—a research, training, and demonstration program for IPM. President Carter also tasked the Council on Environmental Quality to make recommendations to facilitate expansion of IPM.

Some pests can have profound environmental impacts. These leafless trees in midsummer result from the European gypsy moth's (Lymantria dispar) voracious *appetite.*

Agricultural Research Service, USDA

(Euphorbia esula), are toxic *(425). These* harmful plants are spreading rapidly across federal lands and now infest around 17 million acres. Indeed, the threats from certain nonindigenous weeds-called noxious weeds[12]—were deemed significant enough to merit special mention in the 1990 Farm Bill,[13] which amended the Federal Noxious Weed Act to require the development of weed management plans on all federal lands. The Secretary of the U.S. Department of the Interior (DoI) recently setup an agency-wide task force to aid in addressing this requirement (290). In addition, a number of DoI and USDA agencies have signed onto a Memorandum of Understanding to coordinate the prevention and control of noxious weeds (see also chapter 5).

RESPONSES BY CONGRESS AND THE EXECUTIVE BRANCH

The significance of pesticide losses, pest resistance, and emerging pest threats has not been lost on national policymakers. Congress responded directly to a number of these in the 1990 Farm Bill in provisions related to use and registration of pesticides, identification of pest control tools, and control of exotic pests (box 2-4). Pesticide issues have generally remained high on the congressional agenda: between 45 and 152 bills directly or indirectly addressing pesticide issues have been introduced into each Congress since the 98th Congress convened in 1985.[14] In the 103d Congress alone (January 1993 to January 1995), 33 bills dealt directly with pesticide-related issues. Of these, 19 addressed the health and environmental impacts of pesticides, and at least three dealt with future need for effective pest control methods and approaches. This interest continues in the 104th Congress, where eight pesticide-related bills had been introduced as of May 24, 1995. Two dealt with pesticide impacts on health and the environment, and five with meeting future pest control needs.

The most notable related action in the executive branch of government is the Clinton Administration's June 1993 announcement of its intent to reduce the use and risks of pesticides (see also box 5-1 in chapter 5). A major mechanism for achieving this goal is the Administration's stated commitment to develop and implement 1PM practices on 75 percent of U.S. crop acreage by the year 2000 through the actions of three federal agencies—USDA, EPA, and the Food and Drug Administration (FDA).[15] The Administration has

12 A "noxious weed" under the Federal Noxious Weed Act, as amended (7 U. S.C.A, 2814), is "Of foreign Origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure crops, other useful plants, livestock, or poultry, or other interests of agriculture, including irrigation, or navigation or the fish or wildlife resources of the United States or the public health." A total of 93 species have been designated federal noxious weeds by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service, Weed experts believe that hundreds of other species also deserve this designation (338).

13 The Food, Agriculture, Conservation, and Trade Act of 1990.

14 Data derived from OTA's search of the Legislate and Scorpio databases.

15 Note that this is the third administration to develop an 1PM initiative (44), Under President Nixon, the Council On Environmental Quality issued an IPM policy document in 1972 and $12.5 million were allocated to the "Huffaker Project"-a research, training, and demonstration program for 1PM, President Carter also tasked the Council on Environmental Quality to make recommendations to facilitate expansion of 1PM.

BOX 2-4: Congress Anticipates Future Pest Control Needs in the 1990 Farm Bill

Registering pesticides for minor use crops

Title XIV—Conservation; Subtitle H—Pesticides: Amends the Federal Insecticide, Fungicide, and Rodenticide Act to allow the EPA Administrator to reduce or waive the fee for registration of a minor use pesticide if that fee "would significantly reduce the availability of the pesticide for the use."

Reducing pesticide use

Title XIII—Fruits, Vegetables, and Marketing; Subtitle C—Cosmetic Appearance: Directs the Secretary of Agriculture to conduct research to determine impacts of federal grade standards and other regulations on pesticide use on perishable commodities, and to determine the impacts of reducing emphasis on cosmetic appearance in grade standards and other regulations on "the adoption of agricultural practices that result in reduced pesticide use."

Identifying and developing pest control tools to fill future needs

Title XIV—Conservation; Subtitle D—Other Conservation Measures: Directs federal agencies to develop programs for control of undesirable plants (including noxious weeds) on federal lands and for related "integrated management systems" based on education, prevention, and control by physical, chemical, and biological methods.

Title XIV—Conservation; Subtitle H—Pesticides: Directs the EPA Administrator in cooperation with the Secretary of Agriculture to identify available methods of pest control by crop or animal; minor pest control programs (either problems in minor crops or small problems in major crops); and factors limiting the availability of pest control methods (such as resistance and regulatory actions). Requires the Secretary of Agriculture to identify crucial pest control needs where a shortage of control methods occurs and to describe in detail research and extension designed to address these needs.

Directs the Environmental Protection Agency Administrator and the Secretary of Agriculture to develop approaches to pest control, based on integrated pest management and emphasizing minor pests, that respond to the needs of producers.

Requires the National Academy of Sciences to conduct a study of the biological control programs and registration procedures used by the Food and Drug Administration, the USDA Animal and Plant Health Inspection Service, and the EPA. Directs these federal agencies to develop and implement a common process for reviewing and approving biological control applications.

Title XVI—Research; Subtitle F—Plant and Animal Pest and Disease Control Program: Directs the Secretary of Agriculture to set priorities designed to overcome shortages in its pest and disease control research and extension programs where data indicate a shortage of available pest or disease control materials or methods to protect a particular crop or animal.

Directs the Secretary of Agriculture to expand research and grant programs related to exotic (nonindigenous) pests to improve existing methods (i.e., sterile release), develop safer pesticides (e.g., pheromones), and develop new methods of pest control.

SOURCE: Compiled by the Office of Technology Assessment, 1995, from the Food, Agriculture, Conservation, and Trade Act of 1990, P.L. 101–624.

not specified its interpretation of IPM, but the goal of expanding IPM is to reduce the use of pesticides by making a broader array of pest management tools and techniques available to farmers (84).

The executive branch's national IPM initiative encompasses a number of different actions (401). EPA and USDA signed a memorandum of understanding in August 1994 to provide the agricultural community with pest management practices that reduce pesticide risks. According to this agreement, USDA will increase its research on alternative pest control tools and means of transferring these tools to farmers. In addition, USDA and EPA will work together 1) to identify crop/pest situations in which pest control tools will become unavailable because of regulatory action, a lack of alternatives, or pest resistance and 2) to expedite research, development, education, and registration to attack these problems.

Specific programs are now being developed to meet the general goals just identified. USDA has assembled an IPM Coordinating Council with membership from all eight USDA agencies that have related responsibilities, and has requested approximately $22 million in fiscal year 1996 funding for related programs. A major part of the USDA effort will be a program to assemble teams composed of farmers, researchers, extension staff, crop advisors, and others to develop crop-specific IPM systems. This will be funded through the Cooperative State Research, Education, and Extension Service (CSREES). EPA has launched a pilot Biopesticides and Pollution Prevention Division to facilitate registration of biological pesticides, administer EPA's IPM program, and develop activities to prevent pesticide pollution.

DEFINING THE TERMS OF OTA'S ASSESSMENT

The five kinds of biologically based technologies (BBTs) covered in this assessment represent an important segment of the alternatives to conventional pesticides (presented earlier in box 2-1) and a significant part of USDA's emphasis in pest control. The majority of the "safer" pesticides that EPA is promoting to reduce the risks of pesticide use are microbial pesticides and pheromone-based products; these two categories made up 45 percent of all new active pesticidal ingredients registered by EPA in 1994 (401).

OTA's assessment of BBTs thus provides a "bottom-up" view of whether the national infrastructure supporting research, development, and implementation can support diversification of pest control technologies and expansion of IPM. Box 2-5 describes in greater detail several additional technologies not within OTA's scope that are receiving increased attention for the same reasons as BBTs.

Most activity related to BBTs has occurred within the agricultural sector. Pests plague all areas of human activity, and the forces affecting the availability of pest control in the future will affect nonagricultural areas as well. The OTA assessment thus examines application of BBTs to the full array of pest problems, ranging from agriculture, rangelands, and forestry, to parks and wilderness preserves, urban and suburban environments, and even aquatic habitats.

A Caution on Terminology

A multitude of terms characterize the field of biologically based pest control. Moreover, the same terms are used with somewhat different meanings among varying subdisciplines (e.g., insect pest management versus plant disease management) (15). Although some of these differences seem esoteric to nonspecialists, unfamiliar uses of terms can arouse strong feelings among scientists, in part because research funding is often tied to specific definitional interpretations (15). Moreover, some definitional niceties reflect underlying philosophical beliefs about the most appropriate approach to pest management.

The best known example of such controversy occurred in response to the report from a National Academy of Sciences working group (243). That report broadened the definition of *biological control* beyond the use of living organisms to include the use of *genes or gene products* to reduce pest impacts. All of the technologies within OTA's scope would fall within this definition, as might naturally derived botanical pesticides and insect growth regulators (box 2-1). Adherents to the historical, narrower interpretation of biological control worried that other, newer approaches might garner a disproportionate share of research dollars at the expense of

BOX 2-5: Technologies Not Covered in This Assessment Also Receiving Increased Attention

Botanical pesticides

"Botanicals" are chemicals derived from plants that are used in the same way as conventional pesticides. They can be either naturally occurring or synthesized. Examples include pyrethroids originally from chrysanthemum flowers and nicotine from tobacco. Naturally occurring botanicals enjoy popularity among organic farmers and gardeners because they are derived from "natural" sources. However, scientists believe that botanicals are no safer as a group than synthetic chemicals and pose the same questions of mammalian toxicity, carcinogenicity, and environmental impact.

Insect growth regulators (IGRs)

IGRs are naturally occurring hormones or similar synthesized compounds that influence insect growth. Insects repeatedly shed and then form a new outer layer as they grow in a process called molting. IGRs kill insects by interfering with the molting process. These insecticides have low toxicity to mammals, but some IGRs affect crabs, shrimp, and other animals that molt. Concerns about nontarget impacts on these other species, some of which are economically important, have led to stringent restrictions on allowed uses of IGRs. IGRs are now being examined with renewed interest for use in environments where such nontarget impacts are highly unlikely, such as in homes or grain storage elevators. More specific IGRs might be developed for high-dollar pests; however, no species-specific IGRs are presently on the market.

Plant breeding and enhanced resistance to pest damage

For centuries, humans have selected the most hardy strains of crop plants to propagate and grow. Significant reductions of pest damage to plants in agriculture and landscapes can be attributed to the efforts over the past few decades of plant breeders who have developed pest-resistant plant cultivars. Recent advances in genetic engineering have greatly enhanced the possibilities in this area by enabling the transfer of genes that confer resistance to pests between widely unrelated organisms. The new genetic engineering techniques bring great promise, but also certain risks. A number of important issues remain unresolved in the policy arena, such as food safety effects, potential transfer of genes to weedy species, the appropriate venue and standards for regulation, and the ability of pests to evolve tolerance to the plant changes. Of particular significance is that many crop plants are being genetically engineered to produce toxins found in Bt. Scientists worry this will speed the rate at which pests become resistant to Bt—rendering microbial pesticides composed of the bacteria ineffective (see also chapter 4 of this report).

Physical, cultural, and mechanical control

These approaches either manipulate the environment to make it less conducive to pest damage, or directly remove a pest through mechanical means. Examples include crop rotation, sanitation, choice of planting and harvest dates to avoid pest infestations, water management practices, and sdarization (heating soil to kill pests). Most cultural/mechanical approaches are environmentally benign, although tillage can contribute to soil erosion. Use of these approaches is widespread but patchy. They require a knowledgeable farmer, and because most cultural/mechanical approaches do not involve a marketable product, sources of adequate information often are lacking. For this reason, research and development of cultural/mechanical approaches depends primarily on the public sector.

SOURCE: Office of Technology Assessment, 1995; M.L. Flint, University of California, Davis, CA, "Biological Pest Control: Technology and Research Needs," unpublished contractor report prepared for Office of Technology Assessment, U.S. Congress, Washington DC, November 1993.

NOTE: Technologies presented here are a subset of those outside of OTA's scope shown in box 2-1 earlier in this chapter.

their discipline (15). They also felt that some approaches gained unwarranted legitimacy by their association with more "environmentally friendly" biological control: microbial pesticides based on Bt, for example, kill pests by a toxin, and, according to these critics, perpetuate the mind-set of a pesticide-based approach (see also box 2-2). This debate, which continues today, was the focus of considerable discussion during an ongoing study by the National Research Council.[16]

OTA's Definitions of Technologies Covered in This Assessment

OTA's selection of the definitions here balances a straightforward conceptual presentation with policy relevance and commonly accepted usage among scientists and other professionals. The goal is to clarify the presentation of this report while retaining scrupulous technical accuracy. The definitions are not necessarily intended for direct incorporation into statutes, regulations, or policy statements.

Biological Control

Populations of all living organisms are, to some degree, reduced by the natural actions of their predators, parasites, competitors, and diseases. Scientists refer to this process as *biological control* and to the agents that exert the control (i.e., predators, parasites, competitors, and pathogens[17]) as *natural enemies.*[18] Humans can exploit biological control in various ways to suppress pest populations. These approaches differ in how much effort is required, who is involved, and how suitable the approach is for commercial development.

Some organisms become significant pests only when they move to a new locale where their natural enemies are absent and therefore the organism's population expands greatly. One approach to managing these nonindigenous pests is to reestablish control by importing and releasing natural enemies from the pest's region of origin. Termed *classical biological control*[19] by specialists, the goal is permanent establishment of the natural enemies in the new locale. Through reproduction and natural spread, the control agents can then effectively "track" the pest throughout all or part of its new range and provide enduring pest suppression with little or no additional effort. Classical biological control is generally regarded as a public-sector activity having little potential for commercial involvement. Researchers from universities and federal and state government are the primary people involved in the discovery, importation, and release of classical biological control agents. Many farmers, homeowners, and other users of pest control products are unaware of the extent to which imported natural enemies now keep certain potential pests in check, obviating or reducing the need to use additional control measures. Examples of such pests are the woolly apple aphid (*Eriosoma lanigerum*) of the Pacific Northwest, the sugarcane delphacid (*Perkinsiella saccharicida*) in Hawaii, and the weed St. John's wort (*Hypericum perforatum*) in the western United States, all of which are currently under a significant level of biological control.

Some natural enemies, both imported and indigenous, can be repeatedly propagated and released in large numbers. These *augmentative*[20] releases temporarily increase the natural enemy's abundance in a specific target area and therefore

[16] The NRC's Board on Agriculture has an ongoing study of "Pest and Pathogen Control Through Management of Biological Control Agents and Enhanced Natural Cycles and Processes." The report, scheduled for publication in late 1995, discusses issues related to necessary types of research, and complements but does not duplicate the OTA assessment.

[17] Pathogens are disease-causing agents, including certain bacteria, viruses, fungi, protozoa, and nematodes (microscopic worm-like animals).

[18] Natural enemies are also sometimes referred to as *beneficial organisms.* Use of this term can be confusing because some organisms, like honeybees, are beneficial organisms but are not natural enemies.

[19] The term *innoculative biological control* is also used by some specialists (418).

[20] The term *innundative biological control* is also used by some specialists (418).

its impact on the pest species. The temporarily boosted abundance may far exceed that which the environment would normally support. Augmentation can also create a transient population of a natural enemy that could not otherwise persist in the environment (e.g., because it cannot tolerate cold winters). One potential advantage of augmentation is that the release can be timed to coincide with the period of the pest's maximum vulnerability, such as a particular larval stage. In most agricultural applications, augmentative releases occur once or several times throughout a growing season. Live microbial pesticides (discussed in the next subsection) are another form of augmentative biological control. A small U.S. industry now commercially distributes and sells insects that are natural enemies of insect and weed pests, primarily to farmers and ranchers. Approximately 110 different species are now commercially available from more than 130 North American companies (60). Some federal and state government agencies also make augmentative releases.

The action of all natural enemies—indigenous, imported, and augmented—can be enhanced by simply encouraging their survival and multiplication. This *conservation of natural enemies* usually involves specific crop, forest, or landscape management practices that provide the natural enemies with a hospitable environment and limit practices that kill natural enemies—for example, by reducing pesticide use or selecting specific pesticides. The practitioners of this approach are farmers and others who seek to control pests. Usually, no commercial products are directly involved but crop, forest, or landscape management advisors may provide advice to farmers, homeowners, and others about conservation of natural enemies or other related services for a fee. Federal and state governments also provide public education on such management practices through extension and outreach activities.

Microbial Pesticides

A wide variety of microorganisms (organisms too small to be seen by the naked eye) suppress pests by producing poisons, causing disease, preventing establishment of other microorganisms, or various other mechanisms. Such microorganisms include certain bacteria, viruses, fungi, protozoa, and nematodes. A *microbial pesticide* is a relatively stable formulation of one or several microbes designed for large-scale application. The most widely used microbial pesticide today is Bt, formulated from the bacteria *Bacillus thuringiensis*. Its pesticidal properties result from toxins the bacteria produce that can kill certain insect pests. Most microbial pesticides are produced commercially and sold to farmers, foresters, homeowners, government agencies, and other users of pest control products.

Behavior-Modifying Chemicals

Many organisms emit chemical cues that evoke specific behaviors from other individuals of the same or a different species. Pheromones are one category of these chemicals that currently has application in pest management. Pheromones serve to communicate information among members of a single species. Mate-attraction pheromones are now used in pest lures or in traps laced with insecticides or microbial pesticides. Some are sold commercially for pest control, although the primary function of most is monitoring of pest distribution. The pheromone-based method in greatest use is widespread application of pheromones to disrupt a pest's normal mate-finding behavior (and thereby reduce successful reproduction). Farmers, foresters, homeowners, and government agencies rely on commercially produced pheromone products.

Genetic Manipulation of Pests

In this approach individuals of the pest species are genetically altered and then released into the pest population. The individuals carry genes that interfere with reproduction or impact of the pest. The specific method in significant use today is the release of sterile males for insect control. Males of the pest insect are made sterile by irradiation. Following release, they compete with fertile males for female mates, thereby reducing the number of matings that successfully produce offspring. The result is a drop in the size of the pest population.

Plant Immunization

The ability of crop and landscape plants to resist diseases and insect pests can be enhanced through a number of methods that do not involve plant breeding or genetic engineering. One approach of growing importance in the turfgrass industry is the use of grass containing endophytes—certain fungi that live within plant tissues. Plants containing these fungi are less susceptible to damage by insects and diseases. Researchers are working on developing methods of transferring endophytes to plants in which they do not normally occur. Scientists have also found they can enhance resistance to disease in certain plants by exposing them to specific microbes or chemicals or by inoculating them with a less-damaging strain of a disease-causing microbe. The various methods of inducing disease and pest resistance are experimental and not yet in practical use.

The Technologies 3

Any assessment of biologically based pest control faces an immediate paradox. A wealth of technical information and research findings characterize the field, and there is near uniform agreement that use of biologically based technologies (BBTs) is desirable, if they can safely provide adequate pest control.[1] Nevertheless, actual adoption of these technologies is low. Explanations for this seeming contradiction usually center on numerous "obstacles" that hinder adoption of BBTs—some related to current limits to what the technologies can do, others to social, economic, and institutional impediments. This chapter begins by evaluating BBTs and discussing difficulties in setting performance standards for these technologies. It then describes current and potential uses of BBTs in the United States and identifies the factors affecting their future adoption.

EVALUATING THE TECHNOLOGIES

A complex mix of technical, social, and institutional factors contribute to the past successes and disappointments of BBTs (box 3-1). Certain highly effective BBTs have failed because of economic factors or improper use. Straightforward assessment of the technical capabilities of BBTs according to their track record of success is thus impossible. In general, BBT adoption has occurred most frequently where conventional pesticides are unavailable (e.g., because of pest resistance or small market size), unacceptable (e.g., in habitats that are environmentally sensitive or places where human contact is high), or economically infeasible (e.g., because the cost of pesticide use is high relative to the economic value of the resource, as in rangeland management).

Comparison with Conventional Pesticides

Direct appraisal of the technical capabilities of BBTs is also complicated by the question of what standards to apply. In practice, the level of pest control set by conventional pesticides is

[1] See end of chapter 2 for detailed description of the biologically based technologies discussed here and throughout the assessment.

CHAPTER 3 FINDINGS

- Although conventional pesticides dominate U.S. pest management practices, biologically based technologies (BBTs) have penetrated most major applications and joined the mainstream. For example, BBTs are the method of choice for certain widespread pests like the European gypsy moth (*Lymantria dispar*), and have been adopted by a number of major food-processing companies.
- Current use of BBTs is patchy, however. Adoption has occurred most frequently where conventional pesticides are unavailable, unacceptable, or economically infeasible. In such situations, the chief advantages of BBTs become significant assets—namely, that they reduce reliance on conventional pesticides, have generally low impacts on human health or the environment, and, in the case of classical biological control, provide lasting and low-cost suppression of individual pests.
- Most BBTs provide partial solutions to the pest problems faced by farmers and other users and usually must be integrated with other control techniques to provide an overall package of pest suppression. They tend to fare poorly when evaluated against the performance standards set in place by conventional pesticides.
- The field of BBTs is characterized by a wealth of technical information combined with far fewer on-the-ground applications. People involved in the research, development, and use of BBTs attribute the low adoption to numerous technical, social, economic, and institutional obstacles. These obstacles represent real and valid impediments, but they make a precise assessment of the true capabilities and future potential of BBTs difficult.
- Removal of the nontechnical obstacles through a variety of policy actions would surely improve the success record of BBTs. Nevertheless, significant technical issues still need to be resolved, and this problem can be addressed only through appropriate adjustment of the national research agenda.

often the benchmark used for judging other methods. Key features of such appraisals are:

- target range—how many pests are affected;
- kill level and rate—to what extent the pest population is suppressed and how rapidly;
- field persistence—how long a single application continues to provide control; and
- shelf life and stability of commercial products.

Conventional pesticides generally have a wide target range, high kill level, rapid kill rate, long field persistence, and extended shelf life. By any measure, most BBTs do not compare well according to these criteria. Many BBTs have a narrower target range; act more slowly; suppress, but do not locally eliminate pests; and, if sold commercially, have a shorter field persistence and briefer shelf life. Exceptions to these generalizations do exist, of course. Classical biological control can provide lasting pest suppression, and microbial pesticides applied as seed treatments may suppress plant pathogens over a growing season or longer (138).

Conventional pesticides are often described as "stand-alone" approaches to pest control; a single chemical provides significant suppression of many pests. In contrast, most BBTs affect only one or a few pests, and some affect only one life stage of a pest. Pheromone mating disrupters, for example, are "adult-based" strategies and do not affect juvenile pests already present. *Bacillus thuringiensis* (Bt), in contrast, works only on the feeding juveniles (e.g., caterpillar larvae).

The timing for effective use of many BBTs is also relatively narrow, because it must coincide with a particular vulnerable life stage of the pest or specific environmental conditions. Like certain conventional pesticides, the effectiveness of many BBTs is influenced by aspects of the weather, such as temperature and humidity. Also, some are impaired by conventional pesticides; natural enemies, for example, are killed by many chemicals. As a result, recent spraying at the

BOX 3-1: Outcomes of Biologically Based Pest Control

Some notable successes…

Classical biological control

Ash whitefly (*Siphoninus phillyreae*)—First noticed in California in 1988, the pest soon spread to 28 counties in that state as well as to Arizona, and New Mexico. It attacked ornamental trees that make up 17% of street trees in urban areas. Within two years of biological control introductions in 1990, the fly was under complete control, generating net savings in excess of $200 million.

Skeletonweed (*Lygodesmia juncea*)—The rust fungus *Puccinia chondrillina* was released in several western states in 1976. Skeletonweed is now under excellent control in California, Idaho, Oregon, and Washington because of the disease.

Augmentative biological control

Strawberries—An estimated 50 to 70% of California strawberry acreage uses the beneficial mite *Phytoseiulus persimilis* against the two-spotted spider mite *Tetranychus urticae*, an important pest. Use grew rapidly in 1987 when the widely used pesticide Plictran was removed from the market by federal regulation. Other alternatives were not available and growers turned to natural enemies.

And some disappointments

Classical biological control

European gypsy moth (*Lymantria dispar*)—Despite a century of research and introductions of over 50 different biological control agents, most recently in 1994, biological control has not yet been successful and problems with the pest continue to worsen.

Augmentative biological control

Convergent lady beetles (*Hippodamia convergens*)—Lady beetles collected from field populations in California have dominated the market for yard/garden use of natural enemies since they were first sold in the early 1900s. Results of research on the beetles have consistently been disappointing, however, because most fly away within 24 hours after they are released. Some companies are beginning to market lady beetles "preconditioned" to ensure a more sedentary behavior, but the claims of enhanced efficacy remain to be well documented.

(continued)

BOX 3-1: Outcomes of Biologically Based Pest Control (Cont'd.)

Some notable successes...

Microbial pesticides

Bt—Various products based on the bacterium *Bacillus thuringiensis* are now the most widely used microbial pesticides in the United States and worldwide. The primary uses are for control of European gypsy moth (*Lymantria dispar*), various caterpillar pests, and the Colorado potato beetle (*Leptinotarsa decemlineata*).

Black vine weevil (*Otiorhynchus sulcatus*)—In cranberry bogs, this pest has been successfully controlled by nematodes. Favoring success were the soil conditions, susceptibility of the pest, safety of the product, lack of other alternatives, and high value of the crop. In addition, Ocean Spray, a farming cooperative that is the primary user, worked closely with the manufacturer to develop suitable application methods.

And some disappointments

"Milky spore" for control of Japanese beetle (*Popillia japonica*)—First introduced as a classical biological control in the 1930s, commercial formulations of *Bacillus popilliae* became available for control of the pest in turf during the 1980s. A number of lawn care companies experimented with these products, but poor quality control in production meant inconsistent product performance. As a result, lawn care company representatives do not believe that milky spore is effective and will not use it for control of Japanese beetle grubs. For some members of the industry, this experience has generated a high level of distrust for microbial pesticides in general.

Collego—This microbial pesticide is based on a pathogen of northern joint vetch (*Aeschynomene virginia*). First sold in 1982 by Upjohn, Inc., Collego offered excellent control over northern jointvetch in rice fields. The product was taken over by Ecogen, but production costs rose after the change. Eventually, the market size proved too small to justify continued production, and Collego was withdrawn from the market in 1994.

Elcar—This viral insecticide was developed by Sandoz, Inc. for use against the bollworm (*Helicoverpa zea*) where resistance to conventional pesticides was occurring. The virus was very effective and its initial prospects were good. But entry of pyrethroids onto the market at about half the price of the virus turned it into a financial disaster, and Elcar was removed from the market. Interest in this approach is reemerging because the bollworm is developing resistance to pyrethroids as well.

(continued)

BOX 3-1: Outcomes of Biologically Based Pest Control (Cont'd.)

Some notable successes…	And some disappointments
Pheromone-based products	
Pink bollworm (*Pectinophora gossypiella*)—Mating disruption approaches on 27,000 acres of the Parker Valley in Arizona starting in 1989 resulted in a decrease of damage to cotton bolls from 25% (with standard regime of conventional pesticides) to 0% (with the pheromone approach).	European elm bark beetle—Attempts to mass-trap the beetle, the vector of Dutch elm disease, have been unsuccessful because they do not attract enough insects or attract them only after the damage has occurred. Codling moth (*Cydia pomonella*)—Several products are available but the level of fruit protection achieved varies with the product, the initial level of infestation, and the distance of the orchard from sources of mated codling moth females. Inconsistent formulation and poor choice of application sites appear to be sources of the variable outcomes in farm-by-farm application. Researchers believe greater success is likely using an areawide management approach.
Sterile insect approach	
Screwworm (*Cochliomyia hominivorax)*—Large-scale releases of sterile males, starting in the 1950s, effectively eliminated the pest from the United States and northern Central America.	Mediterranean fruit fly (*Ceratitis capitata*)—The success or failure of this approach in the Los Angeles basin is unknown and a source of controversy among scientists. As of November 1994, this pest was still present despite releases of 14 billion sterile flies in 1993.

SOURCES: Office of Technology Assessment, U.S. Congress, 1995; W. Cranshaw, Department of Entomology, Colorado State University, Fort Collins, CO, "Biologically Based Technologies for Pest Control: Urban and Suburban Environments," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994; K. Jetter and K. Klonsky, Department of Economics, University of California, Davis, CA, "Economic Assessment of the Ash Whitefly (*Siphoninus phillyreae*) Biological Control Program," unpublished contractor report prepared for the California Department of Food and Agriculture, Sacramento, CA, June 30, 1994; "Milky Spore Disease May Not Be Effective Biological Control for Grubs," *Turf Grass Trends* 13, May 1994; J. Randall and M. Pitcairn, Exotic Species Program, The Nature Conservancy, Galt, CA and the Biological Control Program, California Department of Food and Agriculture, Sacramento, CA, "Biologically Based Technologies for Pest Control in Natural Areas and Other Wildlands," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994; R. Van Driesche et al., Department of Entomology, University of Massachusetts, Amherst, MA, "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, D.C., December 1994.

control site or drift of pesticides from adjacent areas can affect performance of certain BBTs.

For these reasons, BBTs do not provide a high enough level or broad enough range of pest suppression to satisfy the full needs of farmers and other users whose expectations have been set by conventional pesticides. BBTs thus need to be used in a more integrated fashion with other control techniques to provide an overall package of pest suppression. This requirement means that the performance of BBTs may often depend on the quality of the specific integrated pest management (IPM) system in use—whether it deals with the full range of likely pest problems and can respond to changing pest control needs.

An Important Benefit of BBTs

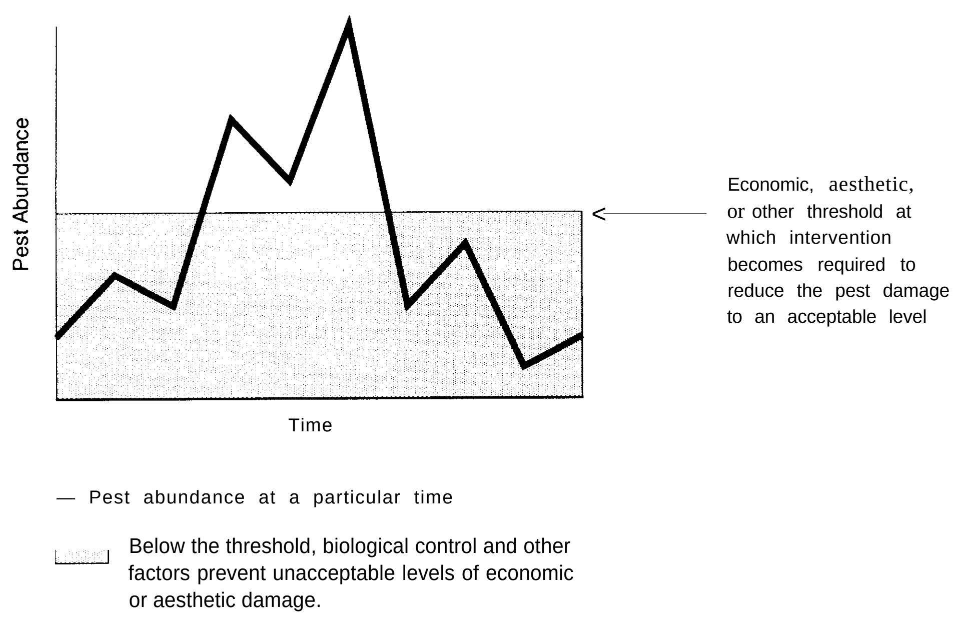
Some of the very characteristics that make BBTs compare poorly with conventional pesticides become advantages in pest management systems that seek to minimize pesticide inputs. Such systems usually involve monitoring (scouting) of pests so that pesticides are applied only when outbreaks occur.

To most people, this concept is simple: Killing pests stops their unwanted effects. To experts, however, this simplicity masks underlying complexity. The harmful effects of a pest are directly related to its abundance. If a potential pest is never abundant enough, its harmful effects may remain at an acceptable level or perhaps undetected. Many pest control practitioners today intervene only to control a pest when it reaches a threshold abundance where unacceptable effects are likely to occur (figure 3-1; see table 2-2 in chapter 2). Potential pests sometimes remain below this level because of the action of naturally occurring biological control agents or other factors, such as weather.

The BBTs covered in this assessment include practices to enhance naturally occurring control when a pest is below its threshold (i.e., conservation of natural enemies) and intervention methods to push pest abundance back below the threshold (i.e., microbial pesticides). The distinction between the two is somewhat fuzzy because certain BBTs, such as augmentative biological control, can be used both to prevent and control pest outbreaks (i.e., when pest densities are either below or above the threshold abundance in figure 3-l).

Conventional pesticides also have been used in both ways. A major difference between BBTs and conventional pesticides concerns the ways in which they affect naturally Occurring control. Many conventional pesticides kill natural enemies as well as pest organisms. Certain pests that otherwise might be kept below threshold levels by natural enemies subsequently surge to outbreak levels (see box 2-2). In contrast, the specificity of BBTs means they are far less likely to harm natural enemies. These technologies thus are more compatible with pest management sys-

FIGURE 3-1: Intervention is Not Always Neccessary to Prevent Unwanted Pest Damage



SOURCE: Adapted by OTA from J.K. Waage, Director, International Institute of Biological Control, Ascot Berks, UK, letter to the Office of Technology Assessment, US. Congress, Washington DC, July 14, 1995.

tems that seek to maximize naturally occurring pest control and to minimize pesticide inputs.

Gaps in the Information

The patchy implementation of BBTs to date means that no precise evaluation of their capabilities is possible. Existing data focus more frequently on BBTs successes than on lessons learned from failures—and in many cases, the necessary long-term followup for evaluating impacts or effectiveness in IPM programs is lacking.

An additional problem arises because so much of the information on BBTs comes from research results. Scientists do not always use the term *control* to mean a level of pest suppression that is applicable to actual field applications. Moreover, because field conditions can greatly alter the impacts of BBTs, research findings can not be directly translated into predictions about potential effectiveness under conditions of practical use (175). This problem is especially significant for areas like plant pathogen control, where very few BBTs are yet in place (308).

What We Do Know about the Effectiveness of BBTs

Biological Control

When successful, classical biological control programs in which the natural enemy of a pest is identified, imported, and released, can provide lasting, highly selective, and effective control. Some programs have caused 100- to 1,000-fold drops in pest density (411). Not all biological control programs are successful, however. In 1990 it was estimated that the 722 biological control agents previously introduced in the United States had resulted in some level of suppression for 63 arthropod pests (123).[2] Some level of control has resulted for 21 U.S. weeds as a result of classical biological control introductions against 51 target species (420).

Results of classical biological control programs are usually reported as "complete," "substantial," or "partial" control (69,123,153). Complete control usually refers to a level of pest suppression at which no additional controls are necessary against the pest. It is the least common outcome of classical biological control, representing about 18 percent of all successful U.S. programs against arthropod pests (153).

Biological control successes generally occur slowly. A significant proportion of the U.S. successes in classical biological control against arthropod pests thus far (at least 85 percent) were accomplished prior to 1964 (69,123,153). Experience indicates that only about a half-dozen major successes can be expected in the United States per decade (415). Although, some researchers attribute the recent slow rate of success to inadequate institutional support from the U.S. Department of Agriculture (USDA) since the 1970s (58), while others suggest that the "easier targets" have already been addressed using this method (9). Recent successes are more common for weeds; only 45 percent of today's successes occurred prior to 1977 (153,420).

Successful biological control programs typically report benefit-cost ratios from reduced pest impacts and decreased use of pesticides of 10:1 to 30:1, with some as high as 200:1 (162,411). These ratios do not incorporate the costs of other failed biological control programs (286,318). One reason for the high per-program returns is that a successful classical biological control program can provide lasting benefits that accrue indefinitely into the future with little, if any, further investment. Many of the greatest successes in classical biological control have occurred in permanent or semipermanent environments such as orchards, forests, or rangelands, where perma-

[2] No readily available data show what proportion this figure represents of all U.S. arthropod pests against which classical biological control has been attempted. On a worldwide basis, for all pests targeted by classical biological control programs, approximately 16 percent are now completely controlled and another 40 percent are partially controlled by this method (411). Note that several natural enemies may be introduced before control occurs, and a project against a single pest can take anywhere from a few years to several decades.

nent establishment of natural enemies is most likely to occur (60).

Benefit-cost ratios have been calculated for relatively few classical biological control programs because documenting program impacts is difficult and costly (58). Little routine monitoring follows most biological control releases, and effects can take five, 10, or more years to become apparent (191,41 1,420). Moreover, the effectiveness of a biological control agent may vary across the pest's distribution because of differences in temperature, moisture, elevation, and other factors that affect survival and population size of the natural enemy and its target pest. The result can be a mosaic ranging from excellent to no control, depending on the specific site (420).

Even fewer attempts have been made to evaluate the overall effectiveness of repeated augmentative releases of natural enemies (41 1,263). The few scientific studies have been conducted on too small a scale to make accurate inferences about results under conditions of actual use (41 1), and scientists are divided about the feasibility and effectiveness of the approach (263,173), The utility of natural enemies in enclosed greenhouses is generally undisputed. Researchers vary, however, in their views as to the potential effectiveness of augmenting natural enemies in field crops; some believe that discernible levels of pest suppression result more from the positive impacts of reduced insecticide use on natural enemies already present in fields, than from the deliberately released natural enemies. At present, high cost and quality control also are issues (e.g., are the natural enemies sold alive and active?) (263,173). Another question concerns the scale at which augmentative releases will be most successful—on small farms, on large farms, or areawide. Nevertheless, companies marketing natural enemies and farmers who use these products believe they are effective and dispute scientists' more mixed view of this technique (269,59).

Augmentative use of fishes for control of aquatic weeds and mosquitoes is a special case. These fishes can be quite effective, although they act more slowly than pesticides and do not eliminate pests completely. Because their use is confined to water bodies of sufficient size, clarity, and warmth to sustain the animals, their usefulness is sometimes limited (191,315) For example, mosquito fish *(Gambusia* spp.) are impractical for certain significant mosquito habitats such as tree holes, tires, and temporarily flooded wetlands-all major sites of mosquito reproduction (191,315). Introductions of fishes for biological control also raise several significant ecological risk issues (see chapter 4).

Although the program to control of the boll weevil (Anthonomus grandis grandis) *relies on conventional pesticides, the pest's successful suppression in some states has resulted in greatly reduced insecticide usage; natural enemies are now more common in cotton fields and keep a number of other former insect pests under control.*

Agricultural Research Service, USDA

Conservation of natural enemies has highly variable effects, depending on the specific crop and location. Quantitative estimates of impacts are impossible because the approach is rarely used as a major and deliberate component of pest management (41 1). Instead, increased effects of natural enemies are more often a consequence of management practices implemented for other goals (such as reduced pesticide use) (9,411). Maximizing the conservation of natural enemies more widely would require the development of extensive site-specific information (41 1). Overall, the approach works only for pests that have potential natural enemies (native or introduced) in the area (411).

The most widely cited evidence for the potential effects of conservation of natural enemies comes from rice production in Asia. There, modification of insecticide spray schedules to enhance the impacts of natural enemies has dramatically reduced outbreaks of the rice brown planthopper (*Nilaparvata lugens*), a destructive rice pest (411). In the United States, the most common way farmers seek to conserve natural enemies is by selecting conventional pesticides that have relatively low impacts on natural enemies (61). Biological control experts hold differing views as to whether any chemical pesticides cause sufficiently low damage to natural enemies for this approach to be successful. Some believe that only microbial, pheromone, or cultural alternatives will enable enhanced reliance on conservation of natural enemies (411).

Microbial Pesticides

The performance of various microbial pesticides differs greatly, as does the degree to which that performance is affected by environmental conditions. Pesticides based on Bt are potent if applied to the early larval stages of susceptible insect pests. Application during other stages causes their effects to drop severely. Effectiveness also varies with the pest's feeding rate; as a result, many Bt products are formulated to include feeding stimulants. Because Bt products can be manufactured using large-scale fermentation techniques, they are less expensive to produce than many other microbial pesticides.

The various Bt-based pesticides are very specific. This precision minimizes nontarget impacts but also has disadvantages. For example, three caterpillars—*Heliothis virescens* (tobacco budworm), *Heliocoverpa zea* (bollworm), and *Spodoptera exigua* (beet armyworm)—are frequent cotton pests. Current Bt products are highly effective against the first, less so against the second, and relatively ineffective against the third (411). In general, Bt products have been most useful against forest caterpillars, Colorado potato beetle (*Leptinotarsa decemlineata*) larvae, and a number of caterpillar pests of vegetables and other crops. Recent evidence suggests that certain pests may develop resistance to Bt, which could limit its future utility (see chapter 4).

Nematodes that have been developed for pest control products kill pests rapidly (within 48 hours).[3] They also show broader spectrum effects than Bt. Control of insect pests is comparable, and sometimes even superior to insecticides, with data showing 100- to 1,000-fold drops in pest densities for such diverse organisms as caterpillars, aphids, armored scales, sawflies, and whiteflies (411). Nematode products are applied using standard spray equipment, traps, or baits; they are generally tolerant of most pesticides and fertilizers (113). Environmental sensitivity—nematodes need adequate moisture and temperatures from about 53 to 86 degrees Fahrenheit—is a limitation of nematode products. They have been used successfully in moist soils but not in plant foliage. The shelf life of nematode products ranges from three to 12 months under refrigeration, but some of the newer formulations can last up to five months at room temperature. Although nematodes can be mass-produced, the high cost remains a problem.

Only two virus-based products are now in use, the European gypsy moth nuclear polyhedrosis virus (NPV) and the beet armyworm NPV virus.[4] Viruses, in general, are expensive to produce because techniques do not yet exist to mass-produce them without living hosts; according to industry representatives, new production tech-

[3] These include the steinernematid and heterorhabditid nematodes. Other nematodes that have not been developed for pest control provide a slower rate of kill. OTA categorizes nematode-based products as a type of microbial pesticide because the nematodes involved are microbes (microorganisms) (276) and sold in commercial formulations (see chapter 2). Some scientists and commercial producers categorize nematodes as natural enemies in part because EPA does not regulate these products as a type of microbial pesticide (see chapter 4). The issue is largely semantic.

[4] Another six have been registered for control of forest and crop pests, including two within the past year for celery looper (*Anagrapha falcifera*) and codling moth (*Cydia pomonella*).

nologies will soon be available that allow less costly production. Viruses also persist in the field only briefly because sunlight causes them to lose activity. A few viruses are broader spectrum, affecting several insects in the same taxonomic family or order, although effects of a given virus on different species can vary (411).

Microbial pesticides based on fungi have high virulence and are amenable to mass production. Their biggest drawback is requiring a moist habitat for activation. Fungus-based herbicides developed thus far against weeds have been highly host-specific, relatively fast-acting, and lethal (420). Fungi developed for use against insect pests have broader host ranges (although narrower than Bt products) and are most effective at high pest densities.

Only one microbial pesticide for plant pathogen control has been in use for any length of time. Galltrol suppresses the pathogen that causes crown gall disease (*Agrobacterium tumefaciens*) (138).[5] However, this one product's effectiveness provides only limited insight into the general usefulness of microbial pesticides against plant pathogens. Crown gall disease is a special case; because the disease results from infection of plant wounds, the microbial pesticide has to be active for only a few hours while the plant wound closes. The plant then ceases to be susceptible to infection (308).

Pheromones and Other Approaches

In successful programs against pink bollworm (*Pectinophora gossypiella*) and oriental fruit moth (*Grapholita molesta*), pheromone mating disrupters have given results equal to or better than those of insecticides (41). The use of pheromones to disrupt mating works only on pests using these chemicals to find mates over long distances, such as most moths—which are a large proportion of the most important insect pests. Pheromones are truly species specific, with each working on only a single pest. They do not injure natural enemies and can be combined with insecticides. In some cases, it may be necessary to combine pheromones and pesticides to reduce the pest population sufficiently so that it can be managed with mating disruption (411). Some pheromone products have performed erratically in the field; the problem has been attributed to poor formulation and to labels that supply inadequate information for proper use (41,175). High costs of pheromone use is another problem.

Experience with the screwworm (*Cochliomyia hominivorax*) program has shown that the sterile insect approach can be quite successful. During the 1970s, however, that program suffered some periods of poor performance as a result of some unsound assumptions about the behavior of the flies; the experience underscores the importance of basic knowledge of the pests' life cycle and behavior when using this approach (411). Efforts to suppress additional pests using sterile releases have had only limited success. Other genetic manipulations of pests are being studied and have not yet demonstrated their potential.

CURRENT USE OF BBTS IN THE U.S.

Table 3-1 summarizes available data on current usage of BBTs in the United States.[6] Usage of BBTs is uneven. The vast majority now in place are for control of insect pests in arable agriculture (cultivated lands), forestry, and aquatic environments. However, use is growing for insect control in urban and suburban settings as new nematode and pheromone bait products become available for turf and household pests. BBTs have virtually no role at present in the control of weeds in arable agriculture, even though this is where approximately 57 percent of conventional pesticide use occurs in the United States. Weed control has been best addressed in rangelands, pastures, and waterways, specifically by classical

[5] About a half-dozen new microbial pesticide products for use against plant pathogens became available in 1994 and 1995.

[6] The focus here is on the United States because the success of a technology abroad may not necessarily translate directly into potential for U.S. adoption. There are marked international differences in farming practices and in important social and economic factors. For example, virus-based pesticides have achieved wider use in countries where lower labor costs keep the cost of production low.

biological control. Few BBTs are yet in use against plant pathogens.

Applications

The goals of pest management vary with the application site. Application sites also differ in who practices pest control and in the range of available, acceptable, or feasible pest control technologies. The necessary or desired level of pest suppression is higher under some circumstances than others; for example, blemish-free fruit production requires very low rates of insect damage, whereas greater pest abundance may be tolerated in forests or rangelands. BBTs may be easier to adopt in the latter circumstance because the technologies usually suppress, but do not locally eliminate, pests. Other pest control technologies that compete with BBTs are more common in some applications, such as major crops. These factors, combined with the uneven availability of BBTs, have generated today's hit-or-miss pattern of BBT use.

Arable Agriculture

Current use of BBTs in arable agriculture (cultivated lands) is confined almost completely to insect pests. A number of major food processors and growers have begun to rely on BBTs in "biointensive" IPM systems (figure 3-2). From 1990 to 1993, for example, the Campbell Soup Company worked closely with Mexican tomato growers to eliminate all uses of chemical insecticides. The resulting system combined monitoring, Bt, pheromones, and *Trichogramma* wasp releases to provide comparable control of insect pests at a lower cost (30).

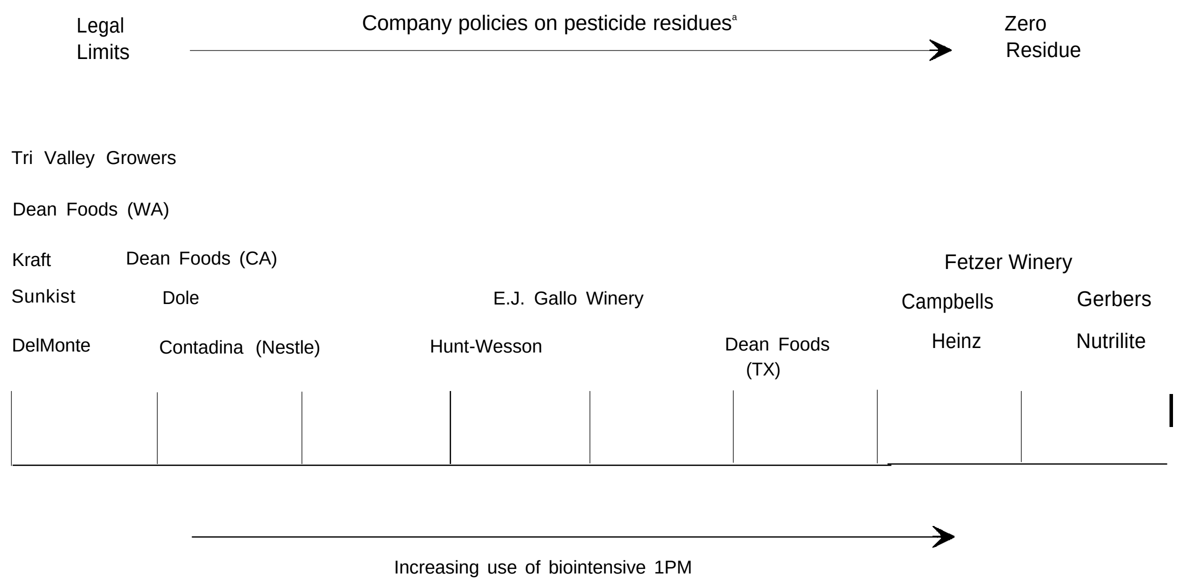
Millions of acres of U.S. crops are currently protected from one or more pests by the introduction of classical biological control agents which have provided some level of suppression for 63 arthropod pests (123,411). Most of these biological control agents were introduced some time ago, but others are fairly recent; for example, introduction of parasites against the alfalfa weevil (*Hypera postica*) from 1980 through 1992 contributed significantly to a reduction in that pest's abundance and impacts (174).

Augmentative releases of natural enemies by farmers occur primarily in vegetable, fruit, and nut crops (table 3-1) (377). Many of these uses are relatively recent. However, augmentation is a long-standing practice in some areas. In the 1930s a number of California citrus growers formed the Filmore Citrus Protective District, a cooperative that now produces natural enemies for use against citrus pests such as mealybugs and scales on more than 9,000 acres (173).

Augmentative use of natural enemies in greenhouse agriculture is growing (411). The approach is widespread in Europe, where cultivation of vegetable crops in greenhouses is more common. Greenhouse agriculture in the United States occurs on only several hundred acres. The greenhouse industry for ornamental plants is much larger (valued at $2.5 billion in 1993), but the potential for use of natural enemies here is lower because less pest damage is tolerated on the products and new chemicals may provide significant competition (box 3-2) (411).

Few data quantify how frequently farmers deliberately modify farming practices to conserve natural enemies on U.S. croplands. Intercropping, modification of cropping practices, and selection of crop varieties to enhance natural enemies all look promising to researchers but have not been widely adopted (411). Some California vineyards and almond growers report that certain vegetation practices enhance natural enemies of arthropod pests and plant pathogens (257,258). Other management practices that incidentally conserve natural enemies are more broadly used. One example is the routine monitoring of natural enemies and pests in commercial orchards; farmers delay use of insecticides if the ratio of predators to pests is high enough to prevent pest damage (411). Vegetable, potato, and cotton growers commonly consider the effects of pesticides on natural enemies when deciding which chemicals to use and when to apply them (table 3-1) (377). Similar practices are widespread among Pennsylvania apple growers (282).

Figure 3-2: Adoption of Biointensive IPM by Major Food Companies



SOURCE: Off Ice of Technology Assessment workshop on The Role of the Private Sector in Biologically Based Technologies for Pest Control, Washington, DC, September 20-21, 1994.

NOTE: The term *biointensive IPM* refers to an 1PM system designed to increase plant health, This goal is generally obtained through the use of BBTs for pest control in addition to other crop management practices. This figure was presented during the OTA Workshop on the Role of the Private Sector. It is included here for illustration purposes only, OTA makes no claim as to the accuracy of the data.

[a]Assignment along this continuum is based upon the company's stated policy regarding the pesticide residue in the final shelf product and the company's level of use of BBTs in 1PM programs.

TABLE 3-1: Available Data on the Use of BBTs in the U.S.

Applications	Insect/ invertebrate pests	Weeds	Plant pathogens
Agriculture arable crops	**Biological control** ■ 63 arthropod pests are under some level of suppression by classical biological control. ■ 28 states operate their own biological control programs. ■ Biological control is used in 10% of greenhouses, 8% of nurseries and 8% of sod production.[a] ■ Augmentative releases take place on an estimated 19% of the cultivated fruit and nut acreage.[b] ■ Farmers purchase natural enemies for use on 3% of the cultivated vegetable acreage.[b] ■ More than 86 U.S. companies produce or market natural enemies with annual sales of approximately $9 to $10 million. ■ Beneficial mites are used on an estimated 50 to 70% of California strawberry acreage. ■ Farmers change or select pesticides to protect natural enemies on 37% of cultivated vegetable acreage.[b] ■ Growers decrease insecticides to protect natural enemies on 22% of cultivated acres of fall potatoes.[b] ■ Growers consider natural enemies when making pesticide decisions for 57% of cultivated cotton acreage.[b]	**Biological control** ■ No weeds are currently under classical biological control. ■ No augmentative biological control agents are available.	
	Microbial pesticides[c] ■ Bt-based microbial pesticides are used on vegetable crops, potatoes, cotton and corn. ■ 46% of nematode sales in 1993 were for use on arable crops.[d]	**Microbial pesticides** ■ No microbial pesticides are now on the market.[e]	**Microbial pesticides** ■ Two microbial pesticides have annual sales exceeding $100,000 for crown gall disease (*Agrobacterium tumefaciens)*. ■ Three microbial seed treatments were first sold in 1994 for seed planted on 3 to 5 million acres of cotton, peanuts, and beans. ■ Three new microbial products for control of postharvest diseases became available in 1994 and 1995.

(continued)

TABLE 3-1: Available Data on the Use of BBTs in the U.S. (Cont'd.)

Applications	Insect/ invertebrate pests	Weeds	Plant pathogens
	Pheromones ■ In 1994 there were 20 registered, commercially available pheromone formulations for the control of over 20 moth pests. ■ Pheromone products are used on 37% of the cultivated fruit and nut acreage.[f] ■ Pheromone products are used on 7% of the cultivated vegetable acreage.[f] ■ Pheromones were used against oriental fruit moths on approximately 10,000 acres of peach and nectarine orchards in 1990. ■ In 1993, pheromones were used to disrupt mating of codling moths (*Cydia pomonella*) on more than 24,000 acres of apple and pear orchards (slightly less than 5% of the total U.S. apple and pear acreage). ■ In 1995, pheromones are expected to be used on over 81,000 acres in Arizona (about 25% of the state's cotton acreage). **Other methods** ■ Sterile insect approach has successfully eliminated the screwworm (*Cochliomyia hominivorax*) from the United States; the method is now in use against the Mediterranean fruit fly (*Ceratitis capitata*) in California.		**Other methods** ■ Cross protection is being used in Florida on a pilot basis for control of citrus decline.
Rangeland/ uncultivated pastures/ forests	**Biological control** ■ 500,000 parasitic wasps were sold for gypsy moth control in 1994.	**Biological control** ■ 18 species of weeds are under some level of suppression due to classical biological control. ■ Programs to conserve and distribute natural enemies operate in Oregon and Montana. ■ 28 natural enemies are now sold by at least seven retail companies for augmentative uses.	

(continued)

TABLE 3-1: Available Data on the Use of BBTs in the U.S. (Cont'd.)

Applications	Insect/ invertebrate pests	Weeds	Plant pathogens
	Microbial pesticides[c] ■ One protozoan microbial pesticide (*Nosema locustae*), produced by two U.S. companies, is in use for grasshopper control. ■ For control of the European gypsy moth, in 1994, Bt was used on more than 374,000 acres in 11 states, and Gypchek (a virus-based pesticide) was used on nearly 6,000 acres in 4 states.		
Urban/ suburban environments	**Biological control** ■ Ash whitefly (*Siphoninus phillyreae*) is under complete control by classical biological control. ■ Natural enemies such as lady beetles, green lacewings, and trichogramma wasps are sold to gardeners. ■ Horse owners are a major market for fly parasites. **Microbial pesticides[c]** ■ Bio-Path roach bait with microbial pesticide has been marketed since 1993 for control of cockroaches. ■ Homeowners represented 35% of U.S. nematode sales in 1993.[d] ■ Bt is sold for consumer use against garden pests and mosquitoes. ■ Four formulations of the fungus *Beauvaria bassiana* became available in 1995 for control of ornamental and turf pests. **Pheromones** ■ Pheromone sticky traps are sold in garden centers for use against moth pests and Japanese beetles (*Popillia japonica*).		**Microbial pesticides** ■ One microbial pesticide is marketed to protect nursery plants, such as rose bushes and other ornamental plants, from crown gall disease. ■ Two microbial pesticides became available in 1995 for use as a greenhouse soil amendment and golf course inoculant.
Aquatic environments	**Biological control** ■ Competitor snails are widely used in Puerto Rico for control of snails that carry human disease. ■ At least three fishes are used for mosquito control. ■ At least seven aquaculture facilities commercially sell mosquito fish. ■ Two fishes are used to control nuisance fish.	**Biological Control** ■ Three species are under some level of suppression due to classical biological control. ■ Grass carp have been released into lakes/rivers/streams of 35 states. ■ Limited use is made of other fishes for weed control.	

(continued)

TABLE 3-1: Available Data on the Use of BBTs in the U.S. (Cont'd.)

Applications	Insect/ invertebrate pests	Weeds	Plant pathogens
	Microbial pesticides[c] ■ Bt-based microbial pesticides are in use for mosquito and blackfly control.		

[a] Based on a limited survey by the USDA NAPIAP program; the meaning of biological control was unspecified.

[b] Based on extensive survey by the USDA Economic Research Service. The survey used the term *beneficial*, but did not specify the meaning. Growers may have included bees in their responses. This is a significant problem for interpreting data on fruits and nuts, but less so on vegetables and cotton.

[c] Annual U.S. sales of microbial pesticides are between $60 million to $100 million annually, mostly for use in agriculture and forestry. Some 249 microbial pesticides are now registered with EPA. This number does not, however, indicate how many are currently produced commercially or their level of use.

[d] Nematodes were sold for control of 33 insect pests on 40,000 acres in 1993. This was expected to increase to 88,000 acres for 1994. The market can be broken down to 35% for homeowners, 46% for minor use crops, and 2% miscellaneous.

[e] Based on extensive survey by the USDA Economic Research Service. Pheromone use could include monitoring and control methods.

[f] Two products formerly were on the market in the United States, Collego for control of northern joint vetch (*Aeschynomene virginia*) and DeVine for control of citrus strangler vine (*Morrenia odorata*). Although effective against their intended targets, neither could sustain large enough markets to justify continued production. DeVine has just recently been put back on the market by Abbott Laboratories as a result of cooperative efforts with EPA.

SOURCES: Compiled by the Office of Technology Assessment, U.S. Congress, 1995, from: R. Cardé and A. Minks, "Control of Moth Pests By Mating Disruption: Successes and Constraints," *Annual Review of Entomology* 40:559-585, 1995; D.J. Greathead and A.H. Greathead, "Biological Control of Insect Pests By Insect Parasitoids and Predators: The Biocat Database," *Biocontrol News and Information* 13(4):61N-68N, 1992; C.D. Hunter, *Suppliers of Beneficial Organisms in North America* (Sacramento, CA: California Environmental Protection Agency, 1994); A. Kuris, Department of Biological Sciences and Marine Science Institute, University of California, Santa Barbara, CA, "A Review of Biologically Based Technologies for Pest Control in Aquatic Habitats," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington DC, October, 1994; Oregon State University, Integrated Plant Protection Center, *Areawide Management of the Codling Moth: Implementation of a Comprehensive IPM Program For Pome Fruit Crops in the Western United States* (Corvalis, OR: July 1994); M. Padgett, Economic Research Service, U.S. Department of Agriculture, Washington, DC, personal communication, June 26, 1995; U.S. Department of Agriculture, Economic Research Service, *Adoption of Integrated Pest Management in U.S. Agriculture,* prepared by A. Vandeman, et al., Bulletin No. 707 (Washington, DC: 1994); U.S. Department of Agriculture, Forest Service, *Gypsy Moth News,* (35): September 1994; U.S. Department of Agriculture, National Agricultural Pesticide Impact Assessment Program, *The Biologic and Economic Assessment of Chlorpyrifos and Diazinon in Ornamentals and Sod Production*, 1994; R. Van Driesche et al., Department of Entomology, University of Massachusetts, Amherst, MA, "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared by the Office of Technology Assessment, U.S. Congress, Washington, DC, December, 1994; A.K. Watson, Department of Plant Science, McGill University, Quebec, Canada, "Biologically Based Technologies for Pest Control: Agricultural Weeds," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.

NOTE: This table summarizes all data available to OTA; the summary is not comprehensive.

BOX 3-2: How Changes in Available Pesticides Affect Adoption of BBTs

Chloronicotinyls (synthetic nicotines) are one of the newest classes of insecticides. The first of these, imidacloprid, was marketed by the Miles Corporation in 1994. The chemical has several useful qualities. It diffuses throughout a plant after being applied to the roots and can persist in woody tissues for weeks or years. Many plant-feeding insects are susceptible. Perhaps most important, imidacloprid is thought to be relatively nontoxic to humans. Finally, it moves slowly through soils—enhancing its insecticidal impact and diminishing the risk of groundwater contamination.

The effect of imidacloprid and related chemicals is likely to be a reduction in use of BBTs. This effect has already been seen in the poinsettia industry, where several greenhouses being set up for biological control of whiteflies in 1994 opted instead to use potting mix treatments of imidacloprid. If experience is any guide, at least one important greenhouse pest—the silverleaf whitefly *(Bemisia argentifolii)* --is likely to develop resistance to imidacloprid within a few seasons, This situation will again stimulate interest in BBTs.

SOURCES: W. Cranshaw, Department of Entomology, Colorado State University, Fort Collins, CO, "Biologically Based Technologies for Pest Control: Urban and Suburban Environments, " unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington DC, 1994; R. Van Driesche et al., Department of Entomology, University of Massachusetts, Amherst, MA, letter to the Office of Technology Assessment, US. Congress, Washington D. C., July 1995.

Microbial pesticides based on Bt are by far the most commonly used in agriculture. They are frequently the method of choice when a pest develops resistance to chemical control methods (41 1). The major uses are for pests of vegetable crops, with recent increases in use on potatoes, cotton, and corn following the discovery of new Bt strains and development of new delivery methods (411). Increases on cotton relate, in part, to the tobacco budworm's development of resistance to pyrethroids (41 1). Some 1PM programs integrating Bt show economic returns equivalent to those of conventional pest control programs because pesticide costs decline in the Bt programs (41 1).

Microbial pesticides based on the bacterium Bacillus thuringiensis, or Bt, are the most common ones in use today.

Agricultural Research Service, USDA

Until recently, Bt-based products were the only microbial pesticides available for use against arthropod pests. The fungus *Beauvaria bassiana* has now been formulated for use against a variety of pests, including grasshoppers, Mormon crickets *(Anabrus simplex),* locusts, whiteflies, aphids, thrips, mealybugs, leafhoppers, psyllids, and mites. Two products by Troy Biosciences based on this fungus, Naturalis-O and Naturalis-T, have recently come on the market. Two other products, Mycotrol-GM and Mycotrol-WP, have just been registered by the EPA and are expected to be available soon.

Virus-based products have not been available in the United States for control of agricultural pests (with the temporary exception of Elcar; see box 3-l). One virus product, Sped-X from Biosys, just came on the market for use against the beet armyworm. NPV viruses that affect the celery looper and codling moth were registered with EPA this year. Virus-based pesticides are now used against vegetable, fruit, and cotton pests in

China, Asia, India, Egypt, Australia, Kenya, and Central and South America; in Brazil alone over one million acres of soybeans are treated with virus-based pesticides each year (411).

The principal uses of pheromones today are as mating disruptants in cotton, fruit, and vegetables. Aerial applications of pheromones to disrupt mating of the pink bollworm in the Parker Valley of Arizona led to a decline in cotton damage from 23.4 percent in 1989 with a conventional pesticide program to zero percent in 1993 (411). Areawide use of the pheromone approach has grown to an estimated 81,000 acres in 1995, or about a quarter of the state's total acreage of the crop (411). Other highly successful commercial applications have been for the oriental fruit moth in peaches and the tomato pinworm (*Keiferia lycopersicella*). From 1991 to 1993, applications of Isomate, a pheromone to disrupt the mating of the codling moth, grew from 4,633 to 24,710 acres of apple and pear orchards in the western United States (259). Adoption of these programs occurred because pest resistance made conventional pesticides marginally or completely ineffective (411).

The most successful use of the sterile insect technique has been in the program to eradicate the screwworm, which eats the flesh of livestock and deer. Releases of sterile male screwworms in the United States began in 1951 and the pest was eliminated from the country by 1982 (see box 5-2 in chapter 5). Continuing programs have eradicated the pest from the north of Central America as well. An ongoing program in place in California against the Mediterranean fruit fly (*Ceratitus capitata*) has not eliminated the pest: The fly persisted in the Los Angeles basin in 1994 despite releases of 14 billion sterile flies in 1993 (411). Whether this result represents a failure of the sterile insect technique or repeated introduction of the pest is unclear.

Various BBTs (natural enemies, microbial pesticides, behavior-modifying chemicals) are under investigation for control of pests in grain storage facilities (344). Cleanit AG of Switzerland is developing a product based on a pheromone that repels mice to reduce rodent damage (115). None are yet in use.

Virtually no BBTs are in use today for control of weeds in arable agriculture.[7] Classical biological control has been attempted for four weeds without success to date. Potential microbial pesticides have been explored for 23 crop weeds, and effective agents found for 13. Two were eventually marketed: Collego was registered in 1982 for control of northern joint vetch (*Aeschynomene virginica*) and DeVine was registered in 1981 for control of citrus strangler vine (*Morrenia odorata*) in Florida citrus groves. These products were later withdrawn from commercial sale because they did not generate large enough markets (see box 3-1 earlier in this chapter). The problem with DeVine was that it proved too effective, persisting in the field and giving good weed control for more than three to four years at some sites (420,49). Small markets also resulted because each microbial product controlled only a single weed, whereas farmers usually have to deal with many weeds at once. This year, the producer of DeVine, Abbott Laboratories, cooperated with EPA to bring the product back on the market (49).

Conventional pesticides have never been able to control some serious plant diseases caused by viruses and bacteria (138). Microbial products and systems for control of plant diseases are just now becoming commercially available (138). These microbes may suppress disease-causing microbes by producing antibiotics or other injurious compounds, by competing with them for nutrients or other essential resources, or by inducing resistance to the disease in the host plant. The extent to which the new microbial approaches will be adopted and the level of control they will provide are uncertain. The best-documented agricultural use of a BBT against a plant pathogen is for crown gall disease—a tumor-producing disease caused by bacteria

[7] A number have, however, been successful against weeds on uncultivated lands, as the next section describes.

(*Agrobacterium* spp.) and affecting crops such as grapes. No pesticides work against this disease (138). Strains of a related species (*A. radiobacter*) suppress the disease, but each strain works only against certain disease strains. Two microbial pesticides for crown gall are sold in the United States, Galltrol by the AgBioChem Company and Norbac 84C by the NorTel Lab, with annual sales exceeding $100,000 (138).

In 1994 at least three new microbial products that enhance plant growth, in part by suppressing root-dwelling bacteria, came on the market: Kodiak, Epic, and Quantum 4000 from the Gustafson Company (138). These seed treatments, which colonize growing roots once seeds germinate, are used in combination with chemical fungicides. Sales in 1994 were for seeds sufficient for planting three million to five million acres of cotton, peanuts, and beans; this figure is expected to expand to 20 to 30 million acres by the year 2000 (138). The first commercial products for control of postharvest plant disease (which blemishes and causes rot on harvested crops) are just now coming on the market also. Bio-Save 10 and 11 (products based on the bacterium *Pseudomonas syringae* from EcoScience Corporation) and Aspire (product based on the yeast *Candida oleophila* from Ecogen) became available in 1995 for control of major postharvest diseases of apple, pear, and citrus (161).

Disease-suppressive soils and composts reduce crop diseases, it is thought, through the action of bacteria, fungi, or other microbes that dwell in these materials. Suppressive soils occur naturally in some areas or can be created by specific farming practices. Almost all are maintained by individual farmers, and no commercial products are available (138). Suppressive composts are widely used in horticulture but are not advertised for their disease-suppressive characteristics.

Pastures, Rangelands, and Forests

Pest problems in these habitats pose special problems. The lands generally are of lower economic value, making it difficult to justify the costs of expensive pest control programs based on conventional pesticides. Many forests and rangelands also encompass environmentally sensitive habitats, such as those adjacent to waterways, where use of pesticides may be restricted or prohibited. The most commonly used BBTs in these areas are various forms of biological control because of the low costs and general lack of impacts on nontarget organisms.

Rangelands and pastures are two of the few areas where BBTs currently are used for weed control. Classical biological control agents have been introduced against 40 U.S. weeds. Currently the approach has provided some level of suppression for 18 weeds and excellent control over some or most of the range of seven of these species (420). The successes include musk thistle (*Carduus nutans*), controlled by the weevil *Rhinocyllus conicus*, and skeletonweed (*Chondrilla juncea*), by *Puccina chondrillina* (420).

A number of programs propagate and distribute weed natural enemies to enhance their effects. The Oregon Department of Agriculture's weed program has introduced 42 natural enemies against 20 target plant pests since it began in the 1970s. Program staff now collect and transfer biological control agents across weed-infested areas to maximize the agents' impacts. In Montana, county extension agents cooperate with high schools and local 4-H clubs to run a similar program involving high school students (266). At least seven commercial suppliers now harvest weed biological control agents collected from the field for sale to ranchers, land managers, and others (155).

Rangeland managers sometimes modify livestock grazing practices to help reduce weed populations. The extent and the effectiveness of this practice are unclear. In areas managed to conserve native biodiversity, the use of livestock to help reduce weeds is sometimes undesirable because the cattle do not confine their impacts to target weeds (332). Under some circumstances, however, cattle grazing can enhance plant biodiversity. Other BBTs for weed control are not yet in use. Plant diseases have been evaluated as potential microbial pesticides for five weeds of

In Montana students and teachers are part of a hands-on program to distribute natural enemies of noxious weeds that degrade rangelands,

W. Pearson, Stillwater Weed Control

pastures, rangelands, and forests, but none has been developed into a commercial product (420).

Biological control has had less success against insect pests of forests and rangelands. Few programs have been undertaken, and these have had mixed results. The most notable success is the larch casebearer *(Coleophora laricella);* introduction of five insect parasites from 1931 through 1983 has provided significant suppression of the pest throughout its North American range of hundreds of millions of acres (284).[8] In contrast, the repeated expensive efforts to control European gypsy moth since 1906 by classical biological control have failed to produce significant suppression of the pest (table 3-1) (284).

Microbial pesticides have proved more successful than classical biological control against the European gypsy moth. Bt now forms the core of the nation's multistate gypsy moth suppression program conducted by the U.S. Forest Service, the Animal and Plant Health Inspection Service (APHIS), and state agencies (382,384). This is the single largest use of Bt in the United States, with annual applications occurring on at least 374,000 acres (382). Isolated infestations of European gypsy moth have been eliminated by Bt applications, but the microbial pesticide has yielded more mixed results in reducing defoliation in high-density areas (284). The European gypsy moth NPV virus (Gypchek), produced by a commercial firm under contract to the Forest Service, also is now applied to about 6,000 acres annually (382). The virus is costly and in limited supply; in 1994 the state of North Carolina appropriated almost all of the U.S. supply to combat the newly arrived Asian gypsy moth.[9]

Several additional techniques complete the current BBT arsenal against European gypsy moth. Two natural enemies are sold by a private company (the National Gypsy Moth Management Group) to federal, state, and municipal agencies for augmentative use at isolated infestations and along the leading edges of moth outbreaks (284). In 1994, an estimated 500,000 wasps (costing from $0.25 to $0.52 each) were sold, to be applied at a rate of 50 per acre. Impacts of these natural enemies are uncertain. Finally, a gypsy moth pheromone has been used to identify and monitor the spread of gypsy moth infestations.

Pheromone-based approaches have limited success in controlling U.S. forest pests (284). The only known successful use of mating disruptants has been to control the western pine shoot borer, *Eucosoma sonamana,* in pine plantations, where pest levels were suppressed 75 percent (60). In the late 1970s and early 1980s, the mass trapping approach was used in Scandinavia against the spruce bark beetle on over 4.5 million acres of forest (310). The pest's abundance declined, but it is unclear whether the pheromone

8 However, according to some scientists, the success of the larch casebearer program is impossible to prove. Too little monitoring 'as conducted to establish a clear cause and effect relationship between the biological control releases and the suppression of the pest (203A). Proving this type of causality in ecological systems is, however, notoriously difficult,

9 The Asian gypsy moth disperses more readily than the European gypsy moth and harms different trees. Detection of the Asian strain in the United States not on] y caused worry about its immediate impact but also raised concern that the two strains would interbreed and give rise to an especially damaging type of gypsy moth.

method caused the drop (39). Nevertheless, it would be the method of choice if another pest outbreak occurred because conventional pesticides are prohibited there (310).

Other pheromone techniques are under development or used occasionally, in particular, against the southern and mountain bark beetles. Pheromones that enhance beetle aggregation have been applied to tree stands prior to cutting, causing the beetles to aggregate and then die when the trees are cut and removed (284). A pheromone that protects trees from attack by repelling beetles has recently been patented and has been tested in the National Forests in Louisiana, and a second is under development (284).

Grasshoppers are the only significant insect pest of rangelands to be targeted thus far by BBTs. Of the more than 300 native grasshopper species of western rangelands, 10 to 15 periodically have population outbreaks and become major pests (284). A microbial pesticide for grasshoppers, based on the protozoan *Nosema locustae,* is produced commercially by two U.S. companies: Bozeman Bio-Tech (Montana) and M&R Durango (Colorado). The current number of acres treated with this product is very small compared with the number treated with chemical pesticides (411). A product based on the fungus *Beauvaria bassiana* was registered by Mycotech Corporation in 1995, as mentioned earlier in this chapter. Two other BBT alternatives under research are a fungus (*Entomophaga praxibuli*) and a parasitic wasp (*Scelio parvicornis*). The latter was recently denied a permit for release by the USDA Animal and Plant Health Inspection Service because of concerns about potential nontarget impacts (299).

Natural Areas, Parks, and Wildlands[10]

Until recently, few BBTs were targeted specifically at pests of natural areas and wildlands. Increasing awareness of how invasive nonindigenous (exotic) species are threatening native biodiversity (338), however, has led natural area managers begin to explore BBT options for pest control—classical biological control, in particular (box 3-3).

Classical biological control has particular advantages in natural areas and wildlands (284). An established biological control agent can provide indefinite control of a pest, tracking its spread and bringing it under control at new sites. Biological control may thus be the only economically feasible option for certain widespread pests like yellow starthistle (*Centaurea solstitialis*)—a weed that displaces native vegetation and degrades wildlife habitat on western rangelands—for which the costs of conventional pesticides would be exorbitant. Classical biological control agents, if properly screened are unlikely to have undesirable environmental impacts (see chapter 4, however, for a discussion of potential impacts and screening methods).

Natural area managers have not wholeheartedly embraced biological control (284). The primary concern is whether impacts of the control agent are confined to the pest or also affect other organisms. Far more so than in agriculture, concerns of natural area managers extend to a wide variety of organisms, and many see potential nontarget impacts as a serious liability. For similar reasons, natural area managers view use of biological control for native pest species with a good deal of alarm. Certain species may be pests in some locales but integral components of native ecosystems in others. Poison ivy (*Toxicodendron radicans*), for example, is an important source of wildlife forage. Moreover, native pests are far more likely to have nonpest relatives in this country that would be especially vulnerable to their biological control agents (332).

Despite these concerns, natural area managers have begun to proceed cautiously with classical biological control programs. Most have been

[10] Natural areas and wildlands are distinguished from rangelands, forests, and pastures. The latter are managed primarily for their resource values, such as cattle grazing and timber. Natural areas and wildlands, in contrast, are managed to support native plants and animals; they include many federal and state parks, refuges, and wilderness areas.

BOX 3-3: How Conservationists are Turning to Biological Control to Help Save Biodiversity

The imported red fire ant (*Solenopsis invicta*) first entered the United States from South America in the 1930s. It has since spread to 250 million acres from Texas to Virginia. Conventional pesticides have proved ineffective at controlling the pest, despite expenditures of more than $200 million. Some experts believe that the mass sprayings in the 1950s and 1960s may even have hastened its spread by weakening native ant species that could compete with the fire ant.

The red fire ant is well known for its aggressive stings to humans that can cause allergic reactions and even death in sensitive individuals. It has similar effects on domesticated animals. Texas veterinarians rank fire ants as a serious threat to animal health and report that annual costs to treat stung animals amount to $750,000 in that state alone.

Now conservation biologists across the country are warning that the red fire ant may have dire impacts on biodiversity as well. In places, some scientists believe that it has reduced native insect species by as much as 40 percent. Seed-harvesting ants have disappeared in many areas of Texas, along with certain lady beetles, spiders, scorpions, and other arthropods. Studies of Texas pigmy mice show alterations in the mice's behavior and ecology where the red fire ants are present. Survival of white-tailed deer fawns is reduced by half where the ants occur: Facial stings sometimes blind or kill fawns. Declines in one endangered grassland bird (the loggerhead shrike) correlate directly with the presence of fire ants. And the evidence suggests that several other migratory grassland birds may be similarly affected.

According to E.O. Wilson, a well-known biodiversity and ant expert from Harvard University, control of the fire ants may be necessary to avert a small-scale catastrophe for insect biodiversity in the South. Such concerns have prompted scientists in Texas and Utah to search for biological control agents to use against red fire ants. Several flies (*Pseudacteon* spp.) that parasitize the ants are currently under study. Instead of providing direct control of the fire ant, researchers expect the parasites to reduce the fire ant's ability to compete with native ants. Several other biological strategies are being considered, such as treating the ant colonies with the species' own pheromones to halt reproduction. Scientists in Florida also are investigating ways of baiting fire ants into carrying the pathogenic fungus *Beauveria bassiana* back to their nests.

The imported red fire ant is but one of several pests now being targeted for control because of their impacts on biodiversity. Purple loosestrife (*Lythrum salicaria*) and melaleuca (also known as the paperbark tree, *Melaleuca quinquenervia*) are other prominent examples. Both are wetland weeds that displace native plants and degrade wildlife habitats.

SOURCES: J. Grisham, "Attack of the Fire Ant: Scientists Hope New Methods of Biocontrol Can Stop the Advance of this Imported Pest," *BioScience* 44(9):587-590, October 1994; C.C. Mann, "Fire Ants Parlay Their Queens Into a Threat to Biodiversity," *Science* 263:1560-1561, March 18, 1994; J. Randall and M. Pitcairn, Exotic Species Program, The Nature Conservancy, Galt, CA and the Biological Control Program, California Department of Food and Agriculture, Sacramento, CA, "Biologically Based Technologies For Pest Control in Natural Areas and Other Wildlands," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.

conducted by federal, state, and local agencies. A handful of related projects have taken place in private reserves; one was recently approved by the Nature Conservancy (284). Most of these programs have piggybacked on better-supported programs aimed at pests of agriculture, rangelands, commercial forests, urban lands, and navigational waterways, because many of these pests also affect natural areas and wildlands. Examples include the gypsy moth, numerous rangeland weeds, salt cedar (*Tamarix* spp.), and hydrilla (a weed that blocks waterways).

Classical biological control programs in Hawaii have targeted at least one weed invading nature reserve forests, banana polka (*Passiflora mollissima*), using introduced plant diseases

(420). Only a few pests of natural areas in North America that have few or no impacts elsewhere, such as purple loosestrife (*Lythrum salicaria*) and melaleuca (*Melaleuca quinquenervia*), are currently the subjects of ongoing classical biological control programs by federal and state agencies (109,284). Natural area managers generally hold little hope that many new BBTs will be developed specifically for these areas (284).

Urban and Suburban Environments

Pest control takes place in intimate association with human populations in urban and suburban environments. Consequently, potential exposure to pesticidal products is high. Markets have developed for BBT products, in part because of their appeal to consumers who wish to avoid direct contact with conventional pesticides. BBT approaches lacking a commercial product have been exploited only rarely in urban and suburban environments because research by academic and government scientists has generally been lacking. For example, classical biological control has been used against few pests of turfgrass and shade trees (60).

Various bait-type products are sold for control of structural pests (including cockroaches and termites) that infest houses and other buildings. Control of these pests is a multibillion dollar industry in the United States. A new microbial product that came on the market in 1993 is called Bio-Path. It consists of a bait station that harbors fungus spores (*Metarrhizum anisolpliae*) designed to infect entering roaches, which then spread the pathogen to other individuals (60).

Use of natural enemies and microbial pesticides around food preparation and storage areas is another recent development. At least one natural enemy is now sold commercially for use in food storage facilities—the parasitic wasp *Bracon hebetor,* for control of Indianmeal moth (*Plodia interpunctella*) in peanuts. Some controversy has surrounded attempts to expand uses into food preparation areas. The small company Praxis met resistance from state and federal regulators when it began selling pest control programs based on parasitic wasps and nematode pesticides for use in cafeterias and restaurants (70) (see box 4-8 in chapter 4).

Natural enemies have found application in interiorscapes (interior plantings) of shopping malls, hotels, office buildings, zoos, and museums (320). One attraction is that they reduce liability considerations related to public exposure to pesticides. An example is the "Tropical Discovery" display of the Denver Zoological Garden, where establishment of natural enemies has cut the costs of pest control in half and reduced potential impacts of pesticides on animals in the exhibit. Use of natural enemies as an overall strategy in interiorscapes can be hampered if none are available for certain pests like brown soft scale (*Coccus hesperidum*),[11] necessitating use of insecticides that may damage natural enemies where such pests are present (60).

Homeowners seeking to deal with turfgrass pests make up about 35 percent of the U.S. market for nematode-based pesticides (411). The grass seed industry now sells several varieties containing endophytes that enhance pest resistance. Sales of turfgrasses with endophytes are expected to grow because of increasing consumer demand for "environmentally friendly turfgrass" (306). Consequently, the development of techniques to transfer endophytes to new grass species is an especially active area of research in the turfgrass industry.

Nevertheless, interest in BBTs by the lawn and landscape industry has been patchy. One 1990 survey of 17 commercial arborist firms found that 11 used Bt, nine used pheromone traps, and three made augmentative releases of natural enemies (248). An important problem has been inconsistent product performance (see description of milky spore in box 3-1, earlier in this chapter). Another is that microbial pesticides compete directly with other "natural" pesticides. For example, Bt-based pesticides active against

[11] A natural enemy for control of brown soft scale is expected to become commercially available in late 1995 (410A).

leaf beetles came on the market for shade tree care in the mid-1980s. Short field persistence, the need for careful timing of application, and high prices resulted in market failure for these products, especially when botanically derived neem pesticides, which appeared in the early 1990s, proved to be more effective alternatives (60).

Another reason for the relatively low interest in BBTs among landscape companies is the industry's increased emphasis on ensuring that plants are healthy by meeting the plant's environmental requirements. Recommended practices include promoting populations of beneficial microorganisms (i.e., conserving them) to prevent plant diseases (110). BBT products are seen as an adjunct to this approach (295).

Although few classical biological control programs have been targeted toward insect pests of urban and suburban environments, an important recent exception is the ash whitefly (*Siphoninus phillyreae*). Control of this pest by an imported wasp parasite (*Encarsia inaron*) has proved so effective that the whitefly is no longer a major pest in California; the biological control agent has now been released to suppress other infestations of ash whitefly in Arizona and Nevada (60).

Three microbial products are available for control of plant pathogens. Urban and suburban applications of Galltrol are limited to protecting nursery materials, specifically roses and other ornamental plants, for sale to consumers (60). Bio-Trek and T-22G are formulations of *Trichoderma harzianum* that became available in 1995 for use as a greenhouse potting soil amendment and a golf course inoculant. No BBTs currently address urban and suburban weed problems, but products for broadleaf weed (i.e., dandelion) control are under development (60,233).

Aquatic Environments

Most applications of BBTs to aquatic pests thus far have been for control of weeds that block navigational waterways and of the larvae of mosquitoes that pose a risk to human health. The method of choice has often been introduction of fish predators.

The grass carp (*Ctenopharyngodon idella*), a fish that consumes most aquatic plants, has been stocked in more than 35 states for control of aquatic weeds (191). The fish clear plants from waterways so effectively that habitats of other fishes, invertebrates, and waterfowl may be destroyed. At least 21 states now require released grass carp to be sterile to limit their impacts, although another 10 states still allow uses of normal reproductive fish.[12] Certain other fishes, such as blue and red tilapia (*Tilapia aurea* and *T. zillii*), also have been introduced to a lesser extent for aquatic weed control (191).

Classical biological control programs have yielded some control for three important aquatic weeds—alligatorweed (*Alternanthera philoxeroides*), water hyacinth (*Eichhornia crassipes*), and water lettuce (*Pistia stratiotes*) (191). Fungi that could be developed into microbial pesticides have been identified for two aquatic weeds, water hyacinth and Eurasian water milfoil (*Myriophyllum spicatum*), but neither has been developed commercially (420).

Mosquitoes spend the earliest part of their lives as swimming larvae and are the most significant insect pests in aquatic habitats. The mosquito fish (*Gambusia affinis*) is the one most commonly used to control the pest. It is now free-living throughout much of the United States as a result of its widespread release for this purpose (191). Several other fishes (e.g., the flathead minnow, *Pimephales promelas*, and the blue-gill sunfish, *Lepomis macrochirus*) have been put to similar use.

Certain microbial pesticides are in use or under development for mosquito control. A strain of Bt (specifically, *Bacillus thuringiensis israelensis* or Bti) is now widely applied for control of mosquitoes and blackflies. Its use is lim-

[12] Sterility is accomplished by making the fish triploid, that is, having three sets of chromosomes rather than the normal complement of two.

ited to upland and freshwater habitats; it is not effective in major sites for mosquito breeding in salt marshes (134). Another microbial pesticide derived from *Bacillus sphaericus* also is commercially available for mosquito control.

Scientists have identified several fungi that kill mosquitoes (*Coelomyces* spp. and *Lagenidium* spp.). A number of other invertebrates (flatworms, nematodes, and copepod shrimp) have been shown experimentally to consume mosquitoes. None has yet been put to practical use in mosquito control programs (191).

BBTs have also been applied to control invertebrate and fish pests. Releases of a snail competitor (*Marisa cornuarietis*) into Puerto Rican waterways during the 1960s greatly reduced populations of the snail *Biomphalaria glabrata*, a carrier of the parasitic worm that causes schistosomiasis. Prior to the biological control program, this human disease infected approximately one million people in Puerto Rico. Northern pike (*Esox lucius*) and walleye (*Stizostedion vitreum*) have been used to control nuisance fishes, such as the ruffe (*Gymnocephalus cernuus*) (191).

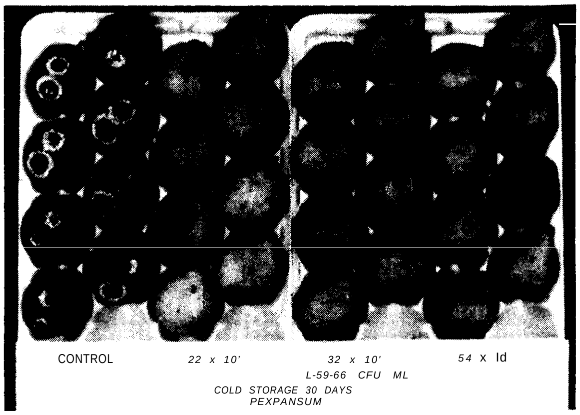
The U.S. invasion of the zebra mussel (*Dreissena* spp.) in the 1980s brought new national attention to the economic and environmental hazards of nonindigenous aquatic pests (338). Scientists have begun to examine various fishes and microorganisms for biological control of this costly pest. Some scientists believe that BBTs have considerable potential for application to aquatic environments generally; for example, classical biological control might control the European green crab (*Carcinus maenas*), a shellfish predator that was recently detected near San Francisco and may imperil the Washington State oyster industry (191). The Australian government has just started a new research center—funded at $1 million annually and with a planned staff of five—to identify biological control agents for nonindigenous marine pests that threaten fisheries or marine ecosystems (192). An important issue, should U.S. interest in aquatic uses of BBTs grow, relates to the virtual lack of federal regulation and the erratic attention by states to deliberate introductions of aquatic species as biological control agents (338) (see box 4-2 in chapter 4).

What's Coming Next

New Microbes and Microbial Pesticides

A wide variety of microbial pesticides are currently under development. When these reach the market they will greatly expand the repertoire of commercial product types. The extent to which these products and approaches will be adopted is uncertain. In some cases, development of new microbial pesticides will involve identification of new strains of microbes currently available. Bt products with activity against a greater range of pests are likely to be developed. Ecogen has already marketed a product (Foil) that acts against both caterpillar and beetle pests by combining the genes of two bacterial strains through conjugation—a naturally occurring process through which bacteria exchange genes.

Other pesticides rapidly coming on line will be based on types of microbes not yet in wide use. Several commercial companies are developing microbial pesticides based on fungi for insect control, including EcoScience Corporation (Bioblast for termite control); Mycotech Corporation (Mycotrol-GH for grasshopper, mormon cricket and locust control, and Mycotrol-WP for whiteflies, aphids, thrips, mealybugs, and psyllids); and Troy BioSciences (Naturalis-O for use on ornamentals against whiteflies, aphids and mites and Naturalis-T for turf use, controlling mole crickets and cinch bugs). Commercial development is well advanced for microbial products (based on bacteria *Pseudomonas fluorescens* and *Erwinia herbicola*) to control fire blight, a very destructive disease of apples and pears caused by the bacterium *Erwinia amylovora*, with sales expected to begin in 1995 (138,161). SoilGard, a product based on the fungus *Gliocladium virens*, for damping-off diseases of seeds and seedlings in greenhouse production of vegetables and ornamental bedding plants, is now in the final phases of development by W.R. Grace Co. (138).



Development of microbial pesticides for controlling the diseases that cause harvested produce to spoil is an active area of research. The unblemished fruit have been treated with a microorganism that prevents the pears from rotting.

Agricultural Research Service, USDA

A number of other microbe-based approaches and products are being researched but are not yet near product development or field use. Scientists predict that more insect viruses (many already identified) will become an attractive option as resistance to conventional pesticides emerges in common pests. Microbial approaches to European gypsy moth control based on protozoans[13] and fungi are under investigation as ways to help combat this tenacious pest (41 1,284). Considerable research interest continues to center on control of common plant diseases such as take-all and root rot diseases of wheat (1 38).

Novel delivery systems for microbial control agents are also under development. One involves putting microbial pesticides that work against plant pathogens into beehives so that bees transport the microbes to the plant (138). Another is based on modifying the algae food of mosquito larvae to contain a mosquito poison (85).

Genetic Manipulations of BBTs and Pests

BBTs are based on living organisms and their products. Consequently, it is not surprising that efforts to improve BBTs focus to a significant degree on genetic modifications through breeding, selection, genetic engineering,[14] and other techniques.

Most microbial pesticides now on the market were developed through the selection of efficacious microbe strains. Many companies involved in the development of microbial pesticides are now attempting to alter such features as kill rate, field persistence, environmental range, and the number of target pests through genetic engineering. Mycogen has recently put four products on the market all based on Cellcap, its genetically engineered Bt encapsulated within a *Pseudomonas fluorescens* bacterium (42). Ecogen brought a genetically engineered Bt on the market in 1995 called Raven (167). Sandoz Corporation recently conducted field tests of genetically engineered Bt in California and elsewhere in the country. Efforts to genetically engineer microbial pesticides are widespread, and they involve most potential product types, including those affecting insects (Bt, NPV viruses, and nematodes), weeds, and plant pathogens (138,191,41 1,420).

The scientific community is divided over the desirability of this approach. Some researchers believe that improvement through genetic modification will be essential for certain types of microbial pesticides to become widely adopted. Others express concern that, as microbial pesticides become more equivalent to conventional pesticides, scientists will engineer out the very characteristics of target specificity and short field persistence that make Bt and other current microbial pesticides relatively benign (41 1).

Similar questions divide scientists over ongoing attempts to genetically modify natural enemies. In this research, breeding, selection, or genetic engineering is being used to enhance the compatibility of natural enemies with conventional pesticides (152). A less precise version of this approach is already practiced in the natural enemy industry; a number of companies collect

13 Protozoans are certain single-celled organisms whose internal structure is more like that of cells from higher organisms than bacteria.

14 Genetic engineering refers to recently developed techniques through which genes are isolated in a laboratory, manipulated, and then inserted stably into another organism. Offspring of the recipient contain the new genes.

their breeding stocks from areas where pesticide use is high and the natural enemies are more likely to have developed some resistance to chemicals. Some entomologists worry, however, that pesticide-resistant natural enemies will discourage the development of biological control methods for other pests (411).

Genetic modification of the pest instead of its control agent has long been practiced in the sterile insect approach. Attempts to extend this method to other types of organisms, such as the sea lamprey (*Petromyzon marinus*)—a parasitic fish that impairs the Great Lakes sport fishery—have been studied but have not yet proved effective (191).

Another approach to genetically modifying pests, by producing pest strains lacking noxious qualities, was first suggested 25 years ago. It is currently under study for a number of medically important pests. Efforts are under way to create genetically engineered mosquitoes that cannot carry and transmit to humans the parasite that causes malaria (4). Similar approaches have tried to make snail vectors of human diseases unable to carry human parasites; as yet, those approaches have been unsuccessful because the genetically altered strains are less viable (191).

Genetic modification of the pest is also being applied to plant diseases. Researchers are trying to develop less damaging ("hypovirulent") strains of the microbes that cause chestnut blight (*Endothia parasitica*, a fungus) and Dutch elm disease (*Ceratocystis ulmi*, another fungus)—diseases responsible for the near elimination of native chestnut (*Castanea sativa*) and elm trees (*Ulmus* spp.) from the American landscape (60,284). The method has already proved successful in Italy where, following inoculation of chestnut trees, a hypovirulent strain spread to become the most common form of the chestnut blight fungus, and chestnut trees are again being harvested commercially.

Although outside the scope of this assessment (see box 2-5 in chapter 2), among the most widely discussed technologies coming on line is genetic engineering of plants for enhanced resistance to pests and pathogens. A number of crop plants, including tomatoes, potatoes, and cotton have been altered to express Bt toxins. Corn seed that has been genetically engineered to produce the Bt toxin has just been approved for commercial sale. Widespread use of such crop cultivars might increase the speed with which pests become resistant to Bt (see chapter 4). The introduction of virus coat protein genes into plants to enhance their resistance to certain viral diseases is being explored, with a new virus-resistant squash expected to become commercially available soon. Questions remain regarding the possibility that introduced virus genes might recombine with other viruses attacking the plant and form new, and possibly more damaging, viral strains.

Other New Tools

Practical applications of techniques discussed in this section lie at least a decade in the future. Allochemicals, for example, are chemicals that plants under attack by a predator emit and that attract the predator's natural enemies. These chemicals might be used to attract and concentrate natural enemies or to trap or deflect pests. Secretion of allochemicals is one of several important plant attributes that may have been weakened in the development of agricultural cultivars because the role of the chemicals in biological control was not well understood (411).

Scientists also are beginning to understand how plants' own sophisticated defense mechanisms might be exploited to suppress plant diseases. These defense mechanisms can be enhanced by exposing the plant or its seeds to certain microbes or chemicals. "Induced resistance" has been demonstrated in at least 25 crops; commercial products based on this approach are under development (233,138). Development of methods to transfer endophytes into plants (including agricultural crops) in which they do not naturally occur is another method under study to increase disease and pest resistance. Plants can also be "cross-protected" by infecting them with a milder strain of a disease agent; this process has been demonstrated in various crop plants. It is now being used on a pilot basis in Florida for control of diseases caused by the citrus tisteza virus which affects 25 million to 30 million sour orange trees in the United States. The same method is being used commercially in South Africa, Brazil, and Australia. Large scale use of cross protection, however, lies well into the future because significant technical problems remain; for example, the same mild strain that gives protection to one crop may produce disease symptoms in another (138).

OBSTACLES TO EXPANDED USE OF BBTS

Explanations of why BBTs are not in wider use usually center on a number of commonly acknowledged obstacles. Certain technical obstacles reflect hard limits to what the technologies can do or how they are produced and delivered in the field. They can be addressed only by adequate adjustment of the research agenda and by provision of mechanisms to ensure that research results become available for field applications (table 3-2). The greater emphasis, however, even among technical experts, is usually on the social, economic, and institutional factors that affect the development and adoption of BBTs, and these require policy solutions.

Integration of BBTs into Pest Control Systems

BBTs almost always need to be integrated into an overall system for pest management—usually an integrated pest management system—that incorporates a variety of tools and techniques to prevent pest problems or to control outbreaks when they occur. While IPM adoption in the United States is growing, it is by no means the dominant approach to pest control. This lack of well-developed IPM systems significantly limits the use of BBTs.

Even the IPM systems in existence today do not always do a good job of incorporating BBTs. Developing integrated programs that include BBTs requires a sustained commitment of resources and expertise (e.g., ref. 133). BBTs must also compete directly with other methods that often provide a superior level of control (see box 3-2, earlier in this chapter). The research on microbial pesticides to bring performance more in line with conventional pesticides is not surprising in this light (149).

Moreover, BBTs require a level and type of knowledge not yet acquired by many pest control practitioners or even by people who advise users, such as members of the Cooperative Extension Service or private pest control consultants. Appropriate information on BBTs may thus be lacking, even where there are users who would be willing to experiment with these approaches (see chapter 5). The proliferation of Internet sites containing information on pest management may eventually provide easier access to information resources for those having the right equipment and software. (See appendix 3-A immediately following this chapter for current list of relevant sites.) At present, however, tracking down correct information is not straightforward or easy; information on the Internet varies in quality and lacks a centralized organization or means of access.

Another problem is that, to a large extent, the field of biological control developed separately from that of IPM (319). This separation poses real difficulties for the full incorporation of biological control into IPM systems. Coordination with other control methods is not always an explicit goal of U.S. research on biological control. Some experts in biological control believe it should never be integrated in IPM programs with conventional pesticides. A symptom of this disciplinary separation is the recent failure to include representation of APHIS's National Biological Control Institute in USDA's current initiative on IPM.

Compatibility with conventional pesticides might be an important determinant of how effectively BBTs can be combined into certain types of IPM programs. Pheromones and many microbial pesticides can be used alongside conventional pesticides (175). Certain microbial pesticides are actually more effective when used in conjunction with chemicals. Biological control poses a different challenge, though. Natural ene-

TABLE 3-2: Priority Research Needs Identified by OTA's Contractors

Research Need	Potential Resulting Benefit
Develop basic information on the biology and ecology of pest systems, including the taxonomy and systematics of pests and control agents	Enable development of more predictive approach to the identification of possible control agents for specific pests Enable development of more sophisticated approaches to biologically based pest management
Improve methods to test for nontarget effects of BBTs	Minimize environmental hazards
Develop application techniques for existing and new BBTs	Enable better use of BBTs under field conditions
Identify new and more efficacious microbes	Improve performance of microbial pesticides
Integrate BBTs into IPM systems	Increase use of BBTs in situations where they will be effective
Improve formulation, production, packaging, and delivery techniques for microbial pesticides (including *in vitro*[a] production methods for viral pesticides)	Reduce costs and improve performance of microbial pesticides
Improve production, packaging, and delivery techniques for natural enemies (including *in vitro*[a] production methods)	Reduce costs and improve performance of natural enemies
Improve formulations for delivery of pheromones	Improve performance of pheromones
Monitor classical biological control agents after release	Improve ability to predict which agents will work Improve documentation of actual efficacy of biological control
Identify BBTs to address pests of natural areas, aquatic habitats, and urban/suburban environments	Address current pest control needs Transfer existing technologies to new applications

[a] *In vitro* refers to production outside a living organism. Current production techniques for most viral pesticides and natural enemies are *in vivo*, that is, the agent is produced on or inside a living organism.

SOURCES: Compiled by Office of Technology Assessment, U.S. Congress, 1995, from G. E. Harman and C.K. Hayes, Departments of Horticultural Sciences and Plant Pathology, Cornell University, Ithaca, NY, "Biologically Based Technologies For Pest Control: Pathogens That Are Pests of Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October 1994; A. Kuris, Department of Biological Sciences and Marine Science Institute, University of California, Santa Barbara, CA, "A Review of Biologically Based Technologies For Pest Control in Aquatic Habitats," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October, 1994; J. Randall and M. Pitcairn, Exotic Species Program, The Nature Conservancy, Galt, CA and the Biological Control Program, California Department of Food and Agriculture, Sacramento, CA, "Biologically Based Technologies for Pest Control in Natural Areas and Other Wildlands," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994; R. Van Driesche et al., Department of Entomology, Univeristy of Massachusetts, Amherst, MA, "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, D.C., December 1994; A.K. Watson, Department of Plant Science, McGill University, Quebec, Canada, "Biologically Based Technologies for Pest Control: Agricultural Weeds," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.

NOTE: This list was derived by comparing and compiling suggested research priorities from background reports prepared by OTA's contractors on the application of BBTs to various categories of pests. A few additions were made by other experts.

mies sold for augmentative uses are highly sensitive to pesticides; suppliers often recommend waiting several weeks following pesticide application before releasing natural enemies.

If pesticides could be selected to minimize their impacts on natural enemies, it might be easier to incorporate the various forms of biological control into IPM systems. One problem is that such information is not widely available. Brian Croft, a professor at Oregon State University, has been accumulating a related database for several years, but support for the project has been erratic and no government agency has attempted to make the information easily accessible to farmers (61,62). Similar data are required for registration of pesticides in Germany (106) (see chapter 4). The impending loss of minor use pesticides may cause some chemicals that are more compatible with natural enemies to become unavailable.

Moreover, it is unclear whether certain BBTs—biological control, sterile insect approaches, and mating disruption—will offer their maximum effects as part of farm-based IPM programs. Some scientists from the USDA Agricultural Research Service believe that certain BBTs work best as part of areawide pest management programs (box 3-4).

BOX 3-4: The Areawide Pest Management Concept

Areawide pest management is an approach that has been widely promoted by E.F. Knipling—former director of the Agricultural Research Service's Insect Pest Management Program and well-known originator of the sterile insect approach that has been so successful in screwworm (*Cochliomyia hominivorax*) eradication.

The concept underlying this approach is that biological methods, specifically, biological control and sterile insect releases, will be most effective if used on a larger geographical scale than just the single farm. Such large-scale programs reduce residual pest populations off the farm and address the tendency of pests and their control agents to move from site to site.

According to Knipling:

> The foundation of most current integrated pest management programs (IPM) is reliance on natural control factors to the maximum extent before resorting to the application of insecticides. While, on a short-term basis, this can go a long way towards reducing the amount of insecticides used, it does not in any way lessen the dependence of individual growers on insecticides as the major component in the integrated system.... We know from experience that natural controls—as vital as they are—do not provide the protection needed for a wide range of persistent insect pests....

Knipling asserts that classical and augmentative biological control will rarely provide the level of control desired by farmers unless the density of the biological control agent is boosted through mass propagation and repeated releases. He believes that several important pests are good candidates for the method, including boll weevil (*Anthonomus grandis*), European corn borer (*Ostrinia nubilalis*), and tropical fruit flies. Knipling's approach remains largely untried to date because of the high costs of even pilot trials of projects at such a large scale.

Evidence from pink bollworm (*Pectinophora gossypiella*) management in Arizona, however, has shown that areawide uses of pheromones can be quite effective. USDA is currently considering areawide programs based on pheromones for codling moth (*Cydia pomenella*) and corn rootworm (*Diabrotica* spp.) as part of its ongoing IPM Initiative.

SOURCES: E.F. Knipling, former Director of Insect Pest Management Program, Agricultural Research Service, U.S. Department of Agriculture, MD, personal communication, June 5, 1995; U.S. Department of Agriculture, Agricultural Research Service, *Principles of Insect Parasitism Analyzed From New Perspectives*, E.F. Knipling, AHN 693 (Washington, DC: U.S. Government Printing Office, 1992).

Understanding the Ecology of Pest Systems

Repeatedly, scientists have called for increased study of the biology and ecology of pest systems. Such information underlies the development of all biologically based pest management, but our current level of knowledge is not high. Increased understanding of pests—how they spread and what causes their populations to rise and fall—would allow better targeting of BBTs to the pests' vulnerabilities. More knowledge of the ecological relationships between pests and their control agents might enable scientists to better predict what controls are likely to work and for what specific pests. As practiced today, the identification of new microbial pesticides and biological control agents is usually based on trial and error, making progress slow.

For example, researchers cannot with great confidence identify in advance *the* specific biological control agent, or even in many cases the *type* of control agent, that will actually suppress a given pest. Instead, scientists usually identify a number of potential agents, release them, and then see which ones, if any, provide some level of pest suppression. Monitoring and evaluation of the impacts of previous biological control programs would help in the development of predictive models to sharpen the focus in classical biological control programs and would improve assessments of the potential ecological risks of biological control releases (see chapter 4). But a chronic lack of such followup studies in the United States means that little such information is now being generated through current programs. The programs of other countries, such as Australia and South Africa, do a far better job in this area (76).

Better understanding of the ecology of pest systems will not, on its own, ensure greater success. Existing theory is not always well incorporated into the development of biological control programs. Moreover, theory only goes so far. The idiosyncrasies of each pest problem will still require case-by-case development of solutions.

Technical Needs and Economic Issues Related to Larger Scale Use

Larger-scale use of BBTs would entail large-scale production, distribution, and application of natural enemies, sterile insects, and microbial pesticides. The necessary technologies are not well developed in many cases. Mass production and application of natural enemies, for example, would be expensive and difficult using current techniques (173). Government agencies and commercial companies currently rear most natural enemies on living material (*in vivo* production). The techniques are labor intensive and expensive. A few of the natural enemies now sold commercially, such as convergent lady beetles (*Hippodamia convergens*) and certain natural enemies of rangeland weeds, are collected from free-living populations. Such collection poses other problems related to effects on the wild populations and the ethics of allowing private companies to remove from public lands natural enemies that have been placed there at public expense (see chapter 4) (185).

As living organisms, natural enemies have a short shelf life and require great care in handling (e.g., a temperature-controlled environment). Basic information about the timing, numbers, and methods of application for natural enemies is scarce. All of these limitations contribute to the current problems with many natural enemies—they are difficult to use, costly, and perform erratically in the field. The development of artificial media for rearing natural enemies (*in vitro* production) would streamline and probably greatly decrease the cost of production. Better packaging and handling methods, as well as better information on application rates and techniques, could improve the consistency and performance of natural enemies. The same technologies could be applied to the production of some types of sterile insects for mass release and could reduce the cost of such programs.

Problems with production and packaging techniques also characterize microbial pesticides. Crossover of fermentation techniques from the pharmaceutical industry has contributed greatly to the development of production capabilities for certain microbial pesticides, including Bt and some fungus-based products. Viruses, however, are still produced in live hosts. This labor-intensive approach has made them so expensive that only one is widely used in the United States (European gypsy moth NPV virus), whereas a number of other NPV viruses are extensively applied in other parts of the world where labor is cheaper (411). Industry representatives generally agree on the need for the development of cost-effective methods of production and storage/ packaging techniques to enhance product shelf life and to improve quality control and performance (149,113).

A major problem is that very little expertise or funding exists in the public sector for developing production methods for natural enemy and microbial pesticide production (138). Similarly, the development of formulations for microbial pesticides and pheromones is typically not well funded. Nor are most scientists, universities, or government research agencies usually willing to participate in research on such practical matters (138). Such research reaps few rewards in the scientific community. The restrictions on open communication imposed by the proprietary nature of the work may further hinder progress (327A).

Past efforts in universities and federal research laboratories have usually stopped, for example, once a microbial strain is identified, with the expectation that it will be picked up by the private sector. But this halt is premature. In the comprehensive cost accounting that companies must do before investing in a product, a number of variables are important—direct R&D costs, costs of production, waste volume generated and costs of disposal, market size, product profitability, and others. Seemingly counter-intuitive decisions by companies *not* to invest in a technology become logical when the total cost equation is examined (149).

Poorly developed production, packaging, and application technologies tend to drive up costs of BBTs, and drive down field performance. The overall result is to reduce the competitiveness of BBTs with other available methods of pest control. Most end up relegated to niche markets where overall expected sales are small. Some BBTs would generate only small markets under the best of circumstances because they address one or only a few pests. Anticipated small markets can doom BBTs where the start-up development costs are high, because the market size may not justify investment by the private sector. According to weed scientists, there are numerous "orphaned" microbial pesticides that would be effective against weeds, but the small market does not warrant the development costs (420).

IMPROVING THE ODDS OF FUTURE SUCCESS

The obstacles just described reflect difficulties in developing BBTs and in moving existing BBTs into practical use. They occur at several key points in the research, development, and implementation of BBTs (figure 3-3). OTA's list is not new. Similar issues have been raised many times over the past 18 years (box 3-5), typically during workshops and meetings of scientific experts, the major goal of which has been to set substantive aspects of the research agenda. Still, numerous issues pertaining more to institutional functioning than to the science of BBTs remain unaddressed. The chapters that follow focus on these institutional problems as well as more technical considerations. Each identifies major issues and provides options that might help resolve these problems in the future.

BOX 3-5: The Message from Experts Remains the Same, but Progress in Bringing BBTs into Use Has Been Slow

In 1978 a special study team coordinated by USDA's Office of Environmental Quality Activities issued the report *Biological Agents for Pest Control: Status and Prospects.* Most of the report's major conclusions are as true today as they were 17 years ago. According to the report:

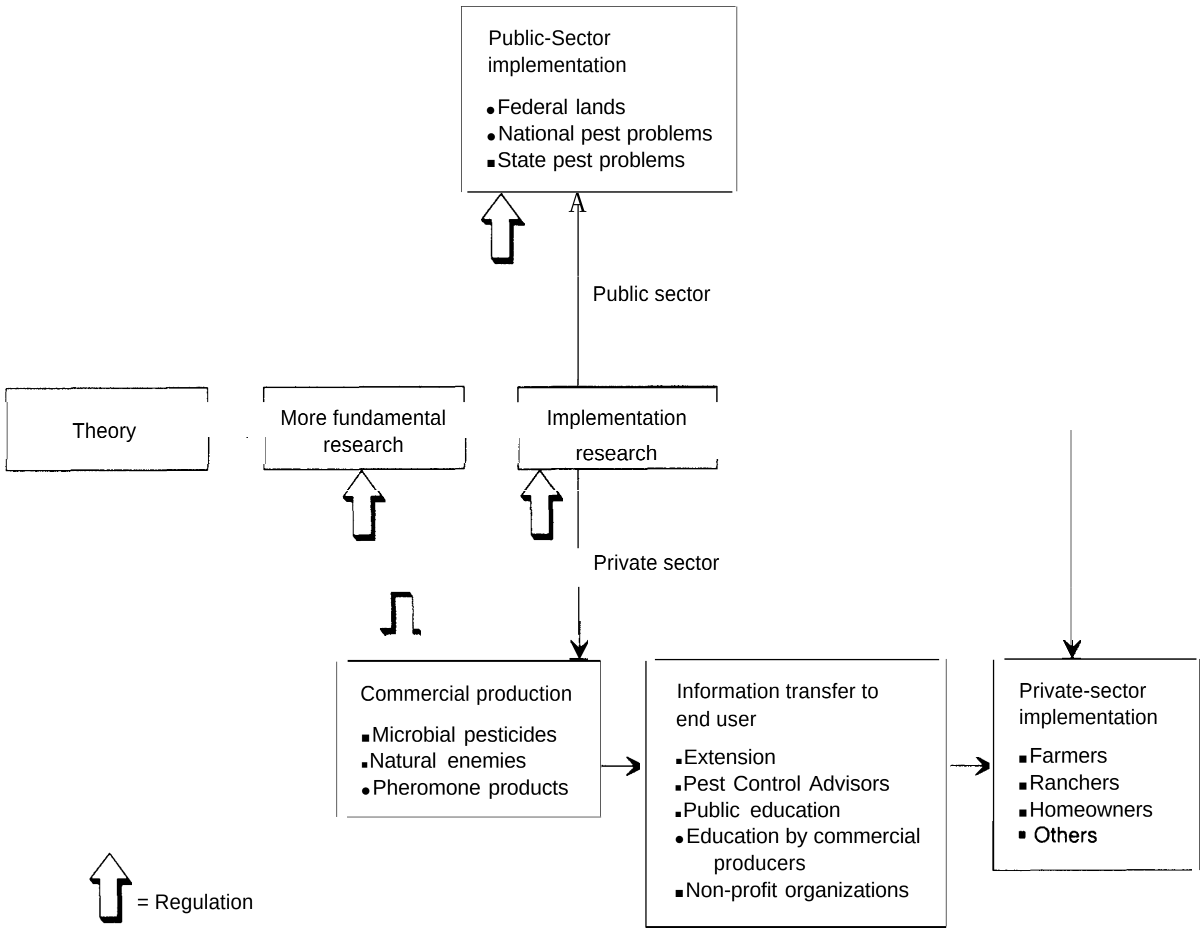
> Pest control is an acceptable and necessary part of modern agriculture and forestry, and is required for the protection of public health and welfare. However, some of the methods used during the past three decades have produced some undesirable side effects. Future needs for pest control can be expected to increase, and, as they do, prevailing conditions and attitudes are likely to dictate an increased emphasis on pest management systems which include the use of alternative methods such as biological control agents.... The practical feasibility of using biological agents... has been amply demonstrated, and the basic principles relevant to the operational aspects of the use of these agents are reasonably well understood.

The study's major findings parallel those of OTA in this report and included the following:

- More research is needed to improve *a priori* predictions of success; to develop production, storage, and application techniques; and to assess the impacts of use;
- Large-scale implementation does not follow easily from demonstrated effectiveness on a small scale;
- Information on pesticide alternatives is not easily available;
- Users need better technical assistance;
- Private enterprise needs incentives to enter this area;
- The regulatory structure needs to be reviewed and clarified; and
- Mechanisms are necessary to coordinate federal and state agencies, the private and the public sectors,

SOURCE: U.S. Department of Agriculture, Biological *Agents for Pest Control: Status and Prospects,* (Washington, DC: U.S. Government Printing Office, February 1978).

FIGURE 3-3: Key Stages of BBT Research, Development, and Implementation



SOURCE: Office of Technology Assessment, 1995.

APPENDIX 3-A: INTERNET SITES FOR INFORMATION ON BIOLOGICALLY BASED PEST CONTROL

Federal agency sites	Address	Description
APHIS Home Page	http://www.aphis.usda.gov	Provides information on the different program areas and proposed rules of the agency.
Consolidated Farm Service Agency	http://bbskc.kcc.usda.gov/cfsa.htm	Contains a large collection of agricultural research data and provides access to various agricultural publications, some pertaining to BBTs.
CSREES Partners in Research, Education, and Extension	http://www.reeusda.gov/partners/partners.htm	Provides a list of the cooperative extension offices and land grant universities and access to their Internet sites. Currently developing a search engine for all CSREES programs.
Federally Funded Research in the United States	http://medoc.gdb.org/best/fed.fund.html	Features information on the research performed by USDA and a variety of other federally funded programs. Provides search engines.
National Biological Control Institute	http://www.aphis.usda.gov/nbci/nbci.html	Supplies information on biological control, implementation, and facilitation grant programs, and the NBCI staff, as well as access to the Biological Control News.
Pest Management Bulletin	http://chppm-www.apgea.army.mil/ento/index.htm#bulletins	Offers information on pest management, some based on BBTs (a publication of the U.S. Army Center for Health Promotion and Preventive Medicine Entomology Program).
Cooperative extension sites		
Cooperative Extension Information Servers	http://www.esusda.gov/partners/ces-locs.htm	Lists the information servers of the cooperative extension system by state (not all cooperative extension sites offer information on agriculture).
Cornell University College of Agriculture and Life Sciences, New York State Agricultural Extension Station	http://aruba.nysaes.cornell.edu:8000/geneva.htm	Provides a search engine for all of the current programs and research of this extension station. Allows easy access to their information on biological control.
Illinois Cooperative Extension Service, Horticulture Solution Series	http://www.ag.uiuc.edu/~robsond/solutions/hort.html	Offers solutions to a various horticultural problems, including pest control, to both homeowners and horticulturists, including some involving BBTs.
Oregon Extension Entomology Report	http://www.oes.orst.edu/entomol.htm	Lists current pests of Oregon and different control measures, including biological controls.
Integrated pest management sites		
Cooperative Extension System IPM National Pest Management Materials Database	http://info.aes.purdue.edu/ipmdb.html	Lists general pest management information sources. Provides a search engine to report summaries and contacts for obtaining reports. Includes information on BBTs.

(continued)

Federal agency sites	Address	Description
CRC for Tropical Pest Management Biological Control Program	http://www.ctpm.org/	Offers IPM and BBT alternatives for pest control in agriculture. Includes literature citations.
National IPM Information System @ Colorado State University- Pest Alert Bulletins	http://www.colostate.edu/Depts/IPM/news/news.html	Offers information on identification of insect pests and pest control measures, including some biological solutions. Serves both homeowners and farmers.
North Carolina State University component of the National IPM Network	http://ipm_www.ncsu.edu	Provides access to various IPM newsletters (national and international) focusing on present research projects.
Entomological sites		
Colorado State University Department of Entomology	http://www.colostate.edu/Depts/Entomology/ent.html	Features pictures of insect pests and their natural enemies. Provides access to entomology newsletters.
EntNet	listmgn@entsoc.org	Provides instructions for subscribing to the Internet list server created by the Entomological Society of America.
Florida Entomologist	gopher://sally.fcla.ufl.edu:70/11/FlaEnt	Provides information, mainly research articles, on insect control. Some mention of BBTs.
Gypsy Moth Home Page at Virginia Polytechnic Institute and State University, Department of Entomology	http://www.gypsymoth.ento.vt.edu/Welcome.html	Provides information on gypsy moths, including control methods such as Bt.
Mississippi State University Department of Entomology	http://www.msstate.edu/Entomology/ENTPLP.html	Provides access to numerous newsletters and databases that contain information on classical and augmentative biological control methods.
Resistant Pest Management Newsletter	http://www.msstate.edu/Entomology/EntHome.html	Focuses on pesticide-resistant insect pests in Mississippi and alternative control methods, including some BBTs.
Rincon Insectaries	http://www.rain.org/~sals/rincon.html	Offers information on Rincon's natural enemy products.
Sites for farmers by farmers		
Farmer to Farmer	http://www.organic.com/Non.profits/F2F	Allows California farmers to communicate via this newsletter and to share success stories of biological control used against common pests.
Noah's Ark Don't Panic, It's All Organic Homepage of an Organic Farmer	http://www.rain.org/~sals/my.html	Escorts user to various WWW and gopher sites helpful to organic farmers, including sites for identifying pests and control methods. Provides information on the Organic Food Law and the California Certification Standards of Organic Farming.

(continued)

Federal agency sites	Address	Description
Sustainable and alternative farming sites		
Alternative Farming Systems Information Center	http://www.inform.umd.edu:8080/EdRes/Topic/AgrEnv/AltFarm	Provides links to sustainable agriculture sites and documents as one of the 10 information centers at the National Agriculture Library of USDA. Supplies bibliographies, many on BBTs.
Information on Sustainable Agriculture	gopher://zeus.esusda.gov:70/11/initiatives/sustain	Supplies information on current research on sustainable agriculture and various news bulletins.
Plants and Sustainable Agriculture	http://www.envirolink.org/pubs/Plants.html	Provides access to sustainable agriculture newsletters and information sources, some containing information on BBTs.
University of California Sustainable Agriculture and Research Education Program	http://www.sarep.ucdavis.edu/	Reports technical reviews, technical information, and summaries of journal articles and workshop presentations on subjects related to sustainable agriculture.
General agriculture research sites		
Purdue University Office of Agriculture Research	http://info.aes.purdue.edu/AgResearch/agreswww.html	Provides a search engine of the agriculture research conducted at Purdue University, some in the area of BBTs.
Biotechnology sites		
Biotech-Related WWW Sites and Documents	http://inform.umd.edu:86/EdRes/Topic/AgrEnv/Biotech/.www.html	Provides access to publications and WWW and gopher sites related to biotechnology.
Biotechnology Information Center	http://www.inform.umd.edu:8080/EdRes/Topic/AgrEnv/Biotech	As one of the 10 information centers at the National Agricultural Library of USDA, provides access information services and publications covering agricultural biotechnology, including a bibliography and resources guide, miscellaneous publications, biotechnology education resources, biotechnology newsletters (national and international), biotechnology patents and biotechnology software.
Institute for Biotechnology Information	http://www.bio.com/ibi/ibi1.html	Serves as a database of U.S. biotechnology companies. Includes information on key personnel, R&D, products, budgets, financing history, addresses, and phone and fax numbers. Contains an action database for the significant activities and strategic alliances of biotechnology companies worldwide.

(continued)

Federal agency sites	Address	Description
Public Perception of Biotechnology Home Page. Department of Crop and Soil Environmental Sciences and the Center for the Study of Science in Society. Virginia Polytechnic Institute and State University	http://fbox.vt.edu:10021/cals/cses/chagedor/index.html	Offers information on a study of the public perceptions of agricultural and environmental biotechnology, including microbial pesticides.
Advocacy and industry group sites		
ANBP	http://www.rain.org/~sals/anbp.html	Reports on regulation of natural enemies and offers information on other issues affecting the natural enemy industry through the News Quarterly of the National Bio-Control Industry.
Biotechnology Industry Organization	http://www.bio.com/bc/bio/biohome.html	Provides a list of members of the Biotechnology Industry Organization, a trade association representing biotechnology companies of all sizes (including agricultural biotechnology companies). Includes membership information and access to newsletters.
Pesticide Action Network North America	gopher://gopher.igc.apc.org:70/11/orgs/panna	Offers information on an organization advocating replacement of conventional pesticides. Includes some citations on BBTs.

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

NOTE: Many of the sources containing information on biologically based pest control are still under construction. The site contents and addresses were current as of August 1, 1995. This information is subject to change.

Risks and Regulations 4

Biologically based technologies (BBTs) pose certain risks, some better documented than others. The significance of these risks depends on how well the regulatory structure prevents the high impacts. Scientists who study the ecology of natural systems are most concerned about the effects of introduced classical biological control agents on the population dynamics of native species and the functioning of ecosystems. Past regulatory review by the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA) has been erratic and inconsistent. The U.S. Environmental Protection Agency (EPA) has done a better job in its oversight of microbial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but critics charge that previous thoroughness and concomitant expense to registrants kept useful products from entering the market. The evaluation of new risks from the release of genetically engineered microbial pesticides could pose a major challenge.

Chapter 4 begins with an examination of potential health and environmental effects from BBTs, summarized in table 4-1. The discussion then turns to some of the tools that scientists and regulators use to evaluate and rank those risks. The remainder of the chapter looks at how EPA, USDA, FDA, and state governments decide which BBT risks are acceptable.

RISKS FROM BBTS

BBTs generally receive favorable ratings from the perspective of public health and environmental safety. Many are relatively host specific, affecting primarily the targeted pest. Unlike conventional pesticides, most BBTs lack mammalian toxicity or pathogenicity. Moreover, the development of resistance by weed and insect pests appears significantly slower for most BBTs than for conventional pesticides. Despite these multiple advantages, the risks from BBTs occasionally may be substantial, and therefore their use deserves scrutiny and, in some cases, long-term monitoring.

Human Health Effects

Human exposures to certain BBTs may occur at many stages of production and application of the BBT and during use of the end product. For example, farm personnel and local residents may inhale microbial pesticides during aerial spraying; kitchen staffs and schoolchildren may work and study in facilities treated with tiny wasps and

CHAPTER 4 FINDINGS

- The environmental and public health risks from biologically based technologies for pest control (BBTs) are relatively low when compared to those from conventional chemical pesticides. Nevertheless, BBTs are not risk-free. The significance of the risks depends on how well the regulatory system screens out the high impacts.
- The relative absence of documented harmful ecological impacts attributable to BBTs may be misleading, however, given the lack of pre- and postrelease monitoring. Some of the most harmful ecological effects, such as declines in native insect populations, have probably gone unnoticed in past decades.
- The risks from certain BBTs cannot be accurately assessed; some scientists argue that they never will be. The wide variation in scientific opinion and the high degree of uncertainty concerning BBT efficacy and ecological impacts heighten the need for public participation in the regulatory process. One committee that would benefit from more diverse representation is the Animal and Plant Health Inspection Service's (APHIS) Technical Advisory Group on the Introduction of Biological Control Agents of Weeds.
- Past regulation of natural enemies by APHIS was inconsistent and incomplete. Proposed regulations were recently withdrawn after APHIS received 252 mostly critical public comments. The agency needs to devise a regulatory framework that ensures environmental safety while encouraging the development and use of BBTs.
- The regulated community gives the U.S. Environmental Protection Agency (EPA) high marks for the creation of its Biopesticides and Pollution Prevention Division. The division is developing some much-needed exemptions and expedited registration processes for certain classes or applications of microbial pesticides and pheromones. Ecologists warn, however, that EPA should not go too far in waiving its environmental testing requirements.
- Many genetically engineered microbial pesticides are making their way through the research and registration pipeline. Scientists are engineering these products to behave more like chemical pesticides, characterized by longer environmental persistence, expanded host range, more toxic mode of action, and faster kill rate. The tracking and evaluation of environmental fate and impacts may pose significant challenges.
- The Food and Drug Administration (FDA) plays a role that is as yet undefined in the regulation of biologically based technologies. The agency is still trying to identify the scope of its regulatory responsibilities regarding the use of BBTs in grain storage and food preparation areas. FDA involvement may increase significantly as application of these products in urban settings grows.
- Certain BBTs appear susceptible to resistance, but apparently at a rate slower than that for chemical pesticides. Widespread use of transgenic plants containing toxins from *Bacillus thuringiensis* (Bt), however, may speed the development of pest resistance to Bt and squander its value as a microbial pesticide.

nematodes; consumers may unknowingly consume microbial pesticides and fragments of arthropod natural enemies in foods, in addition to pieces of the pests themselves. Persons who work in facilities for rearing natural enemies may face occupational exposure to the insect predators and parasites.

Few human health risks from BBTs have been described in the scientific literature. Best documented are allergic reactions, particularly to fungal pathogens (411,420). Workers in insectaries have developed allergic asthma and rhinoconjunctivitis (nasal inflammatory disease) from contact with the eggs, scales, and waste of the arthropod pests and their natural enemies. Respiratory and dermal protection may help retard such effects (205). Another risk is that manufactured microbial pesticides could become contam-

TABLE 4-1: Examples of Potential Risks from BBTs

BBT examples	Potential environmental impacts	Potential human health effects
Conservation of natural enemies	Probably insignificant	No known risk[a]
Classical biological control/ introduction of new natural enemies	Some adverse impacts on nontarget organisms; destabilization of existing control by predators and parasites; habitat destruction; possible evolutionary changes. Many of these risks are shared by other BBTs	No known risk
Release of sterile fishes for biological control	Adverse effects on nontarget organisms; potential for hybridization with wild forms; possible development of resistance, self-reproducing strains, or selective mating patterns; potential transmission of parasites	No known risk
Augmentative releases of parasites and predators	Some risks similar to those for classical biological control; contamination of field-harvested natural enemies by parasites; depletion of natural enemies in collection sites	Allergic reactions among workers in insectaries
Pheromones	Potential adverse impacts on aquatic invertebrates and some fish from lepidopteran varieties,[b] but warning labels advise against such usage; other types of pheromones may have greater potential toxicity to mammals, fish, and birds; undocumented possibility for disruption of mating behavior of other insects; slight risk of resistance	Low oral or inhalation toxicity, possible dermal and eye irritation, from lepidopteran-active products; higher toxicity among other pheromone groups, but minimal human exposure
Bacterial pathogens (microbial pesticides)	Some adverse impacts on nontarget lepidoptera and their avian predators Short-term declines in certain nontarget insects; resistance documented in field populations of pests treated regularly with Bt	Minimal risk to general population; some data suggest possible infection of immunocompromised individuals
Viral pathogens (microbial pesticides)	Minimal effects on nontarget organisms; possibility of resistance in future as field use expands	No known risk
Fungal pathogens (microbial pesticides)	Possible effects on nontarget organisms; early evidence of resistance	Some established human allergens and toxic metabolites
Protozoan pathogens (microbial pesticides)	Possible effects on nontarget species	No known risk
Nematodes (microbial pesticides)	Possible effects on nontarget organisms, particularly those in the soil	No known risk
Release of sterile insects	Some adverse effects on nontarget organisms; possible development of resistance, self-reproducing strains, or selective mating patterns	No known risk

[a] "No known risk" indicates that risks have not been documented. In some cases, the absence of documented effects may be due to a lack of monitoring or observation.

[b] Lepidoptera is a large order of insects that includes butterflies and moths, some of which are considered pests.

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

inated with human pathogens such as *Shigella* and *Salmonella;* each production batch must be screened for the growth of unwanted organisms (314).

Health concerns arise more often from microbial pesticides than from other biologically based approaches. Bacteria, fungi, protozoans, and viruses all raise questions about infectivity; bacteria and fungi trigger toxicity concerns as well (311). Occasional medical case reports describe infection from certain microbial pesticides, although it is unclear whether the organisms have actually multiplied or caused any harm in patients' tissue (125).

Products based on *Bacillus thuringiensis* (Bt), by far the most widely used microbial pesticides, have been the focus of many animal experiments and some human studies. Isolated incidents of eye infection and inflammation of connective tissue have been reported. Some varieties of Bt (esp. israelensis, used for blackfly and mosquito control) are more toxic to mammals than others (e.g., kurstaki, primarily used for gypsy moth and other lepidopteran pests) (125).

Although there is minimal evidence of health risks to the general population, some researchers have suggested that immunocompromised individuals (e.g., people with AIDS) may exhibit heightened susceptibility to certain insect pathogens including Bt (125,311,346). Similar concerns apply to individuals undergoing immunosuppressive cancer therapies (see table 4-1).

A BBT use that may call for extra attention in the future is the application of microbial pesticides to agricultural products after harvest to prevent spoilage. To date, EPA has registered for postharvest use only microbial products that work by preferentially colonizing wounded tissue to the exclusion of microorganisms that cause rot. These microbial pesticides, such as Ecogen's Aspire (a yeast, *Candida oleophila*) and EcoScience's Bio-Save (a bacterium, *Pseudomonas syringae*), although still present in reduced numbers on citrus, apples, pears, and other fruits at time of consumption, are considered by EPA to be as safe as the microorganisms regularly residing on these foods (182). Another approach controls microorganisms by producing antibiotic substances that are toxic to a broad range of organisms. These fungal and bacterial agents, if ever applied to fresh fruits and vegetables, would require a detailed evaluation of toxicity and pathogenicity, especially to immunosuppressed people (81,426).

Minor impacts on mental well-being may result from at least one natural enemy. The Asian lady beetle, *Harmonia axyridis,* was released by USDA from 1916 to 1985 primarily in the southern United States to control pecan aphids (288). Despite the lady beetle's beneficial agricultural effects, some people have come to regard the insect as a nuisance: Lady beetles enter homes in large swarms, where they interfere with daily activities and emit a noxious-smelling secretion. Anecdotal accounts describe families collecting pints of lady beetles in their homes on a daily basis and finding lady beetles crawling on the ceiling, windows, walls, and beds, and in cups, bowls, coffee pots, and so forth. Many state agricultural experts urge homeowners not to kill the lady beetles, in light of the insects' important role as natural enemy of aphid pests (288,252).

Environmental Impacts from BBTs

Many of the effects of BBT use remain unknown (313). Natural enemy companies generally point to an exemplary record of safety (128), whereas conservation biologists argue that the dearth of documented impacts does not mean they have not occurred (220). There have only been occasional studies of environmental effects in the United States, and most of these efforts have been directed toward agricultural crops. The consequences for nontarget native insects, in particular, have been largely ignored (151). Some of these play important roles as natural enemies. Yet unlike native plants and commercial crops, insects (with the possible exception of butterflies, honeybees, and silkworms) have no constituency to advocate for their conservation (284,117).

Despite the incomplete and controversial record, at least a few documented releases of certain biological control agents have disrupted natural communities and brought about localized declines in native species. Some of the very characteristics that make many natural enemies effective in controlling pests (their capacity to harm other organisms, to survive, to reproduce, to disperse, and to evolve adaptations to new conditions) also make them potentially harmful invaders (219). Generalist natural enemies—those less choosy in selecting food sources, hosts, or mates—pose some of the more serious ecological risks. The level of risk depends also on such factors as the reversibility of the release, the potential of the agent to spread, the extent to which impacts may be mitigated, the availability of monitoring, and the predictability of impacts across life cycle and distribution. It is worth noting that some of the more significant adverse impacts that have resulted from biological control releases took place long ago, and many involved generalist predators on small island ecosystems in other countries. In the analysis that follows, OTA's emphasis is on documented impacts in the United States. Where there are no U.S. examples, the text also includes some potential risks based on experience in other countries, as well as some of the theoretical risks postulated by ecologists and other scientists. Many of the introductions of agents that are described would not stand up to scrutiny or be allowed today.

Although the potential consequences from the use of biological control agents and certain other BBTs are worrisome, it is worth remembering that the pests themselves—and the synthetic chemical methods of control—raise health and ecological concerns that at least equal and often exceed those presented by most BBTs (414). Consideration should also be given to other available options for controlling a particular pest situation. The following discussion describes the full range of documented and theoretical risks from BBTs and then puts these risks in context.

Impacts on Nontarget Organisms

Introduced natural enemies, sterile insects, certain microbial pesticides, and pheromones have sometimes affected not only the targeted pest species but also nontarget plants or insects. These nontarget organisms are often related to the pest species. Some serve important ecological roles; others are listed by the U.S. Fish and Wildlife Service as threatened or endangered. Many of the suspected or known impacts have occurred in habitats far and ecologically disparate from the original location of release, and at times long after the introduction or use of the BBT. The release of classical biological control agents raises the greatest ecological concerns, although the extent of risk is controversial. Vertebrate organisms and other generalist species pose many of the more important risks; some of these are addressed in greater detail in OTA's report, *Harmful Non-Indigenous Species in the United States* (338).

The best-documented nontarget impacts involve the release of vertebrate predators. For example, the barn owl (*Tyto alba*), imported in 1958 into Hawaii from California for rodent control, preys also on shearwaters, terns, petrels, and other organisms (313). The small Indian mongoose (*Herpestes auropunctatus*), released in the West Indies, Mauritius, Hawaiian Islands and Fiji, failed to control its target—rats in agricultural fields—but caused the decline of native birds and, in the West Indies, apparently contributed to the extinction of native snake and lizard species (313,284). A predatory snail, *Euglandina rosea*, introduced to many islands throughout the world for control of the giant African snail, *Achatina fulica*, may have helped bring about the extinction of several endemic snails (313).

In some instances, fishes introduced for biological control (including the two most widely used varieties, mosquito fish—*Gambusia* spp., and grass carp—*Ctenopharyngodon idella*) have caused substantial declines in local populations of native fishes (313,338). For example, the mosquito fish, introduced in many regions for mosquito control, has preyed on, and in some locations contributed to the decline of at least 35 other fish species (313). Seemingly innocuous predatory fishes may become harmful as they switch dietary preferences in later life stages. The use of fish-eating fishes to control pest fish species raises special concerns because native fishes are often highly valued resources (191).

Plant-eating (phytophagous) insects introduced for biological control of weeds have spread to other locations where they have contributed to the decline of related native plant species. A few such cases are documented, but others may have gone unnoticed. One example, that of the cactus moth (*Cactoblastis cactorum*), a native of Argentina, illustrates the need to evaluate the effects of a candidate biological control organism on all potential plant hosts. The moth, which feeds only on cacti of the genus *Opuntia*, was released with great success as a biological control agent in Australia (1925), on several Caribbean islands (1957, 1962, and 1970), and in other locations. Together with two scale insects (*Dactylopius* species), the moth effectively controls highly invasive weed species of the cactus, for which chemical pesticides, grazing, burning, and other approaches are economically and environmentally infeasible (75). The moth has had serious nontarget impacts on native *Opuntia* species on Nevis and Grand Cayman; at the time of its release, however, the value of these indigenous plants was not fully appreciated (74).

After dispersing on its own through Haiti, the Dominican Republic, Puerto Rico, the Bahamas, and Cuba, the cactus moth eventually entered the United States, possibly as a contaminant of horticultural stock (220). The moth was discovered in Florida in about 1989. In the Florida Keys it largely destroyed the few remaining stands of the semaphore cactus (*Opuntia spinosissima*), a candidate for listing under the Endangered Species Act. This development probably would have gone unnoticed had it not taken place on a closely monitored Nature Conservancy preserve (313,284). It is likely that the cactus moth will spread north through Florida and west into Texas and Mexico, where it may attack other *Opuntia* species, including weeds, food or feed crops, and ecologically valuable species (75).

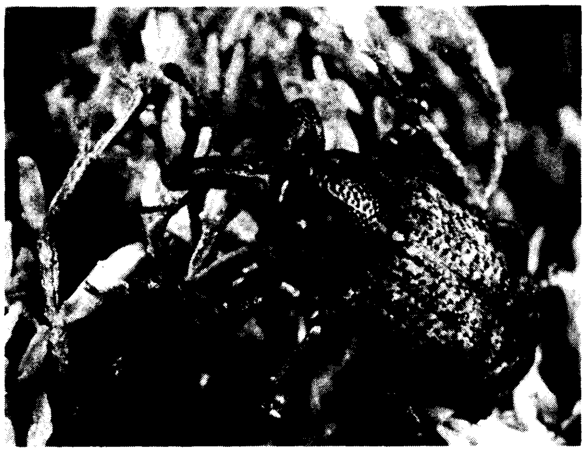
Numerous anecdotal accounts, intensely debated but often poorly documented, describe biological control agents that have parasitized nontarget insects in Hawaii, Fiji, and New Zealand (313). Most of these releases occurred in prior decades.

A documented example of nontarget effects from a microbial pesticide involves certain strains of Bt that can harm nontarget Lepidoptera[1] (313,220). Secondary effects on insect-eating bird species are possible: The decline in food may force them to change location or may depress successful reproduction (283). Some researchers suggest that the decline in nontarget Lepidoptera may be only temporary (411), possibly because the Bt does not form free-living populations (158).

One realm of particular concern involves potential risks in using plant pathogens for agricultural weed control. Farmers usually face a complex of broadleaf and grassy weeds. Development of a microbial pesticide containing sufficient variety of organisms to control several weed species would require a dauntingly complex set of tests to ensure safety. This situation contrasts with that of rangeland noxious weed control, in which land managers may target a particularly troublesome weed species individually (167).

The introduction of natural enemies to control native pests, however, raises concerns because the full ecological role of the pests may not be well understood. Certain native plants that are pests in one context may also be an important source of forage and may support numerous other native species. Debate about the desirability of using introduced biological control agents against native species rose to the surface in 1993. Plans by federal researchers to use a wasp parasite and a fungal disease against rangeland grasshoppers ground to a halt when entomologists

[1] Lepidoptera is the insect order that includes butterflies and moths.



Use of introduced natural enemies against native pests, such as this weevil (Heilipodus ventralis) *on snakeweed* (Gutierrezia sarothrae), *is controversial because of potential impacts on native ecosystems,*

Agricultural Research Service, USDA

pointed out that the control agents might also affect many of the over 280 nontarget native grasshoppers (122). Some may play important roles in native ecosystems, for example by suppressing native weeds such as snakeweed. The case continues to be highly contentious among scientists (204,43).

Interference with Existing Control Agents–Competition and Life-Cycle Disruption

Some evidence suggests that biological control agents have adversely affected native natural enemy populations by outcompeting them for food or other resources. Such competition is notoriously hard to document in the field, particularly among insects, the habitats and behavioral patterns of which are not well studied (313). A few such situations have been reported, one concerning the European lady beetle *(Coccinella septempunctata),* which has been released widely in the United States. The introduced lady beetle appears to be displacing other predatory insects such as the nine-spotted lady beetle (C. *novemnotata),* thereby potentially disrupting the control of pests by native insects (313). In fact, the European species is now the dominant lady beetle by far in many of the agricultural systems it has colonized (170).

Biological control agents can affect nontarget organisms also by interfering with their life cycles, ultimately resulting in the upsurge of pest populations. Reports from Fiji describe the lifecycle disruption of the coconut leaf-mining beetle *(Promecotheca reichei)* by an introduced mite *(Pediculoides ventricosus),* reducing the population of native parasites and thus enabling the beetle population to skyrocket (313).

Habitat Destruction

Damage to the habitats of nontarget species is an important yet underreported risk from the introduction of fishes for aquatic weed control. These fishes dramatically reduce local plant cover, potentially causing significant disruption to both plant and animal communities (313). In the case of grass carp, however, the negative impacts have been reduced somewhat by only using the fish in enclosed water bodies and by releasing sterile triploid fishes (191). The U.S. Fish and Wildlife Service operates a certification facility to ensure that grass carp for biological control are unable to produce viable offspring, and most states require permits and verification of triploidy for grass carp imports (191). The approach is impractical for many fish species, however, and generally not all fish in a treated lot become sterile (313). Although individual fish that are released harm nontarget vegetation, as do their fertile counterparts, the sterilized fish usually will not form reproductive populations that can spread.

Reproductive Effects

A little-documented potential risk from pheromones is the disruption of mating patterns. There is some evidence that the pheromone of bark beetles that stimulates them to flock together may influence the behavior of other beetles. Sex pheromones of Lepidoptera may possibly affect the behavior of certain parasites (313).

Another reproductive concern relates to the use of immunocontraceptive control for vertebrate pests, although these approaches have not yet been used in the United States. Australia plans to use genetically engineered viruses to control foxes and rabbits by inducing the females' immune system to attack male sperm. The control plan will require simultaneous depression of both fox and rabbit populations: Controlling only the foxes would enable the rabbit population to explode; restricting only the rabbits would induce the foxes to switch to other prey, most likely endangered marsupials. Australian scientists are examining potential risks including the capacity of live infectious viruses to multiply, to attack other species including house pets, and to spread abroad.

The rabbit control involves a redesigned myxoma virus, which is specific to rabbits and hares. Lacking a virus specific to foxes, the Australians risk inadvertently sterilizing dingoes (wild dogs) and domestic dogs. Similar concerns have been raised by researchers at APHIS's Denver Wildlife Research Center, who are developing immunocontraceptive therapies with which to sterilize coyotes and deer in the United States (225).

Other Potential Risks

Evolutionary Change among BBTs

Evaluating genetic change among populations of biological control agents after their introduction is difficult and has rarely been attempted (171). Yet some ecologists argue that the conditions of such releases facilitate the rapid evolution of changes in a natural enemy's host range or other important characteristics. Evolved resistance to conventional pesticides occurs with some frequency among arthropods and has been demonstrated experimentally in certain natural enemies (see chapter 2). Introduced species might also evolve an expanded tolerance of physical factors, thereby increasing the range of habitats they may occupy and thus their impacts (313).

Some scientists speculate that biological control relationships could become less and less effective over time as the pest and its natural enemy evolve in response to one another (313), although data are lacking on the likelihood and on the rate at which this might occur. A further possibility is that introduced species might hybridize with native ones to the point that the native species no longer exist in their original form. Little research has addressed this phenomenon. The one documented case involved the introduction of mosquito fishes (*Gambusia affinis* and *G. holbrooki*) that hybridized with another related species (*Gambusia heterochir*) and now threaten the integrity of the latter's gene pool (313).

Inadvertent Introduction of Parasites of Natural Enemies

APHIS's screening of incoming biological control agents generally prevents accidental importations of hyperparasites (i.e., parasites of parasites) (236). A unique example of hyperparasitism among field-collected biological control organisms in the United States concerns the lady beetle (*Hippodamia convergens*). A parasitic wasp may contaminate up to 10 percent of these lady beetles. In the spring of 1994, APHIS decided to prohibit interstate shipment of field-collected lady beetles that had not been held in quarantine and cleared of parasites. Following strong public protests arguing that the collection and dispersal of California lady beetles has been a cottage industry for over 75 years and is thus unlikely to cause further adverse effects, APHIS overturned the decision. The agency continues to urge that field-collected lady beetles be held to identify and remove parasitized individuals (60).

Resistance to BBTs

Pest resistance to conventional insecticides has contributed to the growing interest in biologically based approaches. Initial findings suggest that pests may develop resistance to certain BBTs, particularly bacteria and viruses (9,411), and possibly fungi (420,281) and pheromones (40) as well. The likelihood of resistance or rate at which it might develop is unclear however. Compared with conventional pesticides, most BBTs appear less prone to stimulate resistance. Many biological approaches benefit from physiological modes of action (such as interference with photosynthesis, respiration, transpiration, translocation, and seed production) that make it more difficult for pests to develop resistance to BBTs than to certain conventional pesticides that lack these properties (420).

If pests become resistant to BBTs, making these approaches no longer effective, agriculture will lose an important set of low-risk pest control tools. Indirect health and environmental risks could result if growers were forced to switch back to conventional pesticides, because BBTs offer significant advantages from an environmental and public health standpoint (274).

The bacterial insecticide Bt faces the greatest threat. Future large-scale use of crop plants genetically engineered to contain the Bt toxin could speed the development of resistance and put at risk its effectiveness as a microbial pesticide (112). Unlike Bt sprays, which are applied only intermittently, plants bred to contain Bt toxin in their tissues continuously expose pests to the toxin over the entire growing season. This increased exposure to Bt heightens the selective pressure on pests and may hasten the development of resistance (422,221,146,214). Some scientists believe that resistant pest populations will appear soon after the transgenic Bt crops are planted.

Thus far, evidence of Bt resistance in the United States has been seen only in field populations of the diamondback moth (*Plutella xylostella*). Resistance in the moth has been observed in the Pacific Rim, Florida, and New York (411,326). The Colorado potato beetle (*Leptinotarsa decemlineata*) on Long Island, New York, which was one of the first agricultural pests to develop insecticide resistance (to arsenicals in the 1940s and to DDT in 1952), now shows the potential for resistance to Bt tenebrionis. The silverleaf (sweet potato) whitefly (*Bemesia argentifolii*), another major pest that is notoriously difficult to control because of its expanding resistance toward organophosphate, carbamate, and pyrethroid insecticides, has developed resistance to Bt kurstaki in Taiwan, the Philippines, and Malaysia (112).

There is no published evidence of an insect developing resistance to a virus in the field. Microbial pesticides based on viruses have not yet been used extensively in the United States. Lab results indicate, however, that future large-scale use might result in resistance (411).

The potential that pests will develop resistance to other BBTs is only speculative at this time. Continuous exposure of susceptible insect pests to nematode products, for example, might encourage selection for resistance (411). Theoretically, pest populations might even evolve resistance to the sterile male technique by developing self-reproducing strains or the ability to recognize and mate only with fertile males (313).

Depletion of BBT Agents in Natural Areas

The mass collection of natural enemies impacts regional populations. Unlike most augmentatively released natural enemies, which are raised in insectaries, the lady beetle (*Hippodamia convergens*) and several natural enemies of rangeland weeds are collected from field sites. The lady beetles, for example, are harvested from locations in the California foothills to which the beetles migrate. Lady beetles dominate the biological control market for garden use because of their familiarity to the public, promising anecdotal stories, aesthetic appeal, and long history of commercial sale. Despite some doubts as to their effectiveness (see box 3-1 in chapter 3), the collection and sale of lady beetles continues to increase, with demand often exceeding supply. Supplies are finite, however, and there are increasing concerns about environmental costs associated with the commercial collection of the insect (60). In addition, the collection undermines natural control, which is free to the farmer (416), and interferes with publicly supported biological control programs.

Genetically Engineered BBT Organisms

The environmental repercussions of genetically enhanced microbial pesticides deserve special scrutiny. Scientists are using genetic engineering techniques to expand the target range (194), incorporate more toxic modes of action, increase kill rates, and extend environmental persistence—in essence, to make microbial pesticides mimic their more heavily regulated chemical counterparts. Implications for nontarget species may grow in future years as these products move through EPA registration. University of Florida entomologist J.H. Frank (1995) raises concerns with respect to genetically engineered Bt products (108):

> Research is attempting to increase the range of targets that Bt will kill, to increase commercial profitability.... Where will it stop—how broad would commerce like the target range to be? Why should these commercial interests bother to look out for the welfare of nontarget organisms? Even more, why should they look out for the welfare of beneficial organisms that already exert partial control of some pests and complete control of others? It is not in their interests to do so, because they will be able to sell more product in the absence of these beneficial organisms....

The interests of commercial profitability and the protection of nontarget species may collide over the issue of target range. From an environmental perspective, a key advantage of many BBTs is their relatively narrow range of impacts. Yet products that kill or impair a wider range of species cater to a larger pest control market and hence generate higher profits. Producers of genetically engineered BBTs are developing microbial products with extended target range, although whether their breadth will ever rival that of conventional pesticides remains to be seen.

Some of the environmental effects from genetically engineered BBTs remain unclear. Depending on the properties of the toxins or hormones inserted into the microbe to achieve pesticidal activity, for example, symptomless infections by genetically modified viral insecticides in nontarget organisms could go undetected and later provide a reservoir of infection of other organisms (429).

Putting the Risks in Context

Almost every scientist contacted by OTA about BBT risks prefaced his or her comments by emphasizing that the occupational and environmental risks from conventional pesticides dwarf those from biologically based approaches. For example, chemical insecticides, herbicides, and fertilizers have caused documented adverse impacts on more than 90 species listed under the Endangered Species Act (89), as well as serious health and ecosystem effects. Although beyond the scope of this report, the risks from these synthetic pest control methods help put into perspective the relative safety of most BBT options.

The relative absence of effective low-risk pest control solutions—perhaps intercropping, crop rotation, field sanitation,[2] and row covers would fall in such a category—suggests that difficult choices must be made among suboptimal options, each of which implies an array of hazards for different organisms and population sectors. The risks differ both qualitatively and quantitatively: Chemical pesticides raise significant consumer and occupational health issues, in addition to environmental effects, whereas BBTs affect primarily native species, and native biodiversity is a relatively new category of concern in the United States.

Important risks derive also from failure to control the pests. These organisms, many of them invaders from foreign lands, can damage economic resources as well as native ecosystems. Our nation's food supply depends on efficient, low-cost agricultural technologies, and our environmental and aesthetic needs depend on the preservation of our national treasures such as parks and forests.

Most BBTs have a favorable health and environmental profile, and some provide solutions to pernicious health risks (box 4-1). A well-designed regulatory system could screen out the greater risks from BBTs while facilitating adoption of the vast majority of these technologies. The development of proper recordkeeping and

[2] Field sanitation involves the removal of crop residues that harbor pest stages.

monitoring systems could advance our base of knowledge, improve the development of new BBTs, and eventually allow for a tighter match between risks and regulatory testing requirements.

BOX 4-1: Controlling Public Health Scourges with BBTs

Biologically based approaches can sometimes control the disease vectors or intermediate hosts of malaria, schistosomiasis, and other afflictions of humans and livestock. Fishes, turtles, and fungi, for example, have all been used to control mosquitoes that transmit malaria and dengue fever in the tropics and veterinary diseases, such as heartworm and equine encephalitis, in the United States. The use of BBTs for public health purposes has certain advantages but also raises potential problems.

Over 200 fishes from around the world are known to eat mosquito larvae. In addition, fish that eat aquatic vegetation may modify their habitats, making them less suitable for mosquitoes. A big advantage of using fish for mosquito control is that they generally require little investment or infrastructure to produce an acceptable level of long-term control. In addition, the potential to evolve resistance to fish predators is much less than that to insecticides.

Although sometimes quite effective, however, fish do not completely eliminate mosquito populations; generally they do not provide the level or the rapidity of control achievable with insecticides. Their use is restricted to suitable bodies of water, leaving out many important mosquito habitats. Moreover, the non-target impacts can be severe. The fish most commonly used for mosquito control in the United States, for example, is the mosquito fish, *Gambusia affinis,* from the southeastern United States. This fish often out-competes other native fishes. Mosquito fish develop dense populations and may reduce the food sources or eat the eggs and young of native species.

Fungal species of the genus *Coelomyces* and *Lagenidium* are lethal to mosquitoes. The spores penetrate the insect and can cause mortality within a few days. Areas can be inoculated with fungal pathogens by transporting infected insects or sporangia to the target location. A significant advantage of fungal pathogens over the use of insecticides or Bt is that mosquitoes are less likely to evolve resistance to fungi. Moreover, since the fungi are already widely distributed worldwide, there may be less concern about unpredictable damage to nontarget species.

Fishes and fungi are not the only possible control agents for mosquitoes. Bats and some birds, such as swallows, consume an extraordinary number of mosquitoes, and juvenile turtles have reportedly provided successful control of mosquitoes in cisterns for drinking water in Honduras.

Schistosomiasis is another cause of considerable morbidity and mortality in the developing world. Certain predatory fishes can effectively control juvenile snails such as *Biomphalaria glabrata,* an intermediate host for the parasitic worm that causes the disease in the tropics. In addition, a competitor species of snail, *Marisa cornuarietis,* is used as a control agent in Puerto Rico and is considered to have contributed substantially to the sustained reduction of schistosomiasis on that island; adverse ecological impacts have not been documented. In Florida and other regions, however, the snail feeds indiscriminately on many native plant species.

SOURCES: A. Kuris, Department of Biological Sciences and Marine Science Institute, University of California, Santa Barbara, CA, "A Review of Biologically Based Technologies For Pest Control in Aquatic Habitats," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October, 1994; D. Simberloff, Department of Biological Sciences, Florida State University, Tallahassee, FL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 16, 1995.

In the real world, moreover, many of the possible risks from BBTs pale in comparison with the benefits of use. For example, in the case of coddling moth control, although scientists have postulated theoretical risks with regard to future impacts of pheromones on the mating behavior of introduced natural enemies, in practice so far sex pheromones have proved to be highly effective in concert with augmentative releases of *Trichogramma* wasps. Studies on cotton bollworm and European corn borer suggest that the presence of certain pheromones actually enhances the searching behavior of the wasps (236).

Risks that deserve particular scrutiny in the near future include the growing resistance to Bt and the potential to rapidly reduce its effectiveness through large-scale use of crop plants containing Bt genes; the untested ecological repercussions from the use of genetically engineered microbial pesticides; and, more generally, the effects of BBTs on insect populations, organisms that often play valuable ecological roles and serve as natural enemies of many household and agricultural pests.

Minimizing the Risks

Regulatory agencies use several tools to sort out which BBTs bear more significant risks and to expedite registration of the safer technologies. Many of these tools have not yet been fully developed. A brief explanation of some of these approaches follows.

Establishing Priorities for Risk Evaluation and Testing

Risk depends on the level of hazard as well as the extent of the exposure. Evaluation of BBT risks should consider each of the possible adverse impacts plus the risk from the uncontrolled target pest and from other pest control approaches. Some scientists suggest that a ranking of BBTs along risk categories could help agencies set priorities and fast-track the permit applications of the most promising and least risky BBT candidates. By using more of a tiered testing system—in which more rigorous testing is only required when a potential risk is detected—agencies could streamline the data requirements for safer BBT products.

Developing a hierarchy among risks is controversial, often difficult, and sometimes impossible. It is not easy to generalize risk categories. The rankings may reflect scientific assumptions about the breadth of the host range, as well as broader assumptions about the value to be assigned particular classes of nontarget organisms (219). They could also include patterns of use and likely levels of human exposure.

Most scientists would place terrestrial vertebrates at the top of the risk hierarchy. Introductions of organisms such as the mongoose, myna bird, and giant toad have had severe and widespread adverse impacts due to their nonspecific feeding and their numerical abundance (219).

Many researchers would also designate as high risk those organisms that feed on a wide range of plants and animals (284). Generalist feeders such as the sevenspotted lady beetle (*Coccinella septempunctata*), which APHIS decided to mass-rear as a biological control agent in the late 1980s, have displaced native species in many environments (169). Even a nontarget organism that is rare or endangered—and therefore would not sustain a predator population—may still be vulnerable if related species in the vicinity that are more abundant attract the generalist agents (220).

Among control organisms used against arthropod pests, predators tend to be less host specific and less successful in biological control programs than parasites, suggesting that parasites deserve a lower place in the hierarchy of risks (219). Advantages of parasites include their greater specificity, searching ability, and ability to persist along with the pest at low population levels. Nonetheless, there may be reasons to use predators instead: Their lower specificity and their capacity to switch from one type of prey to another may produce more effective control of fluctuating pest populations (219). Also on the low end of the risk spectrum could be such approaches as the conservation of natural enemies or the use of pheromones in traps.

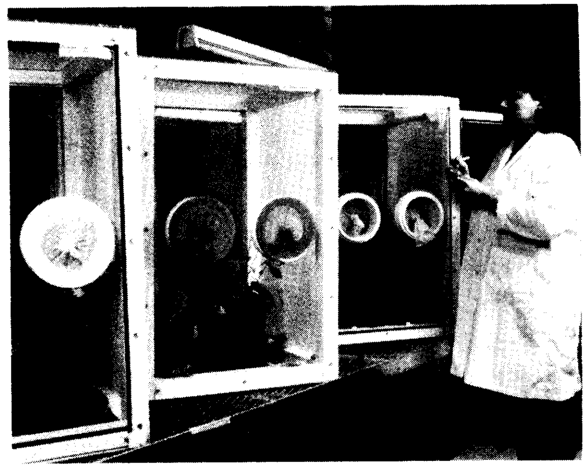
A major difficulty with attempting to order the levels of risk, of course, is that there will always be exceptions. Organisms within categories designated as high risk may prove relatively innocuous, while those that fulfill the criteria as low-risk BBTs may cause unexpected harm. A regulatory system that incorporates reliance on risk categories, therefore, must also include flexibility and substantial safeguards to ensure the recognition of such exceptions.

An advantage of a risk hierarchy is that it facilitates matching the required pre-use evaluations to the likely level of risk posed by a BBT. Evaluation schemes that take into account the variable levels of scrutiny required by different potential risks are called tiered testing. These systems preclude unnecessary testing and wasted resources. APHIS and EPA use tiered testing to varying degrees. The first tier provides maximum opportunity for the identification of any adverse effects. BBTs that pass the first tier are not subject to further testing. Second and third tier testing are used to reveal possible mitigating factors (21 9).

Testing for Host Specificity

Host specificity measures the degree to which a biological control agent is restricted to its target. It provides information on the range of organisms a biological control agent will affect through feeding, reproduction, or other interactions. Scientists use information on host specificity to try to identify the organisms likely to be attacked by candidate control agents in the release environment. Testing of host specificity began for biological control agents targeting weeds in the 1950s. Initially, the potential agent was tested only on the agricultural crops growing in the region into which the control organism was considered for introduction (21 9).

More predictive frameworks have since replaced the crop-testing method, often placing greater emphasis on nontarget threatened and endangered species and other plants of ecological value. Many biological control practitioners advocate use of the centrifugal/phylogenetic approach, which involves testing plants of increasingly distant relationship to the target until the host range is circumscribed. The centrifugal approach is not without its problems, however. For one, it assumes that related plants are more likely to be attacked, whereas, in reality, sometimes widely unrelated plants are attacked (220). This may be more a problem among pathogens than among insects (159). In addition, the centrifugal approach may overlook some important variations in resistance and susceptibility of individual hosts (328).



Natural enemies imported for research on the biological control of weeds are held in quarantine prior to release.

Agricultural Research Service, USDA

The relatedness procedure, the newest approach to host specificity, is a subtractive procedure that involves selecting plants to be tested on the basis of their evolutionary relationship to the target organism, as well as their distribution, climatic preferences, seasonal occurrence, regional weather patterns, life cycles, and other information available in the scientific literature (73). The approach is weighted to favor those potential hosts most closely related to the target organism, but it tests representatives from all other levels of relationship as well. The method has been applied successful y in Australia for the host-specificity testing of *Uromysces heliotropic*, a fungal agent for the biological control of the weed, common heliotrope, *Heliotropism europaeum (139,140,73).*

The relatedness procedure or other host-specificity approaches, if better developed in the future, may make possible the use of shorter, more predictive and reliable testing lists (73). To date, however, the science of host specificity has a long way to go, particularly given the complexity of ecological interactions and the difficulty of measuring them (360).

APHIS and EPA rely on these various testing procedures to varying degrees. APHIS evaluates the data on the basis of whatever approach the researcher uses. If a researcher asks for guidance on host range testing, the agency sends two sample papers, one from 1974 based on the centrifugal procedure and one from 1992 based on the relatedness procedure (360). In practice, however, the choice of nontarget test organisms depends more often on what the researchers happen to have available or readily accessible and know how to test (159,73). EPA's testing protocols emphasize the major agricultural crops.

Another problem is that researchers developing test lists for BBT registration applications often have little background in relevant biological disciplines. Entomologists petitioning to introduce an arthropod species that attacks weeds, for example, commonly lack the botanical training needed to identify likely host plants based on evolutionary relationships, life cycles, and other aspects of plant ecology (159).

Because of their potential to attack agricultural crops, pathogens of plants and plant-eating (phytophagous) arthropods have traditionally evoked the most thorough host-specificity studies. Host-specificity assessment for predators, parasites, and pathogens of insect pests, by contrast, remains in an early stage of development. This situation reflects the lower degree of social, economic, and environmental concern for arthropods than for plants as nontarget organisms. There are far fewer "domestic" arthropods (such as honeybees and silkworms) than there are agricultural crops, and plants are far more likely to be listed as threatened or endangered species, thus deserving special protection. Many scientists argue that the biological control agents used for control of arthropods deserve more careful attention than they receive today.

A single species that feeds on several organisms is often made up of numerous more specialized individuals. Such diverse populations may harbor enough genetic variation to evolve and eventually change hosts. Thus testing should sample as much genetic and geographic variation in the biological control agent as possible, to maximize chances of detecting the variation among individuals upon which natural selection might act (219).

Host Range

Host range refers to the number of different species that a given agent will attack. Although conceptually similar to host specificity, host range focuses on the biological control agent rather than the target. Often the terms are used interchangeably; they refer to overlapping subsets of risk (73).

Examination of a biological control agent in its site of origin provides a basis for predicting effects in the release area (256); so does information on the agent's biology, taxonomy, and ecology (415). To help approximate the range of organisms a biological control agent or microbial pesticide will affect in its proposed area of release, however, researchers also use laboratory and field tests. Lab tests aid in approximating the physiological host range of the control organism—the maximum extent to which an agent could impact potential hosts. Artificial testing conditions—such as use of starved biological control organisms and lack of dietary choice—may inflate the range results for many arthropods and pathogens (219). For example, if a candidate biological control agent does not feed on a test organism in laboratory conditions, it is nearly certain that it will not feed on the organism in field conditions. If the biological control agent does feed on the test organism in laboratory conditions, however, it does not necessarily follow that the same behavior will take place in the field (360).

The actual, or "ecological," host range is always less than the physiological host range

(74). Field tests give a more accurate picture of the extent to which control organisms can be expected to attack nontarget species upon release. The accuracy of extrapolation from the physiological host range (revealed in the lab) to the ecological host range (revealed in the field) needs improvement. Further development and testing of host specificity protocols may better establish what fraction of the potential host range is likely to be expressed in the field (219,73).

Host-specificity and host-range testing are no guarantees of environmental safety. The harmful effects of the biological control organism can include not only eating, parasitizing, or infecting a nontarget organism, but also indirect effects from interfering with shared natural enemies or shared hosts (219). There is also the risk of interspecies mating, especially with threatened or endangered species.

The relative specificity of BBTs requires that they be weighed on a case-by-case basis, each situation reflecting a unique set of potential interactions among the control organism, target organism, and potential nontarget organisms. No standard set of indicator species or single representative sample of nontarget species (e.g., rodent or other model organisms) or nontarget ecosystems will apply to all proposed agents. Moreover, when potential harm to ecosystems is weighed, there may be no easily defined endpoints to the analysis, a factor that makes development of protocols problematic (219).

Evaluating the Risks and Benefits of BBTs and Alternatives

Risk-benefit assessment of BBTs is exceedingly difficult, given the lack of accurate quantitative data on either risks or benefits. To date, much of the available information is unsubstantiated and anecdotal.

Moreover, risk implications may differ with the purpose of the BBT release. Natural area managers usually focus on protecting a large number of valued native species, and thus prefer narrowly targeted pest control methods. By contrast, an individual farmer, rancher, forester, or other producer focuses on the productivity of just a few species. The use of BBTs with lower host specificity may better meet these broad-spectrum needs, but at the same time may involve greater ecological risks (284).

Many difficulties complicate the task of quantifying the relative risks posed by a BBT release and those posed by taking no action against the pest or using other control methods. Benefits and costs may be unevenly distributed socially, geographically, or across generations, and excessive uncertainty or questionable valuation techniques may undercut the analysis (219). A qualitative, multi-factoral comparison of BBTs with other control methods, however, might serve to elucidate some important differences in nontarget effects, impacts on groundwater, residues on crops, and occupational exposures, as well as short- and long-term effectiveness and resistance.

ADDRESSING THE RISKS

This section examines the regulatory structure for most BBTs. The agencies that regulate BBTs have a difficult dual mission: facilitating the development and registration of biologically based technologies while minimizing the risk of harmful environmental and public health impacts. The incongruous nature of these directives suggests that neither will be satisfied completely. The challenge is to incorporate a reasonable degree of ecological scrutiny into a more streamlined and efficient regulatory process.

Although there is no federal statute that directly deals with biologically based approaches, several federal agencies regulate BBTs. EPA oversees the commercial sale and use of microbial pesticides and pheromones. USDA's APHIS regulates the introduction and dissemination of biological control agents including arthropods, mites, nematodes, slugs, snails, and other macroorganisms. FDA monitors the use of BBTs that could become components of stored or prepared food, such as microbial products and fragments of insect natural enemies in stored grain. The U.S. Department of Interior's Fish and Wildlife Service (FWS) evaluates potential impacts of certain biological control organisms on threatened and endangered species. Some states regulate BBTs as well (box 4-2).

This section does not cover in detail regulations for the use of vertebrate animals and fishes as biological control agents. Such agents historically have posed some of the greatest risks, yet they are subject to very little scrutiny by federal agencies. Instead, most authority resides with the states (box 4-3).

BOX 4-2: Regulation of BBTs by Hawaii and Other States

Importation or interstate movement of biological control agents requires filing of APHIS's Application and Permit to Move Live Plant Pests and Noxious Weeds (PPQ form 526). Before APHIS issues a permit, state regulatory officials have the opportunity to review the APHIS recommendation. In addition, state officials may indicate special conditions of entry, containment, and release. In general, however, states lack resources to enforce additional requirements.

Seven states have statutes or regulations governing the entry, distribution or release of biological control organisms into or within their territories: California, Florida, Hawaii, Indiana, Nebraska, North Carolina, and Wisconsin. All of these states will accept PPQ form 526 in lieu of their own permit applications. Many of the specific state provisions are similar to those required by PPQ; California has explicit lists of biological control agents not subject to state permit requirements.

At least one state, Hawaii, imposes requirements more restrictive than federal APHIS regulations. Hawaii's special efforts to keep out certain species stem from that state's history of ecologically harmful introductions to its unique and vulnerable island ecosystems. Hawaii maintains lists of prohibited, restricted, and conditionally approved organisms.[a] Biological control agents not yet listed may be evaluated for host specificity and other characteristics in the state quarantine facility. Advisory subcommittees (on entomology, invertebrate and aquatic biota, land vertebrates, microorganisms, or plants) review applications for introduction of nondomestic animals and microorganisms for biological control and other purposes. The Advisory Committee on Plants and Animals holds bimonthly public meetings to decide whether to permit particular agents for biological control or other purposes.

Although Hawaii has instituted elaborate screening procedures, the state is unable to fully enforce its laws. The Alien Species Prevention and Enforcement Act[b] provides that USDA will inspect mail entering Hawaii from the mainland United States to prevent the entry of plant materials subject to U.S. quarantine laws. APHIS carries out inspections of incoming domestic mail for two hours each day; during the rest of the day, however, the mail just enters the state uninspected. Under the Fourth Amendment to the Constitution, APHIS can open first class mail only with a search warrant; to get one requires probable cause. If the inspectors feel or hear (by shaking the parcel) something that seems like plant material, they can use specially trained dogs to sniff it out. If the dogs react to something, that constitutes probable cause to obtain a search warrant.

The impetus behind the act was Hawaii's desire to keep out lizards, snakes, and other organisms from the mainland United States that could disrupt Hawaii's island ecosystem. Yet the act does not actually apply to these organisms, but only to those listed on U.S. quarantines for interstate commerce. The nonindigenous species of concern to Hawaii damage forests and other natural ecosystems, while U.S. quarantine lists focus on risks to agricultural crops. As a result, virtually none of the species of concern to Hawaii are included under the Alien Species legislation. APHIS lacks the legal authority to prevent the entry of these organisms.

(continued)

BOX 4-2: Regulation of BBTs by Hawaii and Other States (Cont'd.)

Hawaii's inability to enforce its inspection and quarantine laws illustrates a problem that is universal among the states: Although the laws are on the books, biological control agents may be shipped across the border illegally. Hawaii's situation underscores also the difficulties that any state might face in trying to enforce laws more restrictive than federal requirements for the importation and release of biological control agents.

[a] Chapter 4-71, Hawaii Administrative Rules.

[b] Public Law 102-393 (1992).

SOURCES: J. Levy, Operations Officer, Operational Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, April 5, 1995; W.W. Metterhouse, Cream Ridge, NJ, "The States' Roles in Biologically Based Technologies For Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994; "Plant and Non-Domestic Animal Quarantine" *Title 4, Subtitle 6, Chapter 71 (Non-Domestic Animal and Microorganism Import Rules), Hawaii Administrative Rules,* 1995; G. Takahashi, Maritime Supervisor, Plant Quarantine, Department of Agriculture, Hawaii, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May, 26, 1995; 39 USCA Section 3015.

BOX 4-3: Oversight of Vertebrates as Biological Control Agents

A number of the most harmful past introductions for biological control have involved vertebrate animals. The small Indian mongoose (*Herpestes auropunctatus*), for example, is renowned for devastating ground-nesting bird populations, chickens, and lizard predators of insects when it was introduced to the West Indies, Puerto Rico, and Hawaii during the late 1800s. Its importation into the continental United States has been banned. Other vertebrate animals introduced for biological control in the past, including giant toads, ducks, geese, mynah birds, and water buffaloes, have likewise inflicted harm on native species, and many of these examples would probably not be repeated today.

Several species of fishes continue to be released regularly for biological control, with serious ecological impacts. The grass carp and common carp (*Ctenopharyngodon idella* and *Cyprinus carpio*) that have been introduced throughout the United States for weed control also destroy habitats for young fish and increase water turbidity. Introduction of mosquito fish (*Gambusia affinis*) not only results in the suppression of mosquitoes, but also has been associated with a decline in populations of certain native fishes.

The standards and mechanisms for regulation of vertebrate introductions differ markedly from those for arthropods and pathogens covered in most of this chapter. Under current law, the states retain almost unlimited power to make decisions about which vertebrate animals to import or release. Federal incursions in this area have been few and controversial. The state fish and game departments vary greatly in the rigor and comprehensiveness with which they regulate introductions of vertebrates.

A 1993 review of state laws and regulations revealed that although every state except Mississippi has laws governing fish releases, at least 15 states lack any legal standards for evaluating species prior to release. No state ties its releases to any scientifically based protocols, such as those produced by the American Fisheries Society and other organizations, in part because of the costs involved. A number of states, however, do specifically prohibit releases of grass carp, and many other states allow only releases of grass carp that have been sterilized to prevent their reproduction and spread. These provisions, of course, do not address the risks of the more than a half-dozen other fish species used for aquatic weed control in the United States.

SOURCES: Office of Technology Assessment, U.S. Congress, 1993; J.R. Coulson and R.S. Soper, "Protocols For the Introduction of Biological Control Agents in the U.S.," *Plant Protection and Quarantine, Volume III,* (R.P. Kahn, CRC Press, 1989); D. Simberloff and P. Stiling, Department of Biological Sciences, Florida State University, Tallahassee, FL and University of Southern Florida, Tampa, FL, "Biological Pest Control: Potential Hazards," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994.

Animal and Plant Health Inspection Service

Past oversight of introduction of biological control agents by APHIS was unbalanced, incomplete, poorly documented, and difficult to understand for those seeking permits. The agency has taken some promising initiatives in recent years, however; these include increased attention to the environmental impacts of biological control agents of arthropod pests; an effort to consolidate the agency's multiple sources of jurisdiction; an attempt to centralize and make sense of the meager, vague, mixed-up records of past permitting decisions; the implementation of genus-level permitting; and an ongoing effort to adapt and clarify the permit system for environmental releases to better meet the requirements of the National Environmental Policy Act. APHIS staff deserve praise for these initiatives. Less successful, however, have been recent attempts to impose regulatory structure where none existed before (box 4-4). APHIS's proposed rule on the introduction of nonindigenous organisms attempted to screen out harmful organisms, but many people felt that the screen imposed was so fine-meshed as to be virtually impenetrable, thwarting the continued production, distribution, use, or research of biological control organisms.

Outside observers have commented that APHIS should not both regulate and promote biological control. It is difficult to know the significance of this dual role, although clearly it may lead to internal tensions and inconsistent missions within the agency (see chapter 5). The debate over the proposed rulemaking revealed some of these different perspectives. In 1992 the former APHIS Administrator asked the agency's National Biological Control Institute to examine the agency's authority in biological control, meet with interested parties, and propose guidelines for the importation, interstate movement, and release of biological control agents. The National Biological Control Institute developed protocols based on its two years of discussions with participants in the biological control community. Although, according to the APHIS Administrator's Office, this preliminary work was acknowledged in the rulemaking (216), it appears that few of the recommendations were actually incorporated into the final proposal. Following withdrawal of the proposed rule, APHIS formed a new task force that includes the National Biological Control Institute as a member.

Statutory Responsibilities

APHIS regulates the importation of biological control macroorganisms into the United States and their movement between states under the Federal Plant Pest Act[3] and the Plant Quarantine Act[4] (box 4-5) (360). Reliance on these plant pest statutes for jurisdiction often puts APHIS in the position of having to justify its intervention—or avoid action altogether—in matters of direct import to the use of biological control agents. Ongoing jurisdictional questions concern the granting of permits for *release* to the environment because the acts only cover the *movement* of agents; the control of "beneficial" organisms that are not generally considered "plant pests" or "noxious weeds" yet may indirectly cause harmful impacts; and the labeling and quality control of natural enemies. In addition, the statutes appear to suggest a zero-risk standard for introductions of biological control agents—a standard that is unrealistic and provides APHIS with little guidance.

Jurisdictional uncertainties arise also in the case of microbial pesticides based on nematodes. In accordance with the Federal Plant Pest Act, APHIS regulates the introduction and movement of nematodes in the United States. In light of APHIS's official role, EPA retains no jurisdiction over these products; the Federal Insecticide, Fungicide and Rodenticide Act authorizes the agency to exempt pest control products that are

[3] 7 U.S.C. §147a *et seq.* (1957).
[4] 7 U.S.C. §151 *et seq.*; 46 U.S.C. §103 *et seq*. (1967).

BOX 4-4: The Proposed APHIS Regulation for the Introduction of Nonindigenous Organisms

USDA's Animal and Plant Health Inspection Service (APHIS) currently grants permits for biological control agents under regulations that cover plant pests. Scientists and natural enemy companies have criticized APHIS's approach for years because it lumps "beneficial" natural enemies into the same category with agricultural pests. In 1992 the agency's Administrator instructed APHIS's National Biological Control Institute to meet with interested stakeholder groups to develop background information that would help in constructing a regulation more specific to biological control. But such a regulation never appeared.

Instead, in January 1995, APHIS published a much broader proposed rule that applied generally to nonindigenous species and superseded the agency's earlier development of a biological control rule. The proposed regulation was APHIS's attempt to address problems identified in the 1993 OTA assessment *Harmful Nonindigenous Species in the United States*. That report summarized the harmful economic and environmental impacts of organisms that enter the country or spread and then become agricultural pests, degrade parks and federal lands, or displace native species. The OTA report further specified that the piecemeal federal system for screening the importation or release of nonindigenous organisms contributed significantly to these continuing harmful impacts.

Unfortunately, APHIS's proposed rule did not do a good job of regulating both biological control (an area that is actively promoted by the agency and has little firm documentation of past harmful impacts) and other types of potentially harmful introductions. Furthermore, the agency's abandonment of its effort to write a regulation specifically addressing biological control aroused the ire of scientists and industry members who had participated in the earlier process. Such feelings were only compounded by the implied challenge in the rule to the deeply felt belief among many members of the biological control community that theirs is a benign practice with little if any potential for causing harmful environmental impacts.

Response to the nonindigenous organism regulation was swift and almost uniformly negative. Responses could be tracked by interested observers via an Internet listserver constructed solely for this purpose. A total of 252 responses came from biological control researchers, producers, practitioners, and distributors; university entomologists; farmers; weed control committees and districts; local, state and federal agencies; members of Congress; commercial laboratories; and industry associations. Most objected to how the regulation categorized biological control along with other potentially harmful introductions. Many also felt that the permit requirements would place unacceptable financial burdens and time constraints on the natural enemy industry, which already operates with a low profit margin.

Although most respondents expressed similar sentiments, they did not necessarily reflect an unbiased sampling of expert or public opinion. The vast majority were in some way affiliated with the practice of biological control, and the content of the regulation had been rapidly communicated throughout this group by way of several listservers and bulletin boards on the Internet. Jeffrey Lockwood, a scientist known for his concern about the potential ecological risks of biological control, was one of the few to express the opinion that the regulation was not strict enough. This view might have been better represented had other groups, such as conservation biologists, known about the regulation.

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

BOX 4-5: Pest Control Acts

- The **Federal Plant Pest Act of 1957** prohibits the movement of any plant pest from a foreign country into or through the United States without a permit from USDA. The definition of plant pest includes any living stage of "any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." [7 U.S.C. §§150 aa *et seq.* (1957)].
- The **Plant Quarantine Act of 1912** bars the entry into the United States, without a permit, of any nursery stock—and under certain conditions, any other class of plants, fruits, vegetables, roots, bulbs, seeds, or other plant products—in order to prevent the introduction of any tree, plant, or fruit disease or any injurious insect not widely prevalent in the United States. The act also authorizes the Secretary of Agriculture to forbid importation of plants from particular areas and to quarantine any U.S. localities to prevent the spread of a dangerous plant disease or insect infestation. [7 U.S.C. §§151 *et seq.* (1967)].

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

adequately regulated by other federal agencies. Although APHIS claims to regulate these products, and indeed the agency has processed a few nematode applications over the years, in practice most of these products go unregulated. Major nematode production companies contacted by OTA said they neither apply for APHIS permits nor interact with the agency in any other way. Among the states, moreover, only Hawaii controls the entry of incoming nematode products, which are allowed into the state only under specific research permits for greenhouse trials. Hawaii is evaluating nematode products in light of the state's long history of ecological harm by nonindigenous species (209).

The lack of oversight concerning nematodes has had benefits as well as potential drawbacks. It has contributed to the nematode industry's success in getting products on the market, particularly in light of the very low profit margins. What limited information has been generated about these organisms suggests that they are relatively innocuous and unlikely to cause harmful environmental impacts. At the same time, however, the taxonomy of these organisms is poorly understood; some are ubiquitous in nature; and many have a relatively broad host range. It is unclear whether the advantages from regulating nematodes would outweigh the costs, but this matter deserves more explicit deliberation and resolution.

APHIS proposed the Plant Protection Act and the Animal Health Protection Act in 1990 and again in 1995 to consolidate the provisions from 28 statutes under two laws (144). Although they do not completely resolve the mismatch between statutory authority and regulatory needs, these bills take steps to clarify certain jurisdictional questions. Specifically, the recently proposed Plant Protection Act adds to the definition of "plant pest" vertebrate and invertebrate animals, biological control organisms, and undesirable plant species (358). This last term replaces "noxious weeds," liberalizing current noxious weed laws by enabling port inspectors to quarantine unlisted plants even if those plants are not new to or widely prevalent in the United States. The law does not define "biological control organism," but leaves this term to be decided at a later date by rulemaking with public input (144).

APHIS's Permit System

The Plant Protection and Quarantine (PPQ) division serves as APHIS's principal regulator of biological control agents. Through its permitting system, PPQ seeks to protect U.S. agriculture from the introduction and interstate dispersal of harmful plant pests. APHIS includes biological control agents among these regulated pests, a source of contention because arguably most beneficial natural enemies do not fit that characterization. Enforcement by PPQ takes place at major U.S. ports of entry, while permitting is carried out by APHIS headquarters in consultation with the states.

PPQ grants several thousand permits each year for introduction and interstate movement of pathogens, invertebrate animals, and weeds. Pinning down exact information about types and numbers of permits for biological control and level of technical review is difficult; in response to OTA's inquiry regarding numbers of applications evaluated by agency entomologists each year, for example, APHIS supplied figures ranging from eight to 2,500 applications. In truth, most of the applications are processed by clerical staff, but the inconsistency of information supplied to OTA illustrates APHIS's recordkeeping problems and raises questions about its sense of accountability.

It appears that most of the first-time ("unprecedented") applications are reviewed either by one of APHIS's two entomologists or by the agency's plant pathologist. Each year these scientists evaluate about 10 (and sometimes as many as 20) applications for phytophagous (plant-eating) biological control organisms and a roughly comparable number for entomophagous (insect-eating) agents. Numbers of unprecedented applications appear higher in 1995 than in some of the previous years (143). Each application is usually reviewed by one scientist, who consults occasionally with colleagues when questions arise.

PPQ has no process by which to expedite the permitting of unprecedented, taxonomically promising species over those that may carry heightened capacity for ecological harm (such as organisms that attack a wide range of nontarget plants and animals). Rather, APHIS categorizes applications in accordance with the purpose of the introduction (movement or release), the purity of the organism, and, eventually, the outcome of the environmental assessment. Data requirements vary depending on whether the organism is to be imported from another country into quarantine, moved between containment facilities, or released to the environment (box 4-6). APHIS plans soon to address some of OTA's concerns about setting priorities; in particular, the agency is posting on the World Wide Web and APHIS gopher a list of arthropods commonly used for biological control of pest arthropods for which permits will be expedited (360).

Unprecedented releases of biological control organisms require the preparation of an environmental assessment. As part of this process, APHIS's Biological Assessment and Taxonomic Support (BATS) division is required to determine whether the candidate control agent "may affect" endangered or threatened species. Sometimes BATS contacts FWS, although some observers suggest that communication and coordination between the two agencies is not always adequate.

Some researchers have complained that issues regarding endangered and threatened species do not enter early enough into the decisionmaking process. When they were about to release their test organisms, researchers at the University of California had their APHIS permits challenged by local FWS field officers, leading to long, costly and counterproductive delays (24). Another example involved APHIS's evaluation of permits for five types of insects to be used for the control of purple loosestrife (two beetles to eat the flowers, two to eat the leaves, and one root weevil). APHIS approached FWS concerning three of these agents in June 1995, just two weeks before the intended release date. APHIS was completing the final stages of its assessment, and the beetles were unlikely to survive much longer, putting FWS in the difficult position of having to confirm, on very short notice, the introduction of biological control agents against a

BOX 4-6: Categories of Pest Organisms

APHIS divides permit applications into categories as follows:

- **A**—Foreign plant pests new to or not widely distributed in the United States; domestic plant pests of limited U.S. distribution, including program pests; state regulated pests; and exotic strains of domestic pests;
- **B**—Biological control agents and pollinators;

  B(1)—High risk: weed antagonists; shipments accompanied by prohibited plant material or Category A pests;

  B(2)—Low risk: pure cultures of known beneficial organisms; and
- **C**—Domestic pests that have attained their ecological range, nonpest organisms and other organisms for which courtesy permits may be issued.

All biologically-based pest control agents fall under category B, biological control agents and pollinators. APHIS has yet to examine the environmental impacts of organisms in subcategory B(1). Some of the B(1) organisms may include hyperparasites or other impurities; they may come from a particular strain never before introduced or from a new field site. Those organisms designated in subcategory B(2) are pure cultures that have been cleared for release to the environment; most of these have undergone some form of environmental assessment or administrative determination. Some were previously imported into quarantine as subcategory B(1) organisms.

SOURCES: D. Knott, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, May 4, 1995 and August 2, 1995; M. Royer, Biological Assessment and Taxonomic Support, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, April 20, 1995; U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Safeguard Guidelines For Containment of Plant Pests Under Permit,* June 1993.

high-priority pest of natural areas. FWS scientists had many concerns, including possible effects on endangered or threatened nontarget species; the beetles' lack of native natural enemies, and the fact that, once released, the beetles would not be readily controllable. In July 1995, FWS acceded to the release of the beetles. APHIS's handling of these situations, however, raises questions about the timely incorporation of threatened and endangered species issues into the permitting process and the adequacy of coordination with FWS.

According to members of the natural enemy industry, much of the permitting process involves redundancy, delay, and unnecessary paperwork at both state and federal levels. Many of the permit applications are precedented, which means they concern the same biological control organism that was granted a permit previously, coming from the same state or country of origin, imported under the same conditions, and based on the same permit conditions and facilities. Often these repeated releases have been taking place for 10 or 20 years. According to the Association of Natural Bio-control Producers, a distributor selling 20 different products to customers in 40 states would need 800 permits which would have to be reviewed every two years (11). APHIS has somewhat simplified the approval process for pure cultures of precedented organisms, but further streamlining or permit waivers may be warranted.

Rather than waste time and resources renewing old permits, critics contend that APHIS needs a tiered, risk-based system with built-in waivers for repeated biological control releases, so that the agency can concentrate on the more high risk agents. Greater scrutiny may also be called for when the previous release has not become self-sustaining and was cleared before the agency instituted its data requirements (299).

In response to such criticism of its permit process, APHIS says that the agency has many innovations under development. These include new instruction sheets for preparing permit applications and environmental assessments, a customer satisfaction questionnaire, guidelines for containment facilities, optional electronic submission of application data, and plans to formulate categories of organisms excluded from permitting. APHIS hopes to offer some of these materials on the Internet, and eventually to adopt a computerized system, enabling customers to track the progress of their permit applications (360). These changes might address some of the problems identified by OTA. APHIS should be commended on these planned initiatives and encouraged to follow through with these improvements.

APHIS's Data Review

APHIS began doing rudimentary environmental assessments on biological control applications in 1970, upon passage of the National Environmental Policy Act. These early "administrative determinations" were often poorly documented and based on incomplete information. The system continued in place throughout the 1980s.

The new leaders at APHIS in the early 1990s inherited an arbitrary and nontransparent permitting system. In 1991 they revised the outline for prerelease environmental assessments. The new form requested much more extensive data including host specificity, hyperparasites, threatened native species, and effects on natural enemies. In 1993, APHIS again rewrote its requirements for environmental releases. This so-called "NIDR" format, which continues in use today, asks for a detailed description of the proposed action, biology of the target (host) organism and of the organism to be released (including both field and laboratory host range), status in North America, and expected environmental and human health impacts (359). While adding to the data requirements, PPQ has tried to streamline its permitting process in other ways, for example, by granting genus-level permits for *Aphytis* (September 1994), *Encarsia* (February 1995) and *Eretmocerus* (April 1995).

APHIS's review of applications for insect-feeding (entomophagous) biological control organisms has been particularly lax; APHIS had virtually no data requirements for such agents until 1991. Even today, the agency is struggling to develop scientific protocols for testing host specificity and other characteristics of the entomophagous agents. APHIS's environmental assessment for *Scelio parvicornis*, in April 1994, was considered a milestone in denying a permit for an entomophagous agent (299).

Technical Advisory Group

APHIS has a Technical Advisory Group on the Introduction of Biological Control Agents of Weeds (TAG) but lacks a similar body for biological control of insects. This independent voluntary committee was formed in 1957 primarily to provide advice to researchers. Today, TAG reviews applications for biological control of weeds and advises PPQ on whether to grant permission for quarantine or release.

Chaired by a member of the U.S. Army Corps of Engineers, TAG has up to 16 members, half of them from USDA and the U.S. Department of Interior (box 4-7). Usually TAG convenes without complete participation; only about five to nine representatives consistently participate in TAG recommendations (360,51,299). No particular number constitutes a quorum. Although foreigners are barred from voting, the Canadian reviewers participate actively, and there is interest in making them voting members (51). According to APHIS representatives, however, the Federal Advisory Committee Act[5] prohibits voting membership by nonfederal members on federal advisory committees like TAG. In fact, federal advisory committees *can* have nonfederal members so long as they follow the Act's procedural requirements, such as announcement of meetings in the *Federal Register* and formal

[5] Federal Advisory Committee Act, title 5, U.S.C.A., appendix 2, subsections 1-15 (1972), as amended.

BOX 4-7: Technical Advisory Group on the Introduction of Biological Control Agents of Weeds

Membership of TAG Committee

U.S. Army Corps of Engineers, Chair

U.S. Department of Agriculture:

- Animal and Plant Health Inspection Service
- Agricultural Research Service
- Cooperative State Research, Education and Extension Service
- Forest Service

U.S. Department of Interior:

- Bureau of Land Management
- Bureau of Reclamation
- Fish and Wildlife Service
- National Park Service

U.S. Environmental Protection Agency

Weed Science Society of America

National Plant Board

Members-at-Large

- Canada (nonvoting)
- Mexico (nonvoting)

Executive Secretary: (APHIS/PPQ employee)

Reviews by TAG

From 1987 through 1994, TAG reviewed 86 petitions for release or quarantine of organisms. Annual tallies varied from a high of 19 in 1989 to a low of seven in 1993. There were 71 different agents (some went through TAG as applications for quarantine and again for release) petitioned on 28 target plant species, mostly rangeland weeds. Four of the targets, leafy spurge (*Euphorbia escula*), diffuse knapweed (*Centaurea diffusa*), spotted knapweed, and yellow starthistle (*Centaurea solstitialis*), accounted for 43 percent of these petitions. Some 77 percent of the petitions received favorable recommendations from TAG.

SOURCE: A. Cofrancesco, U.S. Army Corps of Engineers, Vicksburg, MS, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 12, 1995; U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Charter for the Technical Advisory Group on the Introduction of Biological Control Agents of Weeds," unpublished draft guidelines, 1990.

recording of meeting minutes. Thus, any decision to restrict TAG membership to federal agencies should carefully weigh the desirability of broader representation against whatever costs these procedural requirements impose.

When PPQ receives petitions for the biological control of weeds, it sends them to the TAG secretary, who distributes them to the TAG representatives for comment. TAG reviews often take about three to four months because of scheduling difficulties of the TAG representatives. TAG conducts most of its business by mail; an annual meeting provides a forum to resolve controversial issues and to meet with weed control researchers. TAG is funded by member agencies, with APHIS paying only for the nongovernmental participation (51).

Although TAG is set up in an informal advisory capacity, in practice PPQ virtually always follows TAG's recommendations. Formally, PPQ makes the final decision, however, as is required by the Federal Advisory Committee Act. TAG reviews only about 10 petitions annually (50). Apparently this represents all of the unprecedented petitions received by APHIS each year for biological control of weeds. Pre-quarantine review is less stringent than that for release but enables TAG to advise and monitor biological control activities in the early stages of development rather than first confronting petitioners years into their research (51). Pre-quarantine review is done only if requested by a researcher (366).

Despite the fact that the representatives often consult with outside sources (51), critics charge that TAG lacks scientific expertise, particularly in plant taxonomy, pathology, ecology and evolution (58). Another complaint is that, as strong proponents of biological control technologies, TAG members traditionally have disregarded some of the negative repercussions of biological control introductions. For example, TAG review may not always screen against harmful impacts on abundant species of native plants.

Although PPQ follows the TAG recommendations, TAG does not use the exact data requirements developed by PPQ. Nevertheless, PPQ generally accepts the TAG decision in lieu of its own data requirements (299). In the early 1980s TAG informally issued to researchers its own internal guidelines, which differed from the PPQ requirements in some important ways. TAG asked petitioners to submit, for example, "dollar figures concerning crop or other losses caused by the weed and costs of its control, versus, if applicable, dollar figures concerning its beneficial qualities" (177), something never required by PPQ. TAG no longer requests such information from petitioners. Nonetheless, researchers commonly submit economic data, which is then considered by TAG in its deliberations (51).

TAG has discontinued its use of published data requirements. Instead, the group has loose guidelines indicating its main areas of review:

- taxonomy of the target weed;
- test plant list;
- host-range testing and impact on nontargets;
- taxonomy of the agent;
- biology of the agent; and
- other issues raised by the researchers.

These guidelines and other information about TAG are not available to researchers in printed form, although experts in the biological control of weeds generally know what TAG expects. A more formal review document could help researchers gauge where to focus their attention and resources. TAG recognizes this problem and is awaiting the development of a final rule by PPQ. At that time TAG will review the incoming PPQ applications for biological control of weeds.

Proposed Rule

As mentioned earlier, APHIS's proposed rule on the introduction of nonindigenous organisms encountered widespread criticism and eventually was withdrawn. Although biological control practitioners considered the proposal heavy-handed, conservation biologists applauded certain of its provisions.

Compared with current protocols, the proposed rule paid more explicit attention to genetic variation in the control organism, recognizing that different genotypes may require independent assessment of their potential for ecological harm. Rather than focusing solely on weeds, the proposal called for the careful appraisal of biological control agents of arthropod pests. In addition, it recognized that there are potential hazards from movement of control organisms between different biogeographic regions of the United States. Finally, the proposal acknowledged that a control agent can harm a nontarget organism not only by eating or parasitizing it, but also by interacting via intermediate organisms (219).

Although many of the data elements in the proposal have been required on a more informal basis since 1991, the proposal extended the agency's regulatory control in a number of realms. Its broad definition of *nonindigenous organism* included any organism proposed for introduction into an area of the United States beyond its established range. Its list of species subject to the rule included organisms which have long been in widespread use as biological control agents throughout the United States.

The proposed rule combined an odd mix of management approaches. On one extreme was the micromanagement of such features as the thickness of plastic bags (0.1270 millimeters) for seeds, the particular taxonomic groups listed to be regulated, and specifications for the submission of samples to three museums. Other provisions, however, suggested a much looser, more fluid approach to APHIS's regulatory oversight responsibilities; examples are the lack of clear standards on purity; the lack of specific protocols for host-specificity testing, and the absence of any reference to pre- and postrelease monitoring of nontarget effects.

That the proposed regulation failed to incorporate any provisions for postrelease monitoring, even for higher risk releases, suggests a possible reluctance by APHIS to confront the impacts of its permitting activities. Over time, without any monitoring, standards for successive applications cannot benefit from knowledge gained about the impact of prior releases (235). Until now PPQ did not even maintain in a usable form the basic records and databases on past releases. The PPQ form 526 database was unable to locate precedented permitting decisions except by the applicant's name (299). The computerized NIDR system instituted in early 1994 for environmental assessment data was redesigned in summer 1995 to enable PPQ to locate precedented permitting decisions by organism (360).

Environmental Protection Agency

In the early 1980s EPA developed special data requirements for biologically based products, but not until fall 1994 did the agency separate out its regulatory review of microbial pesticides and biochemicals from that for conventional chemical pesticides.

Today the regulated community generally gives EPA high marks for its actions on the registration of microbial pesticides and pheromones. The new Biopesticides and Pollution Prevention Division (BPPD) has consolidated the agency's BBT-related activities, streamlined the data requirements, and provided registrants with faster, less costly, more accommodating registration services. Critics charge, however, that the agency is waiving too many environmental data requirements and should pay closer attention to the effects on ecosystems and on insects and other nontarget organisms. EPA's protocols for host-specificity testing, moreover, focus almost entirely on commercial species such as agricultural crops and honeybees, with little regard for native organisms. Finally, a major challenge lies ahead for the agency as genetically engineered microbial pesticides raise unprecedented risk considerations that may require different regulatory approaches.

Statutory Responsibilities

Although EPA oversees the use of pesticides marketed in the United States, the agency has exempted from its jurisdiction all BBTs except those derived from microbes used in pesticide formulations (e.g., bacteria, algae, fungi, viruses, and protozoans) or biochemicals (including pheromones). A further exemption covers pheromones used in traps. BBTs remaining within EPA's jurisdiction are shown in table 4-2.

This arrangement derives from section 25(b) of the Federal Insecticide, Fungicide and Rodenticide Act, which authorizes EPA to exempt pesticides that are adequately regulated by other federal agencies or are of a character not requiring regulation under FIFRA[6]. Detailed testing protocols to accompany the regulatory requirements listed in 40 CFR Part 158 have been spelled out by EPA in its nonregulatory Pesticide Testing Guidelines, Subdivision M (393,394).[7]

[6] In 40 CFR Part 152, Subpart B, EPA exempts all BBTs except eucaryotic and procaryotic microorganisms (cellular organisms with and without a distinct nucleus, respectively) and viruses.

[7] Biologically based pesticides are also regulated under the food additive provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). Section 402 designates as adulterated any food or feed that contains residues of any pest control agent unless such residue is covered by a tolerance under sections 408 or 409 or an exemption from tolerance. To date, however, all microbial pesticides and most biochemical pesticides registered for use on food crops have been exempted from the requirement of a tolerance (223).

TABLE 4-2: Categories Regulated by EPA

Microbial pesticides
Natural and engineered:
■ Algae[a]
■ Bacteria[a]
■ Fungi[a]
■ Protozoans[a]
■ Viruses[a]
Biochemical products
■ Enzymes
■ Hormones
■ Natural plant and insect regulators
■ Semiochemicals (including pheromones)[a]

[a] These categories are included in OTA's scope of BBTs.

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

Biopesticides and Pollution Prevention Division

Within EPA's Office of Pesticide Programs, BPPD coordinates the registration, development, and promotion of biologically based pesticides. Formed in November 1994, BPPD aims to expedite the registration process for microbial and biochemical pest control products, serve as an advocate for the use of safer pesticides, and facilitate cooperative programs with state and federal agencies, universities, and agricultural groups. In creating BPPD, EPA brought together from other divisions scientists experienced with the evaluation and registration of biologically based products. BPPD has established two multidisciplinary teams whose staffs work together in a shared office and are authorized to skip some of the many bureaucratic steps that normally add weeks to the registration process of pest control products (402).

Although BPPD was created as a one-year pilot division, the White House recently approved EPA's decision to make BPPD a permanent division. The division is serving as the model for the restructuring of the Office of Pesticide Programs as a whole. It illustrates the advantages of bringing together into a single group those responsible for the multiple scientific and regulatory steps in the registration process. By speeding the availability of pesticide alternatives, BPPD could play a key role in the Clinton Administration's current initiative to expand use of integrated pest management and reduce reliance on conventional pesticides.

As of April 27, 1995, EPA had registered 43 biochemicals (mostly pheromones) and 45 microbial pesticides (more than half of them bacteria). Seven of these were registered by BPPD in its first six months of operation, and the others by the Office of Pesticide Programs in present and past years. According to BPPD, its turnaround time for registering pheromones and other biochemicals is 30 to 50 percent less than the time required by other EPA divisions for equivalent processing (47). Whether the registration of microbial pesticides will be similarly expedited remains unclear. In general the registration of microbial pesticides is much faster than that of chemicals because of substantially different data requirements and frequent use of data waivers.

Like the new administrators in APHIS's PPQ division, EPA's BPPD staff have inherited a difficult recordkeeping task. EPA's prior decisions are scattered among multiple offices in a variety of formats. At the same time, only rarely does EPA require pre- and postrelease monitoring of effects on nontarget organisms (305). This failure to evaluate impacts, combined with the challenge of consistent recordkeeping, suggests that the agency may not adequately build on past decisions and learn from prior mistakes. This shortcoming will become increasingly important as the number of BBT products submitted for registration grows. Rather than require that registrants take affirmative steps to evaluate impacts, EPA relies on FIFRA section 6(a)(2), which states that if pesticide registrants come across information on unreasonable adverse effects, they must submit that information to EPA. This directive may sometimes prove counterproductive: Legally bound to notify EPA of negative results, producers may be disinclined to thoroughly investigate risks from registered products.

Registration Requirements

BPPD is working to revise and update EPA's data requirements for microbial pesticides and biochemicals. The agency first developed its pesticide testing guidelines for "biorational" pesticides in 1982; those guidelines were rewritten for the microbial products in 1989. Guidelines for the biochemicals remain outdated and not in keeping with current EPA practices.

Producers of microbial pesticides and pheromones contend that compliance with the full product testing requirements can be prohibitively expensive. Although costs of testing are much lower than those for chemical pesticides, the revenue generated by BBTs is much smaller as well. BPPD waives many tests, however, and sometimes some of its fees. To fully test and register a BBT today costs between several hundred dollars and a half-million dollars. EPA's annual maintenance fees are $700 for the first product and $1,400 for subsequent products; the maximum limits or "caps" on the total annual maintenance fees payable by any registrant are usually between $55,000 and $95,000 (less for small businesses) (404). Tolerance fees for food-use BBTs generally range from $20,000 to $25,000, most of which is refunded if EPA grants an exemption (274).

BPPD has been seriously investigating the possibility of waiving both the maintenance and the tolerance fees for microbial pesticides and pheromones. The laws currently allow EPA to reduce or waive these fees for minor crop registrations where the fee is likely to significantly affect the availability of the pesticide. EPA hopes that the elimination of fees for BBT registration will spark an increase in applications (274).

BPPD calls for a customized data package for each active ingredient registered, based on a multi-tier system of data requirements; in contrast, a full set of data are usually required for conventional pesticides (217). EPA requires approval also for all large-scale field tests (more than 10 acres, or 250 acres for certain pheromones) of BBTs. In addition, the agency requires notification before small-scale field testing of genetically engineered organisms.

EPA requires registrants to submit data on efficacy for pesticide products used to control pests that threaten the public health (e.g., disease-carrying mosquitoes). The agency retains authority to order additional data where necessary. Some of the data are only conditionally required; others are waived in specific circumstances. For example, the use of microbial products in packinghouses and other indoor spaces commonly triggers an exemption to the nontarget testing requirements because no outdoor exposure is expected (224).

Pheromones and other biochemicals

EPA is about to publish in the *Federal Register* new exemptions for pheromone products. All straight-chained lepidopteran pheromones, regardless of application mode, are now exempt from the requirement of a tolerance and may undergo field testing on up to 250 acres without an experimental use permit. Past testing on small field plots has been extremely difficult because of the high volatility and specificity of the pheromones. This measure allows for testing of broadcast and sprayable applications of pheromone products over a wide area. Similar regulatory relief measures were provided earlier for all arthropod pheromones in polymeric dispensers (274).

Registrants of pheromones and other biochemicals must submit data on product identity, analysis, and manufacture; chemical residues; toxicology, and impacts on nontarget organisms (389). Often EPA waives most of these requirements. As in the case of microbial products, the toxicology and nontarget organism data are tiered; if the initial testing yields significant adverse effects, additional data points are added (218). Testing only rarely moves to subsequent tiers (305). Moreover, in light of the low toxicity and minimal expected human exposure to pheromone products, EPA, in 1986, waived certain requirements for mammalian toxicology studies on pheromones (218).

Microbial pesticides

Testing for microbial products covers the same general areas: product analysis, toxicology, residue analysis on food crops, and ecological effects. In calculating experimental dosage, registrants must take into account that environmental levels of the microbial agent and associated toxins often increase after application, at least temporarily—unlike environmental levels of chemical pesticides, which decrease over time (394). Toxicology data are set forth in three tiers, but EPA has never required data beyond the first tier (217), which involves short-term tests for toxicity, infectivity, and pathogenicity. Ecological effects testing is tiered as well, with the first tier consisting of maximum-dose, single-species hazard testing on nontarget organisms (394). For genetically engineered microbes, similar data are required on both the complete microbial product and the inserted DNA construct (224).

Environmental Effects

EPA's principles for review of microbial pesticides emphasize the importance of selecting susceptible, nontarget species (including insects, plants, wildlife) when testing for host specificity (394). In its actual testing protocols, however, the agency points to the specific organisms to be tested, chosen by EPA in part for their sensitivity to the test products (304) but mainly for their economic importance, commercial availability, laboratory experience with the organisms, and the fact that researchers "know how to run a good experiment" with them (223,305,394). This approach contrasts with the more unstructured approach employed by APHIS in its host-specificity requirements. Although EPA officials emphasize the flexibility of their system and the ease with which data requirements may be added or subtracted, the extra effort needed to design customized lists of nontarget species and to develop new testing methods for these organisms may well take a back seat to other agency priorities.

EPA focuses heavily on the effects on nontarget agricultural crops, an approach developed with APHIS for the 1982 Subdivision M report.[8] The agency rationalizes that cultivated crops are uniquely vulnerable because they are monocultures, nonmobile (unlike birds and insects), and commonly nonindigenous. Although such thinking may have been fashionable 14 years ago, the potential harmful impacts on nontarget insects and other organisms have since come to be appreciated. Moreover, declines in native natural enemies ultimately may affect agricultural plants by enabling pest populations to grow.

A related concern focuses on the lack of ecosystem testing for microbial and biochemical products. EPA relies primarily on observed impacts (such as unusual persistence in host organs) following administration to the isolated test organism of massive quantities (the "maximum hazard dosage level") of the pest control agent. Such focused testing protocols have procedural advantages, but they overlook the complexity of natural systems and the possibility for harmful ecological repercussions beyond those immediately apparent from short-term laboratory testing on isolated specimens. EPA is spending $1,224,000 in fiscal year 1995 researching ecosystem approaches for testing effects of biochemicals and microbial pesticides.

Genetically Engineered Products

BPPD deals with genetically engineered microbial pesticides on a case-by-case basis. Agency review resembles in most respects that for other microbial products but places increased attention on exposure and effects on nontarget species (305).

[8] Pesticide Assessment Guidelines, Subdivision M: Biorational Pesticides (1982) (393). This document provides guidance on developing data on biochemical and microbial pest control agents. Many of the provisions are obsolete. EPA has rewritten subdivision M only for microbial pesticides (1989) (394).

Recent developments

The first field testing of genetically engineered products took place a decade ago with release of the "ice minus" variant of the bacterium *Pseudomonas syringae,* designed to prevent frost damage on potatoes and strawberries (234).

To date, EPA has registered two types of genetically engineered microbial products, one involving Bt genes inserted into Bt, and the other involving Bt placed in a killed bacterium (305). Raven, registered in January 1995, is a strain of *Bacillus thuringiensis* kurstaki into which the Ecogen Company has incorporated genes of another Bt strain. With respect to environmental implications, EPA views the product as an insignificant departure from standard Bt products, and hopes in the future to exempt from notification requirements similar Bt products with inserted Bt genes. The other products, registered in 1991, use Bt in killed *Pseudomonas fluorescens.* The Mycogen Corporation killed the *Pseudomonas,* which can survive in a wide range of conditions, to prevent it from spreading the Bt genes to new locations. The killed bacterium protects from ultraviolet radiation the encapsulated Bt toxin, allowing for longer field persistence (239). EPA's main concern is to ensure that all the bacteria are dead; the agency requires the monitoring of every batch produced (305).

Other genetically engineered products are undergoing testing. For example, the agency recently approved the field testing of a genetically engineered baculovirus containing an inserted scorpion toxin gene that facilitates a faster kill rate. The scorpion toxin used is only a fraction of the full toxin and does not affect mammals. It may affect some Lepidoptera and other insects.

Notification requirements

EPA's final rule for field testing of genetically engineered microbial agents, published in September 1994, amends 40 CFR Part 172 to require notification of EPA, and preliminary data submission, prior to small-scale environmental testing of microbial agents modified through recombinant DNA technology. The rule applies also to nonindigenous microbial pesticides not acted on by USDA (390).

Some scientists criticize the rule for targeting genetic modification techniques rather than high-risk organisms or outcomes. They argue that the new molecular techniques that manipulate DNA and transfer genes are potentially even safer and more precise and predictable than their traditional counterparts. This view ignores the fact that many efforts to genetically engineer microbial pesticides have thus far focused on expanding target range, altering kill level and rate, and prolonging field persistence—characteristics that could affect environmental impacts in important ways. The critics also say that EPA should worry instead about agents manipulated by other means, such as chemical or radiation mutagenesis, transduction, transformation, or conjugation, which pose greater environmental risks and could pollute waterways (234).

Other scientists counter that gene-splicing techniques are a valid trigger for EPA review; elevated risks stem from the introduction of new living forms that have never had an opportunity to evolve any checks and balances in nature. Scientists' understanding of microbial communities and of the full import of particular species in the functioning of ecosystems is limited. Consequently, genetically engineered microbial pesticides may have wide-ranging consequences that may be difficult to evaluate (172).

Whatever the outcome of this debate, a prudent response by EPA requires scrutiny and flexibility, given the types of characteristics being engineered into microbial products and the paucity of information on potential environmental effects.

Resistance

One of the most significant challenges facing BPPD is the prevention of resistance to Bt. Some scientists believe that large-scale squandering of this microbial pesticide may result from the widespread use of crops engineered to contain the genes for Bt toxin. The use of these transgenic plants is expected to create tremendous selection pressure among lepidopteran and other pest species, resulting in the rapid development of resistance to Bt. The susceptibility of Bt to resistance has already been documented, with early evidence emerging from certain regions of New York, Florida, and Asia. Potential loss of microbial Bt products poses a serious threat to agriculture in locations where pests have evolved resistance to chemical controls. In parts of Mexico, for example, Bt products are among the only options left against the tomato pinworm; the pest has become resistant to other pesticides (40). Campbell and other growers in that region rely on the availability of effective Bt-based pesticides.

Although EPA is working with manufacturers to develop strategies to manage resistance, it is unclear that any of these ad hoc attempts will actually work. Clearly, resistance has not been successfully prevented in the case of chemical pesticides (see chapter 2); EPA has no real track record in this arena (156). Some scientists argue that the effective management of resistance to Bt will require the concerted efforts of multiple parties. A recent article in *Science,* for example, urges development of a national research agenda, with full cooperation of industries, universities, and government, to develop and implement resistance management strategies for conventionally applied and transgenic Bt toxins (221).

To date, EPA has registered only transgenic potato (May 1995) and field corn (August 1995), although other crops genetically engineered for pesticidal properties are coming through the research and registration pipeline (182,156). As part of the registration process for these products, EPA has developed cooperative agreements with producers dealing with tactics to manage resistance (156,214).

Exactly how Monsanto will prevent the development of resistance to Bt from its potato product remains unclear; thus far, the company's resistance management strategy includes few clearly defined elements (402). In some respects, however, EPA views the Bt potato resistance management activities as a test case: Inasmuch as Bt is only partially effective against the Colorado potato beetle, loss of the microbial pesticide against this pest, hastened by its use in transgenic crops, will not create a major new gap in the pest control arsenal. Because the beetle has already developed resistance to many chemical pesticides, however, it is important to try to prolong the effectiveness of every control method available.

Resistance management for Bt field corn—and eventually for transgenic sweet corn and cotton plants—will present greater challenges for EPA. The pests that feed on cotton and sweet corn, and to a lesser extent on field corn, attack a number of vegetable crops and ornamental plants as well (404). Therefore, pest resistance induced by large-scale use of Bt in transgenic cultivars of these crops may make ineffectual the use of Bt-based pesticides against pests that attack not only corn and cotton but also a range of other crops (156).

The resistance management plan for Bt field corn includes: a Bt dosage meant to be high enough to kill all susceptible pests; annual monitoring for development of resistance; farmer education programs; and, once use of Bt corn becomes widespread in three to five years, the required planting of non-Bt corn as a certain percentage of acreage on each farm that uses Bt corn. The effectiveness of these approaches remains uncertain. EPA's agreement requires the Mycogen and Ciba-Geigy corporations to carry out research on many related issues; their resistance management strategies are likely to change as new evidence emerges (404).

Food and Drug Administration

U.S. Food and Drug Administration (FDA), a relative newcomer to the regulation of BBTs, has yet to identify exactly what roles it will play. The agency may face increasing responsibilities in the future, however, as BBTs become more prominent in food-related industries and postharvest uses.

FDA has authority to regulate the BBT uses that are not subject to EPA or USDA jurisdiction. To date, however, the agency has chosen only to advise state and local health officials; to enforce grading standards for natural enemy and other insect fragments in stored grain; and to contemplate possible oversight of the use of BBTs, specifically, insects and nematodes in food service establishments and other food-handling institutions.

FDA could assume a greater role if it desired. It would need to designate EPA-exempted BBTs (i.e., natural enemies) as food additives in cases when the BBTs could become a component of stored or prepared food and USDA lacks regulatory jurisdiction. FDA could then establish and enforce tolerances for BBTs under section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). Although authorized to develop standards for BBTs (195), however, FDA would prefer to remain responsible only for enforcement of the BBT-related regulations set by EPA.

Two recent controversies may help elucidate FDA's current and future roles in regulating BBTs.

Postharvest Grain Storage

Until 1993, FDA, EPA, and USDA struggled to resolve the question of which agency had statutory jurisdiction over BBTs used for postharvest grain storage (195). Previously, EPA had prohibited such BBT use. Following extensive interagency discussion, FDA was chosen to shoulder the responsibilities.

FDA has determined that nematodes and predatory and parasitic insects released into grain storage areas for pest control purposes are unlikely to become a component of food. Therefore FDA, in conjunction with USDA's Federal Grain Inspection Service, will continue grading grain according to the existing standards for whole insects, fragments, parts and other residues, without special requirements for BBTs (1).

In setting these maximum allowable levels, commonly referred to as defect action levels (DALs), FDA recognizes that some foods will contain insects and insect parts at low levels that are not hazardous to the consumer. FDA designates as adulterated, however, those products found to exceed the DAL for insect fragments. Adulterated products are seized by FDA and, if they cannot be cleaned by further processing, destroyed.

Food Service Areas

The release of parasitic and predatory insects and nematodes into food service establishments and food-handling institutions has also created confusion over statutory jurisdiction. Unlike the controversy surrounding postharvest grain storage, this issue has been only partly resolved despite extensive discussions among USDA, EPA, FDA, and members of Congress.

After 11 months of indecision, the agencies decided that neither EPA nor USDA would regulate BBTs when used in food preparation areas. The task of how or whether to regulate BBTs for these uses has been left to FDA. FDA, however, has no formal policy or procedure to date (147) and has not assumed responsibility for conditions in restaurants and other institutions with food preparation areas (195). FDA restricts its activities to the manufacturing side of food products and leaves food preparation areas to state and local health officials. The agency issues recommendations, for the sake of uniformity, which the local and state offices can independently choose to adopt. On the assumption that introduced insects might find their way into food, putting the consumer at risk, FDA has recommended against the use of insects and nematodes as a pest control practice in food preparation areas (195).

The agency is now considering whether to regulate these insects and nematodes as food additives under section 409 of the FFDCA or to leave the decisions up to state health departments. Under section 409 (104) any substance must be an approved food additive or generally recognized as safe (GRAS) for its intended use, if its intended use results in its becoming a component of food. FDA does not consider these insects to be GRAS for their intended use and therefore has the authority to regulate them as food additives (148). It may decide to do so if data show that the insects may become a component of food.

FDA is currently reviewing its position and is willing to receive and review any valid data showing that there is no reasonable expectation that the insects will become a component of the food (147). It is unclear what further action the agency will take. In all probability, FDA will not assume a greater role unless forced to do so, enabling state or local health officials to make their own decisions (box 4-8).

BOX 4-8: Chronology of the Praxis Company's Experience with FDA

For two years, Praxis Integrated Biological Cybernetics, a small company in Allegan, Michigan, has been corresponding with local, state, and federal officials in hopes of obtaining permission to resume its use of parasitic wasps and nematodes for cockroach control in food service areas (restaurants, schools, nursing homes). Despite congressional intervention on behalf of Praxis, an agreeable solution has come only with considerable difficulty, years of delay, and great expense to the company.

In 1993, a Detroit bakery solicited Praxis's help in controlling cockroaches. Uncertain about regulatory requirements, the bakery contacted the Michigan Department of Public Health. Knowing little about these natural enemy products but concerned about their potential effects, the department director prohibited Praxis from any further releases of wasps and nematodes as of October 1993 and recommended that an advisory group be assembled with representatives from EPA and USDA to determine the appropriate regulatory response.

Weary of the inability of state and local officials to come to a conclusion, Praxis's owners sought the help of their representative in the U.S. Congress, the Honorable Peter Hoekstra, who wrote to EPA requesting its assistance in resolving the issue. In response to Congressman Hoekstra's letter, EPA replied that while "EPA registers pesticides and regulates their use, parasites, predators, or *macro*biological agents (including nematodes) are not required to be registered." Because EPA considered these organisms to fall under APHIS's jurisdiction, EPA would not make a determination as to their safety. Congressman Hoekstra proceeded to contact both USDA and FDA requesting an expedited determination on the safety of Praxis's products.

In a letter to the Michigan Department of Public Health dated January 13, 1994, FDA stated that while eating establishments are principally regulated by local and state agencies, FDA felt that the EPA exemption did not cover use in retail food establishments—thus implying that EPA was responsible for making the decision. The letter also stated that FDA would not recommend or condone the use of biological control agents in a public eating facility. The following month, USDA-APHIS responded to Congressman Hoekstra's inquiry, concluding that APHIS, like EPA and FDA, was not responsible for regulating the biological control agents for these specific uses.

In March 1994, FDA reiterated its belief that EPA was responsible and that, if so requested, FDA would assist EPA in making the determination. The contradictory agency responses prompted Congressman Hoekstra to request a telephone conference with the appropriate individuals at EPA, FDA, and USDA. In May, Praxis was notified that these agencies were holding preliminary conferences to decide how to handle the situation. By October 1994, however, neither Praxis nor Congressman Hoekstra had been contacted regarding a solution. Congressman Hoekstra sent a letter in October and a fax in December of 1994 expressing his concern about the delay.

In January of 1995, FDA responded to Praxis in a letter stating that "extensive discussions" had been held to determine statutory authority. It was decided that neither EPA nor USDA-APHIS would regulate the wasps and nematodes. The letter concluded that FDA would be willing to review data supporting the safety claims made by Praxis, but that any action on the part of FDA would not override regulatory actions by the state or other local agencies.

(continued)

BOX 4-8: Chronology of the Praxis Company's Experience with FDA (Cont'd.)

Although frustrated by the 16-month delay, Praxis agreed to send FDA copies of information that had previously been provided. Praxis's owners made another request for the phone conference that had been promised 10 months earlier. In February, after several delays, the phone conference was held. Praxis was asked to provide additional data to enable FDA to determine the safety of the products. At the conclusion of the meeting, FDA promised a final decision within 90 days.

The state of Michigan, meanwhile, convened an advisory group (Michigan Human Living Environment Pest Management Advisory Group) in the summer of 1994 to examine possible human health risks and to recommend safety procedures for the indoor use of biological control agents. In the absence of an FDA ruling, the group submitted its findings and recommendations in June of 1995. The group decided in favor of Praxis, resolving that the Michigan Department of Public Health should allow the use of biological control agents in food service establishments as part of an IPM plan.

FDA's final decision in August of 1995 also supported Praxis. FDA decided not to recommend that the State of Michigan prohibit Praxis from marketing parasitic wasps and nematodes for cockroach control.

Praxis is now free to move forward with its parasitic wasps and nematodes, but the two year delay has considerably drained the company's resources. The company continues to struggle to market its products. According to Praxis representatives, Cooperative Extension agents and university scientists insist that if the company wishes to gain their support, Praxis not only must submit to them proprietary information but also must allow them to publish that material. Convincing Extension Agents to recommend the company's biological control products—or at least not to dissuade potential customers—may prove to be another uphill battle for Praxis.

Source: Office of Technology Assessment, 1995.

REGULATING THE RISKS FROM BBTS: ISSUES AND OPTIONS

Regulatory Structure for Natural Enemy Industry and Biological Control Research

The current regulatory system under APHIS has a number of important flaws. Its requirements and permitting process for the natural enemy industry lack balance, transparency, and efficiency. Small companies must comply with often useless paperwork and critical delays in shipping organisms that have a long history of repeated introduction and widespread use.

Past permitting of classical biological control introductions by researchers has been uneven, with the greatest focus on biological control agents targeting weeds, and relatively little scrutiny of agents affecting insect pests. The existence of an advisory group (TAG) only for weeds demonstrates the varying levels of evaluation. To improve the agency's regulatory decisionmaking, APHIS needs to give more complete coverage to all biological control introductions, and to develop better documentation of nontarget impacts from past introductions.

Significant environmental risk issues exist that APHIS needs to identify and evaluate. The agency's recently proposed (and subsequently withdrawn) regulation on the introduction of nonindigenous species, however, was clear evidence that APHIS has not yet succeeded in assigning priorities and addressing these risks. The proposal was exceedingly stringent in some areas and overly lax in others.

OPTION *Congress could, through its oversight functions, instruct APHIS to streamline its permitting process and to design a more balanced regulatory system for biological control. Components of these changes might include the following:*

- *Developing a more even-handed regulation for biological control with broader input from* *all stakeholders (researchers, natural enemy companies, farmers and other users, wildland managers, state agencies, conservation biologists, etc.).*

- *Formulating an explicit policy concerning the regulation of nematodes. Although formally within APHIS's jurisdiction, nematode products rarely go through APHIS review. The agency needs to carefully consider whether this leaves any significant risk issues unaddressed. Potential impacts on companies producing nematode-based products must weigh into the development of a more formal policy.*
- *Instituting a technical advisory group (TAG) to evaluate proposed introductions of unprecedented biological control agents targeted at insect pests (entomophagous agents), and improving the science underlying the regulatory decisionmaking for these agents by developing appropriate host-specificity testing protocols. The different standards of review for biological control agents targeting plant and insect pests are based on historical concerns about agricultural crop protection and ignore our scientific understanding of the importance of native biodiversity and the value to agriculture of conserving native natural enemies. Enhanced review of entomophagous species may provoke objection from entomologists who are not used to this level of scrutiny.*
- *Developing mechanisms through which to include input from a cross section of nongovernmental organizations, including those concerned with environmental risk and conservation issues, in APHIS's decisions about biological control agents. The Federal Advisory Committee Act allows membership on advisory committees by nonfederal agencies so long as the committees adhere to certain procedural requirements. If APHIS chooses not to expand TAG membership, other channels may be available for nonfederal input.*
- *Requiring post-release monitoring of the nontarget impacts from the highest risk introductions as a condition of the permitting process. The challenge is to develop a mechanism for funding such research, so as not to place undue burdens on a low-profit industry that produces a valuable set of low-risk pest control tools.*
- *Maintaining clearer records of permitted releases, the basis for these decisions, and any subsequent impacts, to improve future decisionmaking. According to APHIS, some of these changes are already in progress; these efforts deserve support and encouragement.*
- *Convening a panel of scientific experts to evaluate APHIS's past regulatory precedents as a basis for future permitting decisions. This review could help APHIS identify some of the high-risk releases and facilitate agency streamlining of other permitting activities.*

OPTION *An opportunity to address some of the flaws in APHIS's regulatory system may present itself in the agency's efforts to consolidate all of its plant protection statutes into a single package.*

EPA's Regulation of Microbial Pesticides and Pheromone Products

Recent actions by EPA's Biopesticides and Pollution Prevention Division to expedite the permitting of pheromones and microbial pesticides have received high marks by the regulated industry. The division's strides in streamlining BBT registrations will need to retain some balance in the long run, especially regarding granting of waivers for environmental testing. Microbial products that have been genetically engineered to behave like conventional pesticides (see chapters 3 and 6) will need to be handled with care, because some will pose risks similar to those associated with conventional pesticides rather than having the relatively benign environmental profile of microbial pesticides registered to date.

OPTION *Congress could, either by amendment to FIFRA or through its oversight functions, instruct BPPD to pay closer attention to possible nontarget impacts on native insects and other noneconomic species, and to begin considering how it will deal with microbes genetically engineered for broader spectrum impacts and faster and higher kill rates. (One option would be to pass these on to other EPA divi-*

sions to be dealt with as conventional pesticides, but such action could substantially thwart development of genetically engineered microbial pesticides by removing the cost incentive to produce such products—see chapter 6.)

Consistency in the Regulatory Structure

Some analysts have identified as an important problem the lack of consistency among APHIS, EPA, and FDA in the agencies' regulatory oversight of natural enemies and microbial pesticides. They suggest that both types of BBTs pose similar questions of nontarget effects and other environmental risks (e.g., 235). They argue that these two categories of BBTs need an overall regulatory umbrella, a single law or a single agency to give microbial pesticides and natural enemies equal coverage.

OPTION *Congress could pass a new law embracing uses of natural enemies and microbial pesticides that would give more similar coverage to these two categories, but OTA does not find sufficient justification for this option. EPA, FDA, and APHIS all have expertise in different areas, which corresponds at least roughly with their current regulatory responsibilities. It is important, for example, that EPA continue toxicity studies on certain microbial products; the other agencies are unequipped to take over that function. Certainly regulatory gaps exist, but these can be addressed within the current institutional framework (see previous options).*

Anticipating the Occurrence of Pest Resistance to BBTs

Scientists believe that resistance is probable for bacteria- and virus-based microbial pesticides and possible for several other categories of BBTs. The rates at which resistance appears are likely to be slower than those for conventional pesticides. Of particular concern, however, is the threat of more rapid development of resistance to Bt-based microbial pesticides from the anticipated large-scale use of crop plants genetically engineered to contain the Bt toxin.

OPTION *The problem of managing resistance to Bt is exacerbated by the lack of clear understanding of its scientific underpinnings and the paucity of demonstrated successes in countering this phenomenon. EPA is requiring the development of resistance management plans as a condition for its registrations of Bt-containing crops, but the effectiveness of these provisions remains uncertain. To prevent the loss of this valuable tool in the pest control arsenal, Congress might consider funding research on mechanisms to halt or reduce the development of resistance (e.g., specific use patterns for the transgenic plants), possibly as part of a cost-sharing program with potentially impacted commodity groups.*

Recent deliberations in Congress have centered on whether EPA should keep or transfer to APHIS its regulatory oversight of plants genetically engineered for pesticidal properties. OTA has identified several technical and institutional factors that favor retention of jurisdiction by EPA. Crops that are manipulated to express the Bt toxin raise many of the same issues (resistance, toxicology, etc.) that EPA has addressed in the context of microbial pesticides. Only EPA has the experience, scientific capacity and infrastructure with which to tackle these difficult problems with any hope of success. Moreover, the agency has the necessary authority to designate specific use patterns, labeling requirements, and training programs that could help prevent resistance and thus the loss of Bt-based pest control tools. APHIS lacks the relevant experience and statutory authority to adequately address the Bt resistance problem.

Adjusting Regulatory Requirements for Chemical Pesticides

Integrated pest management (IPM) involves the combined use of multiple pest control approaches. Conventional pesticides often are used in concert with augmentation or conservation of natural enemies. However, many pesticides kill the natural enemies as well as the pests. Information on such effects could enable pesticide applicators to reduce or eliminate applications of certain conventional pesticides to protect populations of natural enemies.

OPTION *Congress could amend the Federal Insecticide, Fungicide and Rodenticide Act to include product labeling requirements that alert users to the impacts of pesticides on populations of natural enemies. Currently, Germany requires that pesticide labels indicate the level of harmfulness to beneficial arthropods. A U.S. system could incorporate similar provisions. For example, a German label reads:*

> This product is 'harmful' for populations of *Aphidius rhopalosiphi* (parasitic wasp), 'slightly harmful' for populations of *Coccinella septempunctata* (ladybird beetle), 'not harmful' for populations of *Poccilus cupreus* (carabid beetle).

The species listed are chosen based on such factors as sensitivity to the product and likelihood of exposure (106). Although no other countries presently require such a labeling system, the European Union may consider adopting a similar program as part of its efforts to harmonize requirements. (For other regulatory examples from abroad, see box 4-9.)

Anticipating Food Safety Issues

Pressures on FDA to play a role in BBT regulation will grow as applications of these technologies to control postharvest diseases in food-related industries increase. Current ambiguity about the agency's role has had negative repercussions for at least one BBT company and its clients, who need a more predictable and workable system.

OPTION *Congress could instruct FDA to analyze and firm up its current and future role in this area. In view of FDA's recent experience with the state of Michigan and the Praxis Company, a small investment of resources into workshops or policy sessions to review the important issues now would preclude significant bureaucratic entanglements and the resources they consume down the line.*

BOX 4-9: Other Regulatory Systems

The Australian Biological Control Act and the draft code of conduct of the United Nations' Food and Agriculture Organization (FAO) are often cited as regulatory models deserving consideration or emulation by policymakers in the United States. These systems are described here. Also included is the International Convention on Biological Diversity, which raises ownership issues that may affect future prospecting for biological control agents in other countries.

Regulation of BBTs Down Under

Australia relies on a combination of BBT-related laws. The Quarantine Act (1908) and the Wildlife Protection Act (1984) control the importation of exotic organisms into quarantine and for release. The Genetic Manipulation Advisory Committee, which lacks legal authority but wields considerable power regardless, oversees the release of genetically modified BBTs (a mandatory rule is under development). And the National Registration Authority has responsibility for approving commercial biological pesticides such as Bt, in addition to chemical products. The use of non-exotic organisms is not regulated unless they are genetically modified or they merit examination in a manner similar to that of agricultural and veterinary chemicals. The Australians invoke their widely acclaimed Biological Control Act (1984) only as a last resort, when the choice of a target or the use of a particular control agent is likely to be controversial. To date, the act has been summoned only for two programs, controlling the annual weed Paterson's curse (*Echium planatagineum*) and the blackberry (*Rubus fruticosus*). In the latter case the use of the law was threatened but never executed.

(continued)

BOX 4-9: Other Regulatory Systems (Cont'd.)

Australia's Biological Control Act is the only biological control legislation ever adopted by a national government. Several features of the act deserve attention. First, the act directly addresses biological control, unlike laws in the United States which apply to BBTs only secondarily in the context of noxious weeds, conventional pesticides, or other concerns. Second, compliance with the act is not mandatory. It is there to be invoked only if needed. Third, the act places considerable emphasis on the inclusion of all issues and public comments, but where a decision to proceed is then made, the individuals or organizations involved are freed from liability. Fourth, although the Biological Control Act offers a valuable mechanism on certain occasions, it may be used only rarely in light of the substantial time and expenditure involved. Fifth, in contrast to U.S. approaches, the Biological Control Act includes serious consideration of the target organism. When the Agriculture and Resource Management Council of Australia and New Zealand recommends declaration of a target pest, the Biological Control Authority must publish its intention in widely circulating newspapers and journals, giving relevant information and inviting comment. If further information is needed, the Biological Control Authority may initiate an inquiry by the Industries Commission or under the Environmental Protection Act or a specially constituted body, depending on the issues at stake. Decisions on individual biological control agents with which to control the target organism follow much the same course, although publication in the *Commonwealth Gazette* (*Federal Register*) is deemed sufficient.

FAO Draft Code of Conduct for the Import and Release of Biological Control Agents

The U.S. government is participating in the completion of the FAO code of conduct, a voluntary set of standards for the importation of BBTs capable of self-replication—parasites, predators, nematode parasites, plant-eating arthropods, and pathogens. The code will cover agents imported for research as well as for field release, including those used in classical biological control and those packaged or formulated as commercial products. The recommendations of the code do not distinguish between different kinds of BBTs, in contrast to the U.S. regulatory approach which addresses separately biological control importations and the use of microbial pesticides. Pheromones and resistant host plants fall outside the scope of the code. Toxic products of microbes that are used as pesticides, which cannot reproduce and which behave like conventional pesticides, are covered instead by the International Code of Conduct on the Distribution and Use of Pesticides (1990). In the future, the biological control code may apply also to genetically engineered BBTs.

The FAO code describes the responsibilities of governments and of importers and exporters of BBTs before, during, and after importation. Its provisions include, for example, the designation by each government of a competent authority to oversee BBT imports and releases; the use of precautions against the export of BBTs adulterated with their own natural enemies or with other contaminants; and the preparation of dossiers on the pest to be controlled (to justify the importation of a control agent) and on the candidate biologically based control agent (to document its identity and potential human and environmental risks). The draft code emphasizes that every effort should be made to transport the BBT at a life-cycle stage during which it can survive without its host pest (the entry of which could present an additional quarantine risk). The code also stresses the importance of proper labeling, post-release monitoring, deposition of voucher specimens, education and training of users, and other procedures.

(continued)

BOX 4-9: Other Regulatory Systems (Cont'd.)

Convention on Biological Diversity

The United States is a signatory to the Convention on Biological Diversity, an international agreement promoting the conservation of biological diversity and the equitable sharing of benefits arising from the use of genetic resources. The convention does not specifically mention biological control, but it touches upon related issues such as the commitment of countries to control alien pests (Article 8.h) and the creation of conditions facilitating access to genetic resources for environmentally sound uses (Article15.2).

Several countries, most notably China, India, Brazil and Mexico, have interpreted the convention to suggest that the nation importing the biological control agents from abroad must reimburse the country of origin. Article 15.7 calls for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources." Article 19.2 addresses specifically the benefits arising from biotechnologies based upon genetic resources, and emphasizes developing countries' special need for access. Article 15.1 acknowledges state sovereignty over resources: "...the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." These passages could imply the development of a fee system for the collection of natural enemies from abroad. Undoubtedly this option is controversial, however, particularly because the pests themselves commonly originate from those same countries and because the international exchange of natural enemies can be a mutually beneficial enterprise.

At least 98 countries worldwide have been the source of biological control agents for one or more programs, and 121 countries have introduced at least one agent. Countries in the developing world have been the source of 57 percent of all biological control introductions against alien insect pests worldwide and the recipient of 52 percent of all such biological control introductions.

SOURCES: Office of Technology Assessment, U.S. Congress, 1995, compiled from Centre For Agriculture and Biosciences International, *Using Biodiversity to Protect Biodiversity: Biological Control, Conservation and the Biodiversity Convention* (Wallingford, Oxon, UK: 1994); J.M. Cullen and T.E. Bellas, Division of Entomology, CSIRO, Canberra, Australia, "Australian Laws, Policies and Programs Related to Biologically-Based Technologies for Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1995; United Nations Environment Programme, *Convention on Biological Diversity,* June 5, 1992 (as of July 20, 1995: URL=gopher:\\Gopher.UNDP.Org:70/00/Unconfs/English/Biodiv.Txt, no date); United Nations Food and Agriculture Organization, *Draft Code of Conduct for the Import and Release of Biological Control Agents* (Rome, Italy: November 1994); J.K. Waage, Director, International Institute of Biological Control, Ascot Berks, UK, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July, 1995.

From Research to Implementation 5

The federal government plays a large role in the research, development, and implementation of biologically based technologies for pest control (BBTs). At least 11 agencies are involved, and annual expenditures amount to over $210 million. Despite the size of these efforts, BBTs do not move smoothly from research to providing on-the-ground solutions to pest problems (see also chapter 3). This chapter explores some of the reasons for the bottleneck. It begins by describing activities of federal agencies related to BBT research and implementation and then examines how the federal government influences decisions of farmers and other users to adopt BBTs. The chapter concludes by identifying a series of issues and options for improving the flow of research findings into their practical applications.

OVERVIEW

Several federal agencies conduct or fund BBT research. Total funds allocated to BBTs by these agencies exceed $160 million annually, approximately $30 million of which comes from the state matching funds through the Cooperative State Research, Education, and Extension Service (CSREES) (table 5-1). The states also make substantial contributions directly to the State Agricultural Experiment Stations and to land grant universities.

The public sector spends approximately $90 million each year on pest control programs based on BBTs (table 5-2). Of this, about $10 million represents the biological control programs run by 28 state departments of agriculture. The precise amount that goes toward implementing BBT programs is difficult to determine because research on classical biological control sometimes results in significant suppression of a pest following release of an imported natural enemy, although no funds for implementation per se were expended.

U.S. Department of Agriculture

Four U.S. Department of Agriculture (USDA) agencies conduct BBT-related work ranging from regulation to research, implementation, and extension. Today, their activities fall under the umbrella of policies set in place by the Clinton Administration's stated goals to reduce the use of conventional pesticides and to implement integrated pest management (IPM) on 75 percent of U.S. agricultural lands by the turn of the century (box 5-1).

CHAPTER 5 FINDINGS

- The federal government dominates research on biologically based technologies for pest control (BBTs). Total federal funds for research, which exceed $130 million annually, are dispersed among 11 agencies. Despite its size, this expenditure appears to be largely uncoordinated and to lack adequate prioritization.
- Widespread agreement exists that basic research on BBTs is poorly linked to on-the-ground applications. One reason is a lack of research necessary to translate findings into practical field applications, in part because no federal research agency takes responsibility for this function.
- The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) now has a group of scientists developing methods for applying BBTs to control widespread pest problems. The group grew out of clear needs for applied research that were not being served by the Agricultural Research Service (ARS). Its existence engenders considerable institutional conflicts within USDA, however.
- According to some estimates, noxious weeds that degrade western rangelands are spreading at rates of up to 4,000 acres per day. Federal land managers consider biological control to be one of the cornerstones to a cost-effective solution. However, they lack the resources to support appropriate research or programs, and no federal research agency has yet made a large effort in this area.
- Attempts have been made to coordinate biological control activities within and between the federal agencies in the past. But, so far, research scientists say these efforts have been unsuccessful because the coordinating committees and institutes have had inadequate institutional status, authority, and funding.
- Use of BBTs generally requires a significant level of information and knowledge, and farmers often lack clear-cut instructions or authoritative sources of advice on how to apply them. The Cooperative Extension Service is the principal government provider of direct, hands-on services to growers, but most extension agents have had little if any formal exposure to biologically based approaches.
- The Cooperative Extension Service's role in shaping pest management practices is now secondary to that of the more numerous private crop consultants, pest control advisors, and pesticide dealers and applicators in most regions of the country. Like extension agents, many private advisors are not well versed in BBTs or integrated pest management (IPM).

TABLE 5-1: Funding for Research on BBTs

	1988	1989	1990	1991	1992	1993	1994	1995	1996 (est.)
U.S. Department of Agriculture (USDA)									
Agricultural Research Service (ARS)[a]	82	80	82	87	101	98	104	104	104
Cooperative State Research, Education and Extension Service (CSREES)[b]									
Federal	6	9	9	9	9	10	12	13	14
State	24	28	31	27	28	29	29	30	30
Animal and Plant Health Inspection Service (APHIS)[c]	3	4	6	7	8	10	12	10	10
Forest Service	3	5	4	5	5	5	5	5	NA[d]
U.S. Environmental Protection Agency (EPA)	NA	NA	NA	NA	NA	1	1	1	0
U.S. Army Corps of Engineers	0.9	0.8	1.3	1.2	1.4	1.5	1.4	1.4	0
U.S. Department of Interior (DoI)	NA	NA	NA	1	1	1	1	1	1
Total public spending	118	126	133	137	153	156	165	165	>159
Inflation-adjusted spending[e]	≈109	≈112	≈112	≈113	≈124	≈125	≈130	≈129	NA

[a] According to certain former and current ARS scientists, the ARS pest control budget has been declining since 1985. Data obtained by OTA do not confirm this assertion. According to ARS, although the pest control budget has increased modestly in recent years, its purchasing power has decreased; ARS consequently has been unable to fill biological control positions vacated by retirements.

[b] Numbers cover only biological control research and do not include microbial pesticides, pheromones, sterile insects or plant immunization.

[c] APHIS/PPQ Biological Control Operational program budget only.

[d] NA = Not available.

[e] The producer price index (PPI) was used to calculate inflation-adjusted research budgets. In 1982, the base year used, the PPI was 1.00; in 1988 it was 0.926; in 1993, 0.802; and in 1995, it is estimated to be 0.78.

NOTE: Data have been rounded to nearest million, except for the Army Corps of Engineers. This chart presents the best numbers available. The agencies do not usually report their budgets in categories consistent with OTA's scope. They and OTA's contractors exercised care in compiling the numbers; each agency also reviewed and confirmed the budget estimates. Nevertheless, some errors of under- or overreporting may have occurred. An additional complexity is that it is widely acknowledged that the Current Research Information System used to track funds and full-time equivalents has technical flaws and inconsistent definitions.

SOURCES: Compiled by OTA from E.Z. Francis, Director, Toxics/Pesticides and Water Staff, Office of Research and Science Integration, U.S. Environmental Protection Agency, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, June 9, 1995; D.M. Gibbons, The EOP Foundation, Inc., Washington, DC, "Biologically-Based Technologies for Pest Control: Report on the Role of the USDA in Biologically-Based Pest Control Research," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995; W. Klassen, Tropical Research and Education Center, University of Florida, Homestead, FL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995; K. Koltes, National Biological Service, U.S. Department of the Interior, personal communication, June 1995.; D.E. Meyerdirk, Biological Control Operations, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995; R. Nechols and J. Obrycki, Kansas State University and Iowa State University, "OTA Preliminary Assessment of Biological Control: Current Research," unpublished report for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994; S.J. Rockey, National Research Initiative Competitive Grants Program, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, fax to the Office of Technology Assessment, Washington, DC, August 10, 1995.

TABLE 5-2: Funding of BBT-Based Pest Control Programs

Agency	Fiscal year 1994 dollars (millions)
Animal and Plant Health Inspection Service[a]	69.7
Forest Service	11.0
States	9.4
Bureau of Land Management	0.3

[a] Includes all APHIS pest control programs having a major focus on BBTs.

NOTE: Table does not include technology transfer functions through ARS and CSREES or classical biological control research programs in which researchers introduce a biological control agent.

SOURCES: D.M. Gibbons, The EOP Foundation, Inc., Washington, DC, "Report on the Role of the USDA in Biologically-Based Pest Control Research," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995; W.W. Metterhouse, Cream Ridge, NJ, "The States' Roles in Biologically-Based Technologies for Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994; D. Meyerdirk, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.

BOX 5-1: USDA's Integrated Pest Management Initiative

On September 21, 1993, at a joint congressional hearing, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Food and Drug Administration called for a national commitment to develop and implement Integrated Pest Management (IPM) on 75 percent of U.S. crop acreage by the year 2000. The USDA announced an Integrated Pest Management Initiative in December of the following year. Its goals include involving farmers and practitioners in the development of IPM programs, increasing the use of IPM systems, and developing active partnerships between the public and private sectors. To achieve these goals, the Administration budget for fiscal year 1996 recommended a significant increase in funding for the IPM initiative's principal programs. The budget requests for 1996 include $7 million for a regional competitive grants program; $9.5 million for ARS's areawide pest management program; and $5 million to be passed through the Cooperative State Research Education and Extension Service to the Cooperative Extension Service and State Agricultural Experiment Stations to meet priorities identified on a regional and local level. As of August 1995, the Congress had appropriated no increase to the Extension Service and only $360,000 to be used for regional programs.[a]

The Clinton Administration's commitment to IPM is the third attempt to create a national IPM program since the term *IPM* first came into use in the 1960s. Both the Nixon and the Carter administrations funded multiagency research, training, and implementation programs. These programs inspired broad interest at the state level but were unable to provide a similar sustained effort at the national level. Funding for IPM programs was redirected after the 1980 election.

The design and direction of the Clinton Administration's IPM Initiative is based on years of thoughtful planning and analysis at local, regional, and national levels. In June 1992, USDA and EPA jointly sponsored the National IPM Forum which brought together participants from all sectors involved in agriculture—including 13 federal agencies—to examine constraints and obstacles to the adoption of IPM. The following year, with partial funding from EPA, several regional workshops of growers were convened in order to follow up on the national forum. In 1994, the Experiment Station Committee on Organization and Policy and USDA jointly funded the Second National IPM Symposium.

(continued)

BOX 5-1: USDA's Integrated Pest Management Initiative (Cont'd.)

Early in 1994, under the auspices of the Deputy Secretary of Agriculture, the planning for USDA's IPM initiative began. It was decided that USDA would approach IPM at state and regional levels to identify and address the needs of growers. Essential to accomplishing this task are IPM teams composed of producers, land-grant universities, crop advisers and consultants, and private industry. In 1995, 23 teams involving 42 states were convened to identify important research and education needs and to establish guidelines for evaluating the efficacy of USDA IPM programs. Equally important, the proposed competitive grants program for funding IPM research would award grants (up to $500,000 per year for five years) to similar multidisciplinary teams to ensure that the work addresses real-world concerns of growers and that the results feed directly into field use.

The USDA's IPM initiative addresses a number of the criticisms raised in this chapter. It could encourage organization and cooperation among the federal government, states, growers, and researchers, and improve the connection between IPM research and its implementation. Ultimately, the impact of the USDA IPM initiative on pest management will depend on sustained commitments from USDA, the Administration, and the Congress. Whether support will be forthcoming from Congress is as yet uncertain.

[a] This reflects wording of the agricultural appropriations bill for fiscal year 1996 from the House of Representatives; as of August 1995 the Senate had not put together its agricultural appropriations bill.

SOURCES: J.R. Cate, and M.K. Hinkle, *Integrated Pest Management: The Path of a Paradigm*, National Audubon Society, (Alexandria, VA: Weadon Printing, Inc., July 1994); L. Elworth, Special Assistant for Pesticide Policy, Office of the Assistant Secretary for Science and Education, U.S. Department of Agriculture, personal communication, May 5, 1995; B. Jacobsen, U.S. Department of Agriculture, Washington, D.C., fax to OTA, August 17, 1995; U.S. Department of Agriculture, Cooperative State Research, Education and Extension Service, "Request for Proposal, National Integrated Pest Management Implementation Program, Fiscal Year 1995," special projects guidelines, unpublished white paper, 1995; U.S. Department of Agriculture, Office of Communications, "USDA's Integrated Pest Management," (IPM Initiative, Release No. 0942.94, December 14, 1994).

Agricultural Research Service

An estimated $104 million of the Agricultural Research Service's (ARS) annual budget goes toward research on BBTs, supporting the efforts of around 1,166 FTEs[1] (table 5-1) (114). Approximately 300 BBT-related projects were under way in 1993 (247). ARS represents the single largest concentration of BBT research in the United States. In some BBT research disciplines, the majority of U.S. scientists work for ARS; for example, seven of the 11 U.S. specialists in biological control of postharvest plant diseases[2] work for ARS (161).

ARS counts among its past accomplishments complete economic control of 11 insect pests and three weeds by classical biological control (58). The agency also played a key role in the screwworm (*Cochliomyia hominivorax*) program that eradicated this pest from the United States. Ongoing BBT research includes projects such as biological control of the rangeland weed yellow starthistle (*Centaurea solstitialis*), and suppression of diamondback moth (*Plutella xylostella*) in cabbage using a combination of pheromones, parasitic wasps, and *Bacillus thuringiensis* (Bt) (20,88,430).

ARS researchers working on BBTs are distributed throughout the agency's 129 laboratories across the country, with biological control activities occurring at 49 locations (349). The agency also has four laboratories abroad (Montpellier, France; Buenos Aires, Argentina; Tuxtla-Gutier-

[1] Full-time equivalent employees. Any given FTE in the count may represent an overall summation of part-time efforts by a number of employees.

[2] Such diseases cause decomposition or rot on fruits, vegetables, and other commodities after they have been harvested.

rez, Mexico; and Panama) that conduct foreign exploration for classical biological control agents, as well as worksites in Australia, Italy, and Greece (320). No other federal or state agency possesses this capability for foreign exploration; although some state agencies, universities, and private organizations conduct foreign exploration, and other federal agencies (the Animal and Plant Health Inspection Service, the Forest Service, and the U.S. Fish and Wildlife Service) sometimes contract with international organizations to help identify potential biological control agents. Nevertheless, ARS's effort underlies numerous high-priority U.S. efforts in classical biological control (188,246,416).

ARS's pest research focuses on certain categories of pests more than others. Projects addressing insect pests account for approximately 75 percent of its BBT research (247). The remaining 25 percent is divided among plant pathogens (11 percent), nematodes (2 percent), and weeds (12 percent) (247).

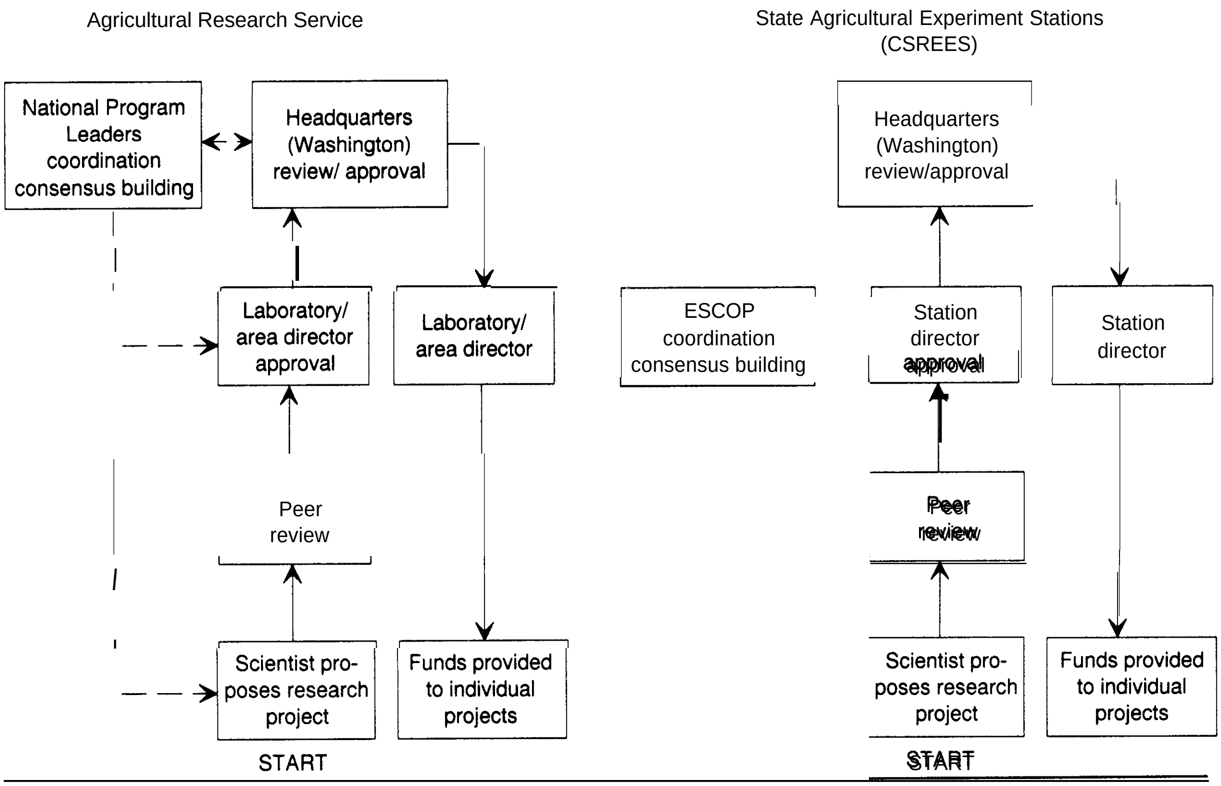
Federal land managers believe that rangeland weeds are important pests and that BBTs could play an integral role in controlling them (388). ARS's approximately $6 million weed-related work takes place primarily at the Rangeland Weeds Laboratory at Bozeman, Montana (280). The laboratory is relatively small, with a staff of four ARS scientists. The Forest Service has also assigned a scientist to the laboratory and provides $300,000 annually to fund the researcher's work. The Clinton Administration's budget proposal for fiscal year 1996 would end funding for ARS's other long-standing California-based program for biological control of weeds, although its past successes in weed control have been highly valued by state officials and others (26). Despite the relatively small allocation of resources by the agency, federal land managers give ARS scientists high marks for their collaborative efforts to address rangeland weeds. For example, ARS recently compiled a comprehensive summary of findings on weed natural enemies for use by federal, state, county and other rangeland managers (348).

The major criticisms of ARS are that, despite the agency's accomplishments, it has difficulty responding in a timely fashion to externally identified research goals and priorities, and too much of its BBT research does not find its way into applications on the ground. A number of factors may contribute to these problems. In general, ARS does not seem to have found a satisfactory way to set research goals and at the same time enable creativity and productivity among its scientific staff in accomplishing these goals. A surprisingly large number of former and current ARS staff reported their concerns about the agency's internal management to OTA during the course of this assessment.

The process by which ARS allocates funds to research, on paper, seems to provide a clear mechanism for focusing efforts on national research goals through involvement of the National Program Staff (figure 5-1). The scientist in the role of a National Program Leader is supposed to provide national leadership for a specific topic area. At least three National Program Leaders deal with BBTs. However, in practice, because the National Program Leaders lack funding authority, their influence on the overall research agenda—based on consultation and consensus building among ARS scientists located in laboratories across the country—is largely voluntary and sometimes ineffectual. Congress has with some regularity set de facto research goals by targeting appropriations for work on certain key pests, and ARS solicits related research proposals from staff scientists. According to agency critics, the quality of research can suffer when such political pressures run high (200).

Even when clearly identified goals emerge, the agency's structure imparts an inflexibility that can make it difficult to reallocate resources and staff to newly identified priorities. Existing resources are usually tied up in ongoing projects, reflecting the long periods of time required for certain types of research. However, this also leaves little funding for new initiatives. In addition, ARS managers say scrutiny by members of Congress can strongly deter attempts to move

FIGURE 5-1: General Schematic of the Decision Processes by which the Agricultural Research Service and State Agricultural Experiment Stations Award Research Funds



SOURCE: Office of Technology Assessment, 1995,

NOTE: Dashed line represents influences of the National Program Leaders (NPL) or the Experiment Station Committee on Organization and Policy (ESCOP).

projects from one congressional district to another even when warranted by changing pest problems (349). Experience with the silverleaf whitefly, *Bemisia argentifolii,* (formerly known as the sweetpotato whitefly strain B, *Bemisia tabaci)* demonstrates ARS's limitations in responding rapidly to emerging pests (box 5-2) (200). The agency was unable to mobilize a significant research effort until after the five-year USDA program was put into effect. By that time, the pest had risen to the top of the political agenda and funds were directed to the Animal and Plant Health Inspection Service (APHIS) for its control.

Perhaps in part because of such delays, ARS's research does not always match the needs of operations agencies involved in pest management. For many years APHIS, the agency with principal responsibility for control of agricultural pests, annually submitted a prioritized list of research needs to ARS (364). APHIS representatives say the agency was unable to identify tangible results that supported their operational responsibilities (364) and consequently in 1992 moved to less formal methods for communicating their needs (428). According to ARS, however, virtually all of APHIS's ongoing biological control programs are based on research accomplished by ARS; the role of APHIS's methods development staff (discussed later) has been to scale-up the findings from ARS research (320). The differing views suggest that, although ARS research does support APHIS operations, it requires significant adaptation to be put into practical use. The differing views also seem

BOX 5-2: Case Studies of USDA Pest Control Programs Involving Biologically Based Technologies

Eradication of the screwworm

The screwworm (*Cochliomyia hominovorax,* the larval stage of the screwworm fly) is a parasite that consumes the live flesh of cattle, hogs, horses, mules, sheep, goats, dogs, other domestic and wild animals, and humans. During the first half of the century, this pest caused significant damage in the southern United States. For example, between 1932 and 1934, 1.3 million livestock animals were infested by the parasite, and over 200,000 animals died in the Gulf states.

In 1951 USDA began a program to eradicate the screwworm from the United States by releasing sterile male screwworm flies into wild populations. Poor management of the production and distribution of the flies and misunderstandings of the pest's behavior and ecology led to setbacks in the Southwest between 1972 and 1976. Program scientists identified the main causes of the problems, and, by 1982, the screwworm became the only pest to be eliminated from the United States.

The screwworm program began prior to the separation of APHIS and Agricultural Research Service into two distinct agencies. After the separation, these two agencies worked together on the program until the mid-1980s. APHIS continues the program today in Mexico and Central America.

The scientists involved in the program attribute its success to several factors, including USDA's long-term commitment and sustained funding. Staff for the eradication program devote 100 percent of their time to it; in contrast, other USDA scientists work on several projects at once. Other contributing factors include regulations to control the movement of infested cattle, and cooperation among veterinarians, farmers, and federal officials. The eradication program in Mexico has been less successful partly because of the continued movement of contaminated cattle.

The boll weevil eradication program

Since 1892 the boll weevil (*Anthonomus grandis*) has caused considerable damage to the U.S. cotton industry. Aggregate losses amounted to $12 billion as of 1990. Losses per year in the mid-1970s were estimated at $200 million to $300 million. In the 1960s ARS began a program to eradicate the boll weevil from the southeastern United States. The main objectives were to reduce economic damage from the pest, to reduce the use of pesticides, and to conserve the natural enemies of the other pests in cotton fields such as the beet armyworm (*Spodoptera exigua*), fall armyworm (*S. frugiperda*), and bollworm, also called the corn earworm and the tomato fruitworm (*Helicoverpa zea*). To date, the boll weevil eradication program has succeeded in eight of the cotton belt states, while four others are engaged in on-going programs. Farmers have gained $12 for every dollar they have spent on this program. Because of decreased pesticide sprayings against the boll weevil, the beet armyworm and fall armyworm are now controlled by their natural enemies in many cotton fields.

Success of this program has been attributed to the strong coordination among federal agencies, state governments, and farmers. APHIS coordinates the overall program with the Boll Weevil Eradication Foundation, organized by the farmers who provide a majority of the funding. Farmers usually supply over 70 percent of the program funds, while the remainder comes from USDA (mainly APHIS) and the state governments. Although areawide spraying of pesticides is the main control method, a pheromone trap for monitoring boll weevil abundance, developed by ARS, is an essential component of the program. After the areawide sprayings, traps allow fieldworkers to detect and take action against each new infestation before the pest becomes abundant and spreads to uninfested fields.

(continued)

BOX 5-2: Case Studies of USDA Pest Control Programs Involving Biologically Based Technologies (Cont'd.)

Russian wheat aphid

The Russian wheat aphid (*Diuraphis noxia*) first appeared in the United States in 1986 and has since spread to 15 states and caused more than $850 million in losses to wheat farmers. In 1988, scientists from APHIS, the Agricultural Research Service, and CSREES began research to identify classical biological control agents for the Russian wheat aphid.

APHIS has received a majority of the congressional line-item funds for the control of this pest—between $1 million and $2.5 million annually from 1990 to 1995. The agency's biological control program has not yet succeeded in establishing any natural enemies that provide adequate control. Scientists criticize APHIS for putting too much emphasis on the introduction of potential biological control agents while neglecting to carry out effective followup studies tracking the agents' impacts. Little is known about the effects, good or bad, of the introduced species on the Russian wheat aphid, on other introduced natural enemies, or on native species and ecosystems. Of the 24 species and over 100 geographic strains released, only four of the imported parasites are suspected of having become established in the wheatfields, and their effectiveness against the Russian wheat aphid remains unknown. Field workers and scientists are unable to correctly identify the released parasites because of their close resemblance to native strains and to other parasites released by ARS for control of different aphid pests. Some aphid predators (which are mainly lady beetles) released by APHIS prior to the Russian wheat aphid program have also become established, although their effectiveness against the pest is uncertain.

Scientists involved in the program feel it is too early to judge its success because establishing an effective biological control agent can take years. Others argue, however, that the program has been rushed because of APHIS's responsibility to suppress pest outbreaks. The result has been the release of numerous natural enemies without correct identification of their taxonomy or adequate knowledge of their ecological effects. Biological control programs lacking such information are less likely to succeed. For this reason, biological control is not often the best route for quick suppression of a pest, unless adequate knowledge is available at the project's inception about the ecology of both the pest and its natural enemies.

The silverleaf whitefly

The silverleaf whitefly (*Bemisia argentifolii*)—initially identified as strain B of the sweet potato whitefly (*Bemisia tabaci*)—first appeared in Florida in 1986. It attacks at least 600 different crops, including melon, cotton, tomato, lettuce, and many ornamental plants. The spread of the silverleaf whitefly across the country caused extensive crop losses estimated at $200 million to $500 million between 1991 and 1992. The Imperial Valley of California has been one of the hardest hit areas; from 1991 through 1994, an estimated 9,000 local jobs disappeared and crop losses exceeded $300 million due to the pest.

The initial response of scientists and federal agencies to the silverleaf whitefly was uncoordinated and lacking in focus. Scientists who began studying the problem were working in isolation, and thus their work was unlikely to yield rapid solutions. Despite warnings in the late 1980s by its own scientists, ARS began to mobilize a significant response to the pest only when damage skyrocketed during the 1991 outbreak in the Southwest. And according to numerous critics, APHIS and ARS had difficulty cooperating during early phases of the outbreak. USDA officials attribute the early inaction to the lack of an official mechanism for USDA agencies to jointly address new pest problems.

(continued)

BOX 5-2: Case Studies of USDA Pest Control Programs
Involving Biologically Based Technologies (Cont'd.)

Actions by grower organizations and commodity groups played a significant role in improving the focus of efforts to control the silverleaf whitefly. These groups lobbied for congressional action, resulting in direct appropriations in fiscal year 1993 of $2.6 million to APHIS for the development of a biological control program. The Office of the Secretary of Agriculture stepped in to provide guidance in development of a cooperative USDA program; in 1992 the five-year action plan was put in place to coordinate the efforts of ARS, APHIS, CSREES. The grower and commodity groups also supplied direct funding to local extension scientists, which supported the essential research for developing local and regional control methods.

To date, the most effective measures for controlling the silverleaf whitefly are cultural practices, chemical insecticides, and a microbial pesticide based on the fungus *Beauvaria bassiana*. APHIS's biological control program has not yet yielded a successful natural enemy. As in the case of the Russian wheat aphid, the agency has been criticized by outside scientists for releasing multiple biological control agents with too little forethought or post-release monitoring.

SOURCES: S.L. Birdsall and D. Ritter, Imperial Valley Agricultural Commissioner and Whitefly Program Coordinator, respectively, unpublished data on the economic impact of the silverleaf whitefly in Imperial Valley, Imperial Valley, CA, 1994; H. Browning, State Agricultural Experiment Station, University of Florida, Gainsville, FL, personal communcation, August, 1995; W. Dickerson, Plant Pest Administrator, North Carolina Department of Agriculture, Raleigh, NC, personal communication, July, 1995, and August 1995; T. Engle, Budget and Accounting Office, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 21, 1995; M.J.R. Hall and W.N. Beesley, "The New World screwworm fly in North Africa," *Pesticide Outlook* 1(2):34-37, 1990; P. Karieva, Department of Zoology, Univeristy of Washington, Seattle, WA, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August, 1995; E.S. Krafsur, Department of Entomology, Iowa State University, Ames, IA, personal communication, July, 1995; W. Lambert, extension entomologist, Univeristy of Georgia, personal communication, August, 1995; N. Leppla, Assisstant Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, August, 1995; R.L. Metcalf and R.A. Metcalf, *Destructive and Useful Insects: Their Habits and Control 5th Ed.* (New York, NY: Mcgraw-Hill Inc., 1993); S.K. Narang, National Program Staff, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, fax to Offfice of Technology Assessment, U.S. Congress, Washington, DC, August 17, 1995; J.R. Nechols, Department of Entomology, Kansas State Univerisity, Manhattan,KS, personal communication, July 24, 1995, August 21, 1995; D. Prokrym, Project Leader, Russian Wheat Aphid Biological Control Project, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Niles, MI, personal communication, August 10, 1995, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 11, 1995; D. Stanley, "Whitefly Causes Bleak Times for Growers," *Agricultural Research* 16(2), January, 1991; N. Toscano, Department of Entomology, Univeristy of California-Riverside, Riverside, CA, personal communication, August, 1995; U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Biological Control of the Russian Wheat Aphid," APHIS Pub. No. 1507 (Washington DC: December 1993); U.S. Department of Agriculture, Animal, and Plant Health Inspection Service, Plant Protection and Quarantine, National Biological Control Laboratory, *Russian Wheat Aphid Biological Control Project—FY 1993 Project Report,* prepared by D.R. Prokrym, J.R. Gould, D.J. Nelson, L.A. Wood and C.J. Copeland (Niles, MI: 1993); U.S. Department of Agriculture, Economic Research Service, *Economic Returns to Boll Weevil Eradication,* prepared by G.A. Carlson, G. Sappie and M. Hammig, AER Pub. No. 621 (Washington, DC: September 1989); R. Van Driesche, et al. Department of Entomology, Univeristy of Massachusetts, Amherst, MA, "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, December 1994.

characteristic of the lack of good communication and cooperation between ARS and APHIS. According to outside observers, even ARS research results that might be relevant to APHIS's programs do not consistently filter through to APHIS because of poor communication between the agencies (114,176).

The working environment for individual scientists within the agency may also affect the ease with which ARS's research on BBTs moves into practical applications. Agency scientists complain that the funding environment is highly competitive, and that funds get siphoned off at several levels, leaving only a minimum amount for actually conducting the research. Some low-profile areas central to the development of BBTs, such as taxonomy and systematics, receive relatively little support (58). According to some ARS scientists, the necessary work to take research on BBTs "out of the laboratory and into the field" is discouraged. Instead, performance is judged by the number of scholarly publications—a criterion usually applied to academic scientists whose work is supposedly less mission oriented.

One mechanism for converting research results into practical applications is the Cooperative Research and Development Agreements (CRADAs) through which outside institutions help to fund federal research and obtain licensing rights to research discoveries in return. ARS has supported numerous collaborative research projects with private industry (320). As of July 1994, ARS had a total of 16 ongoing agreements related to BBTs. However, only five of these involved private sector companies or organizations; the rest were agreements with other federal agencies, states, foreign governments, or universities (300). ARS recently began to develop another new program for transferring technologies to the private sector that might provide additional opportunities for companies to help fund ARS research; the program is expected to start in fiscal year 1996 (417A) (see options in chapter 6 for additional discussion of cooperative agreements with the private sector).

ARS scientists working on classical biological control express specific dissatisfaction with the organizational structure of the agency and how it affects their ability to do timely work. They point to the 1972 restructuring of the agency as a major blow because it destroyed the previous tight coordination of related research within the agency (58). ARS had a National Program Leader for Biological Control until 1992 when the program was changed to Pest Management. Coincident with a switch in senior management, the emphasis changed back to Biological Control in 1995 (349). Whether this action will help provide the focus and coordination ARS scientists desire in the area of biological control is uncertain.

Overall, ARS as a research institution has great capabilities in the area of BBTs. Improving the flow of research findings into the field to solve real-world pest problems poses a number of challenges, however.

Animal and Plant Health Inspection Service

The Animal and Plant Health Inspection Service (APHIS) has significant responsibilities for protecting American agriculture from pests under the Plant Pest Act, the Federal Noxious Weed Act, and the Plant Quarantine Act.[3] Its functions related to the regulation of natural enemies are discussed in further detail in chapter 4. This section focuses on APHIS's pest control responsibilities.

APHIS's pest control programs incorporate a number of BBTs (table 5-3). The agency has placed special emphasis on biological control. In 1992 the APHIS Administrator issued an agencywide policy directive (the APHIS Biological Control Philosophy) stating:

> APHIS believes that modern biological control, appropriately applied and monitored, is an environmentally safe and desirable form of long-term management of pest species. APHIS believes that biological control is preferable when applicable; however, we also recognize that biological control has limited application to emergency eradication programs. Where possible, biological control should replace chemical control as the base strategy for integrated pest management (222).

In 1994, the North American Plant Protection Organization[4] adopted a similar philosophy based on APHIS's model (197). University and state scientists outside the federal government,

[3] Federal Plant Pest Act (1957), as amended (7 U.S.C. 147a *et seq.*), the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.* (1974)) and the Plant Quarantine Act (7 U.S.C. 151 *et seq.* (1967)).

[4] The North American Plant Protection Organization is part of the International Plant Protection Group that is comprised of representatives from Canada, Mexico, and the United States.

TABLE 5-3: Technologies Used in Pest Management Programs of the Animal and Plant Health Inspection Service (USDA)

Pest	Biological control	Sex pheromone trap	Sterile insect technique	Other
Insects				
Apple ermine moth (*Yponomeuta malinella*)		X		P
Boll weevil (*Anthonomus grandis*)	X	X		P, C, F
Brown citrus aphid (*Toxoptera citricida*)	X			
Cereal leaf beetle (*Oulema melanopus*)	X			
Cherry ermine moth		X		P
Euonymus scale (*Unapis euonymi*)	X			
Fruit fly detection		X		P, F, M
Grasshopper/MC	X, MD			P
Gypsy moth (*Lymantria dispar*)	X, MD	X	MD	P
Imported fire ant (*Solenopsis invicta*, *S. richteri*)	MD			P
Japanese beetle (*Popillia japonica*)	X	X		P
Medfly (*Ceratitis capitata*)	MD	X	X	P, F, M, C, E
Mexfly (*Anastrepha ludens*)	MD		X	P, F, C, E
Pine shoot beetle (*Tomicus piniperda*)	X			P, MT, C, E
Pink bollworm (*Pectinophora gossypiella*)	X	X	X	P,C, E
Russian wheat aphid (*Diuraphis noxia*)	X			
Sweet potato whitefly (*Bemisia tabaci*)	X			
Weeds				
Common crupina (*Crupina vulgaris*)	X			
Diffuse and spotted knapweed (*Centaurea diffusa*, *C. maculosa*)	X			
Leafy spurge (*Euphorbia esula*)	X			C
Purple loosestrife (*Lythrum salicaria*)	X			
Catclaw mimosa (*Mimosa pigra*)				P
Onionweed (*Asphodelus fistulosus*)				P
Goatsrue (*Galega officinalis*)				P
Hydrilla (*Hydrilla verticillata*)	X			P
Little bell morning glory (*Ipomoea triloba*)				P
Liverseed grass (*Urochloa panicoides*)				P
Mediterranean saltwort (*Salsola vermiculata*)				P
Branched broomrape (*Orbanche ramosa*)				P
Small broomrape (*Orbance minor*)				P

(continued)

TABLE 5-3: Technologies Used in Pest Management Programs of the Animal and Plant Health Inspection Service (USDA) (Cont'd.)

Witchweed (*Striga* spp.)	CS
Plant pathogens	
Black stem rust (*Puccinia graminis*)	C, RV
Chrysanthemum white rust (*Puccinia horiana*)	P, RV
Golden nematode (*Globodera rostochiensis*)	C, RV

TABLE KEY:
X = Used
C = Cultural control
CS = Chemical stimulant
E = Environmental (hot or cold air treatment)
F = Food bait trap
MD = Methods under development
MT = Mechanical Trap (traps of a particular shape , size, or color)
P = Pesticide
RV = Resistant varieties
Sterile Insect = Use of sterile insects

SOURCE: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Control Operations, unpublished 1994 data provided by D. E. Meyerdirk, Senior Staff Officer, April 1995.

however, are somewhat skeptical about the extent to which APHIS adheres to the policy (338A).

Although APHIS has identified 10 criteria for selecting target pests for biological control, the agency says that advice from the National Plant Board[5] and political considerations often emerge as the most significant factors (365). APHIS currently funds 14 pest control programs based on biological control at a total annual cost of approximately $11 million (230). Half of this money is committed in designated budget lines to only two pests. The agency has long complained that such a precise designation of funds for specific pests decreases its ability to respond to newly emerging pest threats. However, the designation also ensures that the money goes to the specific pest problem and is not diffused among several programs. Biological control programs often affect several states and, consequently, involve significant allocations of funds. The APHIS program for leafy spurge (*Euphorbia esula*), for example, covers 17 western states and cost $1.8 million in fiscal year 1994 (356).

One measure of the agency's commitment to biological control was the creation of the National Biological Control Institute in 1990 in response to a perceived need to increase the prominence of and coordinate biological control within APHIS, between APHIS and the other USDA agencies, and between APHIS and organizations outside the government. The institute's mission is "to promote, facilitate and provide leadership for biological control" (363).

APHIS created the National Biological Control Institute the same year the USDA established the Interagency Biological Control Coordinating Committee ("IBC^3") by a memorandum signed jointly by the administrators from ARS, the Cooperative State Research Service,[6] and APHIS. Two other USDA agencies, the Forest Service and the Extension Service, also partici-

[5] The National Plant Board is composed of federal agriculture officials and individuals from state departments of agriculture.

[6] The Cooperative State Research Service (CSRS) has since been merged with the Extension Service to become the Cooperative State Research, Education, and Extension Service (CSREES). CSREES is discussed later in this chapter.

pated. The committee's purpose—"to provide leadership in biological control within USDA and in proposing uniform departmental policies in such matters" (119)—was similar to that of the National Biological Control Institute. Unlike the institute, however, the committee never had any direct funding. In 1993, the committee attempted to make biological control a top USDA priority by proposing a National Biological Control Program to enhance biological control research, education, and implementation efforts in the federal government. That program called for an increase of $53 million over three years. Both the Cooperative State Research Service and APHIS received small allocations of funds in 1994 associated with the proposed program, but the proposal was never fully acted upon (75,324). As of 1995, the Interagency Biological Control Coordinating Committee had lapsed into inactivity.

Reviews of APHIS's National Biological Control Institute's impacts are mixed. The institute is effective at outreach beyond the beltway and is highly respected by scientists in state government, universities, and other institutions. Over the past four years, the institute has awarded approximately $1.5 million in grants for implementation projects, educational and informational materials, postdoctoral fellowships, meetings and workshops, publications and the development of databases (363). However, the institute's highly regarded staff and expertise are not always paid attention to within APHIS. For example, efforts by the National Biological Control Institute to involve stakeholders in the development of biological control regulations were not incorporated into the broader proposed rule that APHIS issued for nonindigenous species (see chapter 4). That rule was later withdrawn because of negative public comment. APHIS is now starting a new rulemaking process in which the agency again will seek out extensive public input (353). Moreover, the institute has not been incorporated into the working group representing various agencies in the USDA IPM Initiative. This oversight is unfortunate because it perpetuates the historical separation of biological control and IPM pest control disciplines (see chapters 2 and 3 for discussions of the relationship between biological control and IPM).

To support its implementation programs, APHIS has a methods development staff which conducts applied research on how to get BBT methods into the field to solve widespread pest problems. About $5 million is expended annually on biological control research, and $10 million overall on all BBTs (230).[7] APHIS created the Methods Development because ARS and other research agencies were not adequately addressing APHIS's pest control development needs, especially the scale-up necessary to apply methods more broadly. The existence of the methods development staff within APHIS is a source of some tension with the USDA research agencies, however. In 1991, when the Secretary of Agriculture initiated the silverleaf whitefly program, critics argued that APHIS should not have received funding for implementing a control program until more basic research by other agencies and scientists had demonstrated that technologies were available to control the pest (78). The criticism perhaps reflects an inherent overlap between research and implementation programs in classical biological control. The desired endpoint of both is the establishment of a natural enemy that provides widespread, lasting, and effective suppression of a pest; in national pest control programs the respective roles of research by ARS and implementation by APHIS in achieving this goal have not yet been well delineated.

A related concern is whether APHIS can operate objectively in regulating its own biological control programs (82). Critics point to what they claim are fast-paced and sloppy attempts to put biological control in place when a new pest rises to the top of the political agenda. Because of a

[7] In addition to Methods Development, APHIS's Animal Damage Control Division spends about $1.3 million annually developing BBTs for vertebrates, specifically immunocontraceptives and genetically engineered vaccines for coyotes (225)

Federal programs based on the release of sterile insects have eliminated the screwworm (Cochliomyia hominivorax) *from the United States.*

Agricultural Research Service, USDA

lack of communication, these efforts sometimes interfere with those of scientists in ARS or the State Agricultural Experiment Stations, eroding their relationships with APHIS (246). Experience with the Russian wheat aphid *(Diuraphis noxia)* and silverleaf whitefly tend to support this view (box 5-2). Regulatory, research, and implementation functions related to biological control all coexist in the same organizational unit of APHIS called Plant Protection and Quarantine. This situation creates significant potential for internal pressuring of regulators to expedite permitting of new biological control introductions, especially when there is great political urgency to find solutions to existing pest problems.

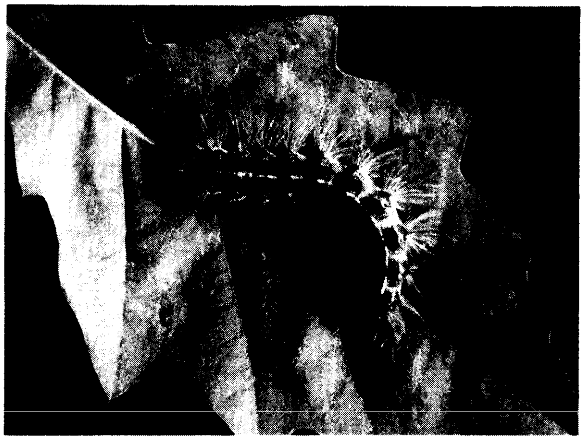
APHIS has statutory authority to conduct pest control programs and to regulate biological control introductions. The agency also has a legitimate role in developing methods to apply BBTs in the field, because these needs are not currently met by any other agency. Better insulation of each of these functions from one another, however, would perhaps ensure the best performance of all three. The current trend within APHIS may run in the reverse direction, however. The agency recently downgraded its operational biological control program (including the laboratories) and placed it under authority of the methods development staff. State agriculture departments hoping to increase the level of coordination of biological control activities worry that APHIS's action will result in a loss of identity, effectiveness, and funds for biological control operations (229).

Forest Service

The Forest Service manages the 191.5 million acre National Forest System (roughly 8 percent of the U.S. land area and 29 percent of all federally administered lands). The system encompasses 156 national forests, 19 national grasslands, and 98 other units (334). In addition, under the Cooperative Forestry Assistance Act, the Forest Service controls insect pests and diseases on other forested areas in the country (public and private, some through various cost-share arrangements).[8] To fulfill these responsibilities, the agency has units for pest management research, Forest Insect and Disease Research (FIDR), and for pest suppression, Forest Health Protection (FHP).

FIDR received $24 million in fiscal year 1994 for pest management research, of which approximately $4.5 million was used to fund work on BBTs (114,324). The latter amount was divided between biological control (approximately $3.1 million) and behavioral chemicals ($1.4 million) (114). Among funded projects in fiscal year 1995 are two new biological control studies for rangeland weeds ($300,000) and hemlock woody adelgid *(Adelges tsugae) ($150,000),* with foreign exploration for natural enemies being conducted out of the ARS laboratory in Europe (320,324). The Forest Service established a quarantine facility in Ansonia, Connecticut, in 1992 to facilitate and accelerate the agency's research and development of biological control (58). Research on BBTs is likely to increase as a result of the agency's 1993 strategic plan, "Healthy Forests for America's Future," which emphasizes eco-

8 Cooperative Forestry Assistance Act of 1978, as amended (7 U.S.C A. 2651-2654; 16 U.S.C.A. 564 *et seq.")*



National programs to suppress the gypsy moth (Lymantria dispar) *are based largely on Bt and the gypsy mothNPV virus.*

system management and calls for increases in the research, development, and use of biological control, microbial pesticides, and pheromones (381A).

FHP conducts a wide array of pest control programs. Those programs targeting insect pests rely to a significant extent on BBTs. In fiscal year 1994, BBTs were used for over half of the almost 14,000 acres of National Forests treated for insect pests (383). The diverse methods involved include pheromones and microbial pesticides based on Bt, fungi, viruses, and nematodes (383). The largest pest management effort targets the European gypsy moth *(Lymantria dispar),* relying primarily on Bt, gypsy moth NPV virus, and pheromones to monitor distribution. In 1995 the Forest Service plans to use Bt to control the gypsy moth on 505,603 acres and the NPV virus on 2,263 acres of federal and cooperative lands. Total cost of the gypsy moth program in fiscal year 1994 was $11 million, of which $8.3 million went to Bt applications.

Conventional pesticides remain FHP's method of choice for other pest categories, however. In fiscal year 1994 more than 54,000 acres of National Forests were treated for plant pathogens with chemical fungicides and fumigants, and almost 38,000 acres were treated for weeds with chemical herbicides (383). Use of natural enemies against weeds that same year occurred on 6,400 acres (383).

According to Forest Service insiders, the research unit, FIDR, has not always been able to provide the solutions required by the agency's operations unit, FHP. Part of the problem is that the research timetable does not always match the needed expediency for pest control because some techniques may require significant, and time-consuming, basic research before they can be put into practice (a problem similar to that experienced by ARS). Moreover, although FHP and FIDR conduct joint programs, the researchers at FIDR rarely communicate with the land managers, leading to the criticism that FIDR is not connected to the field. Like APHIS, FHP has begun conducting research on field applications because FIDR cannot fulfill all of its needs. Researchers worry, however, that the quality of biological control work will decline as the number of people involved increases. Some of these problems may dissipate somewhat as the Forest Service moves increasingly toward trying to manage forests to prevent pest problems (i.e., maintaining "forest health") rather than reacting to pest outbreaks.

The Forest Service has only recently begun to address problems with rangeland weeds on federal lands. One Forest Service scientist has been assigned to the ARS Biological Control of Weeds Laboratory in Bozeman, Montana (280). The Forest Service is also a member of the Federal Interagency Committee for the Management of Noxious and Exotic Weeds that was established in 1994 to coordinate federal efforts related to the identification and management of weed problems.

Cooperative State Research, Education, and Extension Service

The Department of Agriculture Reorganization Act of 1994 combined the mission and functions of the Cooperative State Research Service with those of the Extension Service (the Federal partner in the Cooperative Extension Service) to create the Cooperative State Research, Education, and Extension Service (CSREES) (98). The goal of reorganization was to pull together the research and higher education funding of the

Cooperative State Research Service and the technology transfer and education program responsibilities of the Extension Service in order to improve the movement of research findings to application and use via education. The complete integration of the two former agencies has not yet been accomplished; most notably, their budgets remain separate. This section describes the research-related functions of CSREES. The role of CSREES in education and technology transfer will be discussed later in the chapter in the section dealing with educating and influencing users of pest control.

CSREES administers federal research funds through the the National Research Initiative (NRI) and through formula funds and special grants directed to land grant universities by way of the State Agricultural Experiment Stations. The National Research Initiative is a competitive grants program that funds more fundamental research. These characteristics separate it from other sources of agricultural research funding. The program was established in 1991 following release of the 1989 National Research Council report "Investigating Research: A Proposal to Strengthen the Agricultural, Food, and Environment System." The study concluded that fundamental research in agriculture is underfunded. Although 70 percent of funds go to the land grant universities, grants from the National Research Initiative also support research of academic scientists not associated with land grant universities and of ARS scientists (247,292). Grants totaling approximately $13 million were awarded to biological control and IPM research in fiscal year 1994 (291). Of the 31 existing National Research Initiative programs, BBT research may be funded by any of seven programs (depending on the focus), including Entomology, Nematology, Weed Science, and Plant Pathology (292,371). A separate funding program specifically for biological control began in 1994 (371). The money came from a congressional line item for regional IPM that was eliminated in the 1996 House of Representatives budget proposal; its ultimate fate was uncertain as of August 1995 (291).

Within the National Research Initiative, BBT research is identified as mission oriented, although funded projects range from more basic to more applied. The application for funding asks for information about how results will relate to development of IPM programs (371). According to Sally Rockey, division director of the National Research Initiative, this applicability to pest control programs does influence research funding decisions. CSREES can increase scientists' willingness to consider applications of their work through specific calls for more mission-oriented research in announcements of funding opportunities (292). Funding recommendations are made by a panel of researchers who rank submitted proposals following external review and then make recommendations to the Chief Scientist of the National Research Initiative. A Scientific Advisory Committee provides additional advice on programmatic issues (292).

The Land Grant Universities and the State Agricultural Experiment Stations are research institutions established within the states by the Land Grant Act (also known as the Morrill Act) and the Hatch Act,[9] respectively. The Land Grant University System was designed to provide higher education, especially to the children of farmers and industrial workers, and to apply research knowledge to the solution of society's problems through outreach and extension programs (337). The Hatch Act created a research partnership between the federal government and the states by providing funding for the State Agricultural Experiment Stations. These stations are the sites of much of the nation's agricultural research. Formula funds are provided under the act and then matched by the states. These funds, as well as other competitive grants, are funneled through CSREES. For fiscal year 1995, CSREES directed $13 million in federal funds towards biological control research through the National Research Initiative and the State Agricultural

[9] Hatch Act of 1887, as amended (7 U.S.C. 361a-361i).

Experiment Stations. States provided an additional $30 million in matching funds (114,292).

In comparison with the role of the directors of the State Agricultural Experiment Stations, CSREES has a minor role in allocating formula funds to specific research projects (figure 5-1). Scientists submit research proposals to the station directors for internal review; the directors have a good deal of discretion in their funding decisions (265). Proposals that are endorsed are submitted to the CSREES headquarters in Washington, D.C., for final approval. Each station director then designates funds from that agricultural station's budget to approved projects (265).

Directors of the State Agricultural Experiment Stations make their decisions within the context of broad strategic plans (90). Since 1986, these plans—national guidelines setting the vision and mission for the State Agricultural Experiment Stations—have been set in place every four years and periodically updated by the Experiment Station Committee on Organization and Policy.[10] The broad nature of these plans and the diffusion of funding authority regionally among station directors, however, means that the State Agricultural Experiment Station System, like ARS, lacks effective mechanisms to address national goals (316).

An additional aspect of the system of state agricultural experiment stations and land grant universities is how it reflects state trends. Senior faculty at some of the nation's universities complain that as the state priorities shift (from agricultural to urban), allocations of faculty slots and research funds at land grant universities and state agricultural experiment stations devoted to such practical matters as pest control are declining (66,307). Within the University of California system, for example, administrators recently moved to consolidate pest management programs at the Davis and Riverside campuses. They began dismantling the agriculture department at Berkeley, which included the oldest biological control program in the country.

State Agriculture Departments

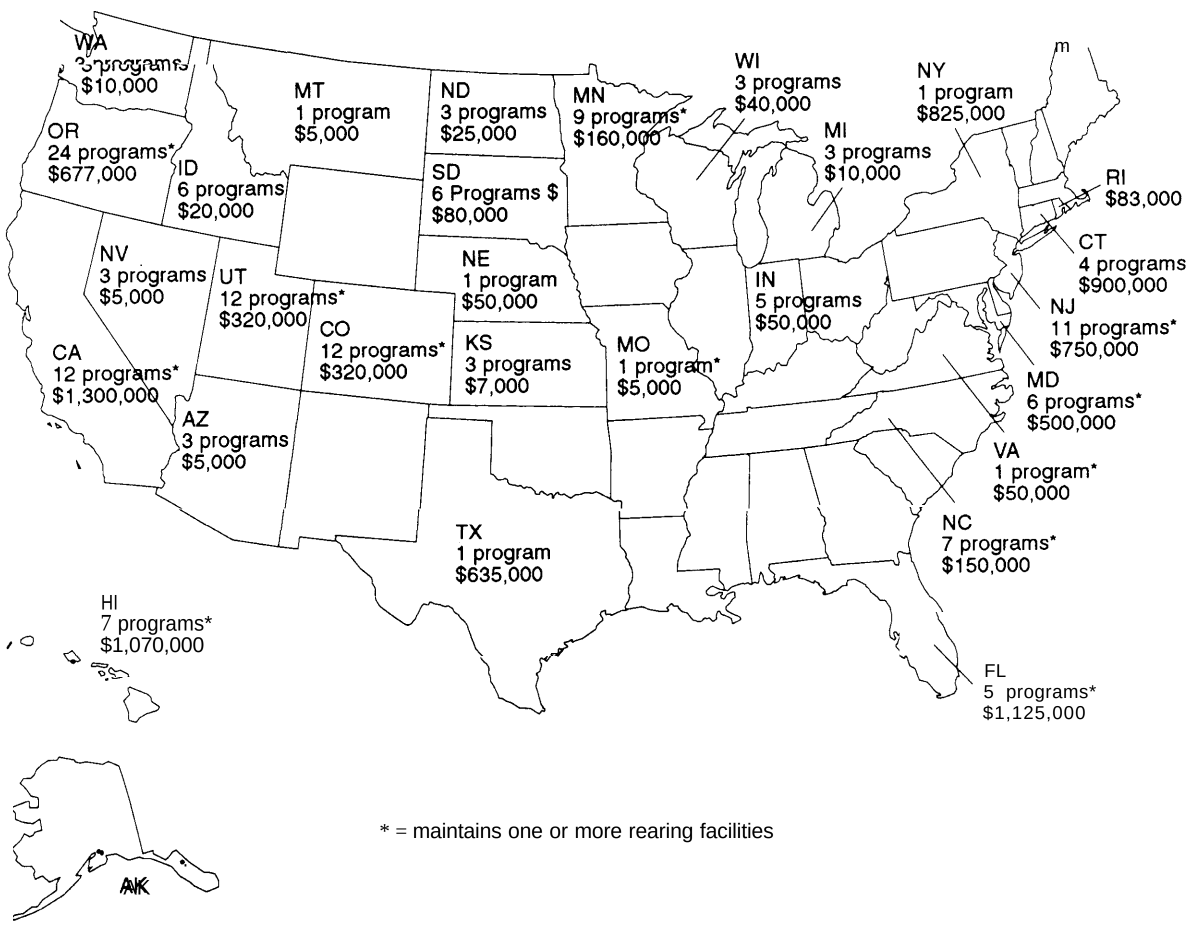
The states are involved in BBT research and implementation through several routes. They provide research matching funds for the State Agricultural Experiment Stations through CSREES and also directly fund experiment stations and land grant universities for BBT work. Precise estimates of the direct funding are unavailable, but the amounts are probably significant; state and private-sector contributions made up 86 percent of total funding for the State Agricultural Experiment Stations in 1990 (154). In addition, a number of state departments of agriculture have developed their own programs to research and implement biological control against important pests affecting their states. These state government programs are the focus of this section.

In recent years, state departments of agriculture have been increasing their use of BBTs in integrated pest management systems because of concerns about groundwater pollution, food safety, and pest resistance (228). Biological control, in particular, now plays a key role. Currently, 28 states have biological control programs, at a total annual cost of almost $10 million (figure 5-2) (228). Several states maintain insect-rearing facilities as part of these efforts, although budget constraints have caused some to close over the past four years; total state funding declined by $2 million from 1990 to 1994. California has the largest program; it is part of an overall movement within the state to reduce reliance on conventional pesticides (box 5-3).

State-funded BBT programs (most are applied classical biological control) generally work cooperatively with APHIS, the Agricultural Research Service, the Land Grant Universities, and the U.S. Fish and Wildlife Service (228). A

[10] The Experiment Station Committee on Organization and Policy is a subcommittee of a CSREES committee with representation from every State Agricultural Experiment Station.

FIGURE 5-2: Biological Control Expenditures and Programs in State Departments of Agriculture



SOURCES: Compiled by OTA from W.W. Metterhouse, Cream Ridge, NJ, "The States' Roles in Biologically-Based Technologies for Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.

close relationship with APHIS results from common regulatory responsibilities and the location of APHIS operational staff within each state to assist with implementation programs. States depend on APHIS to provide educational services and deliver materials for field implementation (228). Once a released biological control agent becomes established, however, it usually becomes the state's responsibility to distribute the agent further, although sometimes APHIS continues distribution when a state cannot (320).

Since 1966 there have been a number of successful federal-state biological control programs. Of the 28 states with biological control programs, 22 have cooperative efforts with federal agencies. Successful programs include cereal leaf beetle *(Oulema melanopus),* involving USDA, ARS, APHIS, and the states of Michigan and Indiana; Colorado potato beetle *(Leptinotarsa decemlineata),* involving ARS and the state of New Jersey; and the gypsy moth programs, involving ARS, APHIS, the Forest Service and several states (228).

■ U.S. Department of the Interior

Historically, the resource management agencies of the U.S. Department of the Interior (DoI) conducted their own research to support manage-

BOX 5-3: California Takes an Active Role in Changing Pest Management Practices

California is perhaps the nation's leader in changing pest control practices and the adoption of BBTs. The state supports a diverse agricultural mix, with a significant emphasis on minor crops. Thus regulatory restrictions on pesticides and declining availability of minor use chemicals are expected to hit the state especially hard. Innovations in pest control practices have also been driven in part by its health-conscious population. California has a long history of involvement with biological control and IPM; it was the site of many of the most significant developments in the field, including the widely cited successful introduction of the vedalia beetle (*Rodolia cardinalis*) to control cottony cushion scale (*Icerya purchasi*) in citrus.

The changes occurring in California reflect an overall effort within the state to shift away from a reliance on conventional pesticides. They are not haphazard; California has actively sought to develop strategic goals and policies to accomplish them.

The California Environmental Protection Agency's program to regulate pesticides parallels that of the U.S. EPA. Its policies have an important influence on the decisions of pesticide manufacturers because of the size of California's potential pesticide market. The state now requires extensive reporting of pesticide use. It also licenses pest control advisors, who must be college-educated in an agriculture-related field, fulfill course requirements, and participate in continuing education. State regulators are currently considering a proposed requirement that pest control advisors undergo four hours of training in the use of biological control and natural enemies.

The California Department of Food and Agriculture has the largest state program for biological control. It maintains an insectary for rearing natural enemies, and programs to implement biological control, costing about $1.3 million annually. Recent projects have addressed euonymus scale (*Unapis euonymi*), grape leafhopper, and water hyacinth (*Eichhornia crassipes*).

The University of California is home to an active statewide IPM program that is perhaps the best in the country at promoting pesticide alternatives, including BBTs. Funded partly through USDA, this program sponsors hundreds of IPM research projects. It has been particularly effective at getting research results into the field: Of the 180 research projects funded between 1979 and 1988, about 43 percent resulted in pest control products or information that are now in use. A disproportionate number of the nation's experts in BBTs are on the faculty of the University of California, and many have collaborated with private consultants and growers to develop innovative approaches using BBTs.

Farmers within the state have developed their own ways of promoting pesticide alternatives. The publication *Farmer to Farmer*, written by and for farmers to share success stories in sustainable farming practices, originated in California. Regional organizations such as the Community Alliance with Family Farmers Foundation have worked with growers to develop biologically intensive farming practices such as the use of natural enemies and other BBTs in almond orchards. Not surprisingly, many of the biggest natural enemy companies are located in California.

SOURCES: C.M. Benbrook and D.J. Marquart, *Challenge and Change: A Progressive Approach to Pesticide Regulation in California*, contractor report prepared for the California Environmental Protection Agency, Department of Pesticide Regulation (Sacramento, CA: April 1993); Community Alliance with Family Farmers Foundation, "BIOS: A New Project Promoting Biological Almond Farming," Davis, CA, 1995; J.I. Grieshop and R.A. Pence, "Research Results: Statewide IPM's First 10 Years," *California Agriculture* 44(5): September-October 1990; M.L. Flint, et al., *Annual Report, University of California Statewide IPM Project* (Davis, CA: University of California, September 1993); M.L. Flint and K. Klonsky, "IPM Information Delivery to Pest Control Advisors," *California Agriculture* March-April, 1989; T.L. Jones, Special Assistant to the Director, Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA, personal communication, U.S. Congress, Washington, DC, July, 1995; W.W. Metterhouse, Cream Ridge, NJ, "The States' Roles in Biologically-Based Technologies For Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.

ment functions. This arrangement changed with the formation of the National Biological Service, the newly consolidated research arm of the department that was established in November 1993 by an order of the Secretary of Interior.[11]

The National Biological Service inherited a somewhat mixed portfolio of BBT-related research programs. Most of these had grown out of specific concerns of federal land managers rather than any overarching program or stated goal to implement BBTs. For example, the National Biological Service is studying insects and fungi as potential controls for non-native invasive plants for the National Park Service and the Fish and Wildlife Service. Past efforts have included working with USDA and the National Park Service to evaluate bacteria for control of gypsy moth (427). Other related research projects are evaluating waterfowl and fish predation as potential controls for zebra mussel (*Dreissena* spp.), several species of flea beetle for control of leafy spurge, and several weevil species for control of purple loosestrife (*Lythrum salicaria*) (427). Expenditures by DoI on BBT research totalled around $1 million in fiscal year 1994 (181). This figure includes $85,000 to $100,000 in funds from the Bureau of Land Management "passed through" to help support the ARS weeds lab in Bozeman, Montana (290).

The Department of the Interior has only a few pest control programs using BBTs. These programs are scattered haphazardly throughout DoI within at least four resource management agencies. The Bureau of Land Management uses biological control on weeds in nearly all of the Western states. The weed targets include field bindweed (*Convolvulus arvensis*), gorse (*Ulex europaeus*), poison hemlock (*Conium maculatum*), diffuse and spotted knapweed (*Centaurea diffusa*, *C. maculosa*), yellow starthistle (*Centaurea solstitialis*), leafy spurge, and purple loosestrife. The lack of greater emphasis on BBTs within DoI is somewhat surprising, given the technologies' potentially high compatibility with management of environmentally sensitive areas. It may, in part, reflect the historical lack of emphasis on pest management among federal land management agencies (338). The result has been a growing belief among many managers that pests of natural and less managed areas—specifically nonindigenous species that kill, consume, parasitize, or compete with native species—are now significant threats to the biodiversity and continued value of these natural resources (338).

A number of DoI agencies are members of the Federal Interagency Committee for the Management of Noxious and Exotic Weeds mentioned earlier in the chapter (303,388). This group arose in response to new requirements in the 1990 Farm Bill[12] that all federal land managers develop programs for control of "undesirable plants." In addition, concern had been growing for some time among staff within the Bureau of Land Management that noxious weed problems were rapidly outstripping the Bureau's ability to manage them with conventional methods. The interagency group has representatives from four agencies in the USDA: the Forest Service, ARS, APHIS and CSREES; six agencies in DoI: the National Park Service, the Bureau of Land Management, the Fish and Wildlife Service, the National Biological Service, the Bureau of Reclamation, and the Bureau of Indian Affairs; the Department of Defense; and several other agencies. Among this group's stated goals is to increase the necessary research to discover and develop biological control agents for weed control (388).

DoI initiated several related efforts in 1995. The Secretary of the Interior designated a new task force to address noxious weeds specifically on DoI lands and issued a secretarial order requesting that DoI bureaus develop coordinated weed prevention and management strategies (290,303). The departmental manual's guidance

[11] CFR Vol.. 58, No 229 December 1, 1993, 63387.
[12] The Food, Agriculture, Conservation and Trade Act of 1990, P.L. 101-624.

on weed control was revised, and now specifies incorporation of integrated pest management, including biological control, into weed control programs. The revised guidance also established a committee to coordinate DoI weed control activities and instructed the National Biological Service to provide scientific information and research support for the DoI weed programs, including development of integrated weed management systems (303).

Army Corps of Engineers

The Army Corps of Engineers has had a research program on biological control of noxious and nuisance aquatic weeds since 1959, funded at around $1 million for the past few years. In cooperation with USDA, the Corps conducts research to identify natural enemies for weeds that impede navigation, restrict water flow, and dominate the natural system by the formation of single species stands. In the 36 years of joint research, the Corps believes that the program has been extremely successful. Scientists have released 12 biological control agents for the management of four plant species, including alligator weed (*Alternanthera philoxeroides*), water hyacinth, water lettuce (*Pistia stratiotes*), and hydrilla (*Hydrilla verticillata*). These programs cover 15 states. Corps scientists have also been involved in evaluating three potential pathogens for weed control. Aside from ARS collaborators, no one else in the federal government conducts similar work to address aquatic weeds.

Through the Department of Defense's membership in the Federal Interagency Committee for the Management of Noxious and Exotic Weeds, scientists from the Corps's aquatic weed program have recently become involved in developing systems to enhance implementation of weed control programs using BBTs and other methods (51). One project under way is the construction of a database of ongoing research on weed control. The other is development of an expert system that will eventually provide users with information on various options for controlling specific weeds, constraints on the use of these methods, and their effectiveness.

The Army Corps of Engineers program for biological control of aquatic weed, such as water hyacinth (Eichornia crassipes) *is one of two weed control programs slated for elimination in the current round of federal budget proposals.*

The Clinton Administration proposed eliminating the approximately $10 million budget for the Corps's aquatic weed program in its fiscal year 1996 budget proposal. As of August 1995, the fate of the program was as yet undecided in Congress.

Environmental Protection Agency

The Office of Research and Development of the U.S. Environmental Protection Agency (EPA) administers a research program to provide risk assessment tools. These research activities are undertaken in part to assist the EPA's Office of Prevention, Pesticides, and Toxic Substances during pesticide registration, special review, and review of premanufacture notices submitted by industry (107). EPA's research focuses primarily on microbial pesticides. Its purpose is to assist in making sound evaluations of the risks and benefits of microbial pesticides, including those based on bacteria, fungi, and viruses, and certain genetically modified organisms (398). Funding for microbial pesticide research at three EPA laboratories totaled $684,600 for fiscal year 1995. It included cooperative field studies with universities regarding the potential fate of microbial agents and their effects on terrestrial environments, food web interactions, ecosystem functions, freshwater populations, and nontarget marine and estuarine animals (107).

Other Federal Sources of Funding

The National Science Foundation and the National Institutes of Health provide a small amount of funding for BBT research, primarily on the natural enemies of arthropods and behavior modifying chemicals (247). Between 1989 and 1993 the National Science Foundation awarded an average of $1.5 million annually for research on biological control, and a total of $388,000 for research on behavior-modifying chemicals. The agency also provided several grants for studies of the systematics of parasitic Hymenoptera (a taxonomic group that contains a number of biological control agents). In 1993, the National Institutes of Health awarded $500,000 for biological control research and close to $1 million for research on behavior modifying chemicals (247).

Funds from several small programs of USDA also are potentially available for BBT research, although researchers have been somewhat disappointed in the level of BBT work supported by these programs (247). The Small Business Innovation Grants program funded one to three biological control programs per year between 1989 and 1992. The Alternative Agriculture Research and Commercialization center, whose charge is to aid in the commercialization of agricultural products for industrial use, contributed $170,000 to develop a microbial pesticide based on Bt in 1993. That same year, USDA's Sustainable Agriculture Research and Education program funded two biological control projects.

The Interregional Research Project No. 4 ("IR-4"), funded by CSREES and ARS, carries out the necessary research to supply data required for registration of pesticides (including microbial pesticides and pheromones) for use on minor crops. Over the 10-year period following the program's expansion in 1982 to cover "biorational" products, it supported research projects on 13 microbial agents (130). BBTs represent only a minor component of the program; most funds go to research on conventional pesticides (247).

EDUCATING USERS

In addition to direct administration of research and implementation programs, federal and state agencies affect the adoption of BBTs by farmers and other users. The major institutions involved are the Cooperative Extension Service and Land Grant University system. Decisions of users to adopt BBTs also may be influenced by produce standards, and other legal and financial mechanisms. Today, private consultants play an increasingly important role in pest control decisions, sometimes far surpassing that of government programs. This section begins by exploring farmers' perspectives and then examines some of the factors that influence their adoption of BBTs.

The Farmers' Perspective

Most farmers have little or no information on the efficacy, quality, economic feasibility or other aspects of BBTs (141,270). Even farmers who use these technologies often lack clear-cut instructions on how to apply them. Many BBTs are labor-intensive and their optimal use requires a significant amount of information (59) (see chapter 3). Few farmers will embrace technologies that seem to involve many inexact procedures and unknown consequences (6,240).

Farmers also lack information on their specific pest control options (271). Growers need information on what BBTs are available and how to obtain the best results using the technologies. Such information—custom-designed for the target audience and specific to the local crop, pest, and environmental conditions—is usually unavailable (79,253). In a survey of organic farmers, about 60 percent said existing information sources failed to meet their needs (260). In many cases such information has never been developed (292). Implementation of even the most effective BBTs suffers when the base of research on their application is inadequate.

Some of the well-known advantages of BBTs (e.g., superior environmental profiles, and lower susceptibility to resistance) accrue to the broader agricultural community rather than to the individual grower. Farmers may wonder whether it is truly in their personal best interest to switch to BBTs. Of more immediate concern to most farmers are the effectiveness, cost, and demonstrated success of the product, as well its ease of application, safety, compatibility with natural enemies, and other factors (49,114,135,179,213). Unlike conventional pesticides, many BBTs cannot be applied across wide areas with the expectation of consistent results (see also chapter 3) (253).

Despite their pragmatic concerns about cost-effectiveness, many farmers would prefer to use less chemical-dependent technologies (101). They are prompted in part by consumer demand, the development of pesticide resistance, the declining array of registered pesticides, economic considerations, and the growing awareness of the effects of chemical pesticides on local groundwater supplies. Environmental and occupational health concerns play a role as well. A 1992 study of 297 fruit growers in Michigan, for example, found that less than 1 percent planned to increase pesticide use, while 61 percent said they would decrease pesticide use in the future by adopting IPM or organic techniques (231). In some cases the use of BBTs and other IPM approaches has resulted largely from economic considerations. These practices sometimes prove economically superior to conventional approaches (238), for example, when pests become uncontrollable due to resistance or when pesticide use (and therefore costs) can be reduced through IPM.

Use of some BBTs has become widespread practice in certain crops and geographic regions (see chapter 3). In Florida a majority of cabbage growers use Bt rather than conventional pesticides against diamondback moths, because they want to conserve natural enemies such as lady beetles and lacewings (213). Florida growers often use pheromones as a scouting tool, but less frequently for trapping pests given the high costs of this technique. Roughly 30 to 40 percent of Florida strawberry farmers release predatory mites to control spidermites, and many citrus growers rely on parasitic wasps to control citrus snowscale (*Unaspis citri*) (213).

In California nearly 300,000 acres of citrus with low pest abundance have been set aside as biological control zones. Growers follow crop management practices that conserve the native natural enemies, and they also augment the biological control populations when necessary. According to the California Citrus Research Board, such orchards can be highly cost-effective, relying on natural enemy populations built up over many decades (18). But they are precarious arrangements; for example, natural enemy populations that had been built up over half a century in one Corona (California) orchard were destroyed by mass-spraying of malathion against the Mediterranean fruit fly (*Ceratitis capitata*). The growers subsequently abandoned the orchard (18).

Even a number of more prominent firms are interested in diversifying their pest control technologies (see figure 3-1 in chapter 3). The Dole Company rears predatory sixspotted thrips (*Scolothrips sexmaculatus*), while the Gallo Wineries use *Trichogramma* wasps, green lacewings, and predatory mites (270). The goal of Fetzer Vineyards is to produce or buy 100 percent organically grown grapes by the year 2000 (94). Campbell Soup Company has nearly eliminated the use of synthetic insecticides on its processing tomatoes in Sinaloa, Mexico, using pheromones, *Trichogramma* wasps, and Bt (38). Campbell's IPM efforts (box 5-4) show that IPM is feasible and even profitable on a crop for which some companies consider non-conventional methods neither promising nor practical (137).

For some crops and pest control needs, however, few BBT options exist. According to one blueberry growers' marketing cooperative in Michigan, commercial buyers do not tolerate *any* evidence of pest activity—a standard that few

BOX 5-4: Campbell Soup Company

Campbell Soup Company has dramatically reduced its reliance on conventional pesticides in certain regions by adopting IPM systems that incorporate BBTs, field scouting, and disease monitoring. The company employs its own in-house IPM specialists who conduct field research and put the programs in place.

Campbell's most active IPM efforts take place in tomato farming. The company has nearly eliminated synthetic insecticide usage and has reduced fungicide application by more than 50 percent in its processed tomato operations in Sinaloa, Mexico. Growers use Bt to control armyworm; *Trichogramma* wasps to control tomato fruitworm (*Helicoverpa zea*); and synthetic sex pheromones to disrupt the mating of tomato pinworms (*Keiferia lycopersicella*). Other IPM techniques include: selecting fields and planting times to minimize risks of virus diseases that are transmitted by whitefly pests; monitoring pest and natural enemy abundance using pheromone traps and scouting; and using a computerized disease forecasting system that tracks hourly temperature and leaf-wetness to pinpoint when to spray fungicides to control late blight. Taken together, the IPM programs in Sinoloa save an estimated $400 per hectare when compared to conventional pesticides.

Campbell Soup encourages its U.S. tomato growers to use IPM, but the level of adoption trails its Mexico operations. Comparison of the company's operations in Sinaloa and California illustrates how locational differences—such as labor costs, infrastructure, and pest pressures—can affect adoption of BBTs and IPM. In Mexico, the company conducts monitoring and other IPM activities for the grower, while in California, the choice of pest control method rests with the individual farmer. The company encourages California growers to reduce pesticides and offers education programs. Campbell Soup also demonstrates BBTs and other IPM techniques in growers' fields, with the company assuming all financial risks for drops in yield during the experimental period. In Mexico, low labor costs make more labor-intensive techniques cost effective, such as those involving pheromone dispensers, natural enemies, and scouting. Also, the absence of native natural enemies in Sinaloa makes augmentative releases essential; in northern California the native natural enemies partially protect tomatoes against fruitworm and other regional pests.

Campbell Soup Company relies heavily on land grant universities and extension in developing its IPM programs and educating California growers. The company actively seeks out researchers whose work is relevant and provides small grants to direct their attention to particular issues.

SOURCES: H.A. Bolkan, "Campbell Soup Company Integrated Pest Management," *IPM Monitor,* Summer, 1994; Campbell Soup Company, Integrated Pest Management Research and Implementation, "Economic Profitability and Environmentally Compatible Alternatives," *Products and Progress Report* 1994–1995; R.K. Curtis, Campbell Soup Company, Sacramento CA, letter to Eduardo Martinez Curiel, Consul of Mexico, February 1, 1994; R.K. Curtis, Campbell Soup Company, Sacramento, CA, personal communication, Summer 1995; P. Marrone, President, Novo Nordisk Entotech, Davis, CA, personal communication 1995.

BBTs can attain (see also chapter 3) (331). Consequently, the only suitable BBT presently available is Bt for use against cranberry fruitworm (*Acrobasis vaccinii*) and leaf rollers. Growers would like more BBT options, particularly for major pests such as blueberry maggot (*Rhagoletis mendax*), Japanese beetles (*Popillia japonica*), and the many diseases affecting blueberries (331).

Technology Transfer to End Users

The Government's Role Through Extension

The principal governmental provider of direct, hands-on assistance to growers is the Cooperative Extension Service. The system is made up of federal personnel at the USDA Cooperative State Research, Education, and Extension Service (CSREES), as well as state and county-level agents. These components are often loosely coordinated through the land grant colleges. Extension is represented in nearly all of the nation's 3,150 counties (342). However, private pest control consultants seeking assistance in solving difficult pest problems frequently bypass county agents in favor of the more technically educated state specialists (412). Each state runs its extension program differently. In Vermont, for example, all extension is closely tied to the state university, while in New York State each county runs its own program, even though all are officially under the umbrella of the Cornell Cooperative Extension (121).

Although extension programs historically played a key role in farmers' pest control decisions, today this role is minimal in most states (114). In general, the Cooperative Extension Service is financially strapped and the workforce spread thin among multiple responsibilities, ranging from programs aimed at preventing pregnancy and drug use, to nutrition education for low-income families. Despite the recent retirement of many "old guard" extension agents, who entered the land grant colleges after World War II and were trained in conventional pest control, the more recently educated and, in some cases, IPM-oriented agents may have only limited opportunity to bring nonchemical practices to the field (98,166).

Most extension agents have had little if any formal exposure to biologically based approaches (207). The relationship between the Agricultural Research Service and Cooperative Extension is a distant one (114), and many of the extension-affiliated land grant colleges offer at most minimal training in BBT use.

Moreover, in many parts of the country, the limited amount of research on applications of BBTs provides little locally generated and regionally relevant information (97,207). Consequently extension specialists often do not have many "field-ready" BBT options. They also lack the resources to do the applied research needed for implementation. Many extension personnel feel caught in the middle between a clientele who asks for pesticide alternatives and a research pipeline that fails to deliver effective, ready-to-use technologies (180).

This inadequacy helps explain the lack of detail found in most of the educational materials produced by the 27 states that support biological control as part of their IPM programs (97). A small, informal survey of randomly selected states in the Northeast, North Central, South and West found tremendous variation among the states in their extension publications' educational value to growers regarding BBTs (247). Of the 13 states sampled, New York consistently topped the ratings; it was the only one having extension manuals devoted solely either to natural enemies or to pheromones (247). Another small survey that evaluated extension publications from the North Central states concluded that the coverage is usually too perfunctory to provide the skills necessary to adopt biological control (207).

In fiscal year 1995, CSREES received approximately $14 million in appropriations for extension work in IPM research and implementation. It is uncertain whether increases in this area proposed under the USDA IPM Initiative for fiscal year 1996 will occur (see box 5-1). In contrast, at least in certain regions of the country, extension scientists expect increased responsibilities in this area; according to a 1994 survey of 38 extension entomologists in North Central states, most spend slightly more than 10 percent of their time on classical biological control programs, but they expect this percentage to triple over the next decade. Most of the agents also reported an increase in questions from growers about biological control and pesticide reduction (207).

Private Pest Control Advisors

In most regions, the Cooperative Extension Service now plays a role that is secondary or intermediary to that of the private information sources such as pesticide dealers, pest control advisors, crop consultants, and pesticide applicators (253). Extension agents may develop demonstration projects and training activities for growers and commercial crop consultants, and sometimes they validate private sector recommendations or investigate unusual pest outbreaks. But most growers rely far more on private sector advisors than on government agricultural experts (253). The lack of funding for extension activities at universities has strengthened the private pest management business (270). Often the Extension agents are far outnumbered by private advisors (291). Large farm operations, which can spread the cost of obtaining information over more units of production, depend particularly heavily on private consultants and can afford to hire the very best (see box 5-4) (141).

Most private advisors have been educated with an orientation toward conventional pesticides. Most are not well versed in biologically based methods—around 5 percent, according to some natural enemy companies (269). The extent to which advisors use BBTs varies tremendously; some are eager to embrace these technologies but do not have adequate information or find that few biological approaches suit their pest control needs. Some advisors lack confidence in the BBT options and do not want to harm their reputations by recommending a technology that they themselves question (282).

Moreover, most private pest control advisors are affiliated with the chemical industry. There are also about 3,500 "independent" consultants who do not work for chemical suppliers (340). In California, for example, about 200 (less than 10 percent) of the pest control advisors who are active in agriculture are considered independent; the rest work for chemical companies, distributorships and applicators (141). In a few states, such as California, Arizona and Florida, some of the pest control advisors specialize in BBTs (435). Independent consultants charge growers a fee, averaging from $3.75 per acre for wheat to $17.40 per acre for vegetables (340), whereas those affiliated with pesticide companies offer free advice as an incentive for product purchases.

Independent consultants may be more inclined than industry-affiliated advisors to recommend nonchemical technologies. A study of pest control advisors in California found that those not involved in the sale or application of pesticides were much more likely to seek help from the extension personnel than from pesticide company representatives or other information sources (102). A 1994 nationwide survey of the farmers under contract with independent consultants found that 20 percent of the vegetable growers were releasing beneficial insects and 39 percent were using pheromones (340)—rates of use substantially higher than the national averages (e.g., ref. 377).

Few states have licensing requirements for private pest control advisors (309). Many advisors are, however, certified by professional societies such as the American Society of Agronomy and the National Alliance of Independent Crop Consultants (7,16,166). The societies have developed certification standards to eliminate the need for government intervention. These standards vary among states. No state government requires pest control advisors be trained specifically in BBTs (5), although such training has been proposed in California (see box 5-3). Likewise EPA has no certification requirements for private pest control advisors and offers no guidance to the states in this area (431).

EPA does annually pass through about $2 million to CSREES for development of model curricula for training pesticide applicators (370). These curricula suggest including a section on IPM, although very little specificity is included regarding what techniques might be covered. The curriculum, with modifications related to state laws, is used by the Cooperative Extension Service in all states to annually train over 500,000 private, commercial, and urban pesticide applicators (370). Under the Federal Insecticide, Fungicide and Rodenticide Act, however, EPA is barred from requiring IPM training for licensing of pesticide applicators. Pesticide applicators unfamiliar with BBTs might pose an obstacle to growers interested in experimenting with these technologies.

Other Factors Affecting the User's Choice

A number of institutional factors and marketplace forces may also affect farmers' pest control decisions. The precise influence of most has not been rigorously documented. For example, the market for foods grown with reduced or no pesticide use, and the prices consumers are willing to pay for these foods, may affect whether and how great a cost farmers are willing to incur in switching to pesticide alternatives. Bankers who are unfamiliar with IPM or BBTs and who perceive the methods as presenting a higher risk of crop failure may be unwilling to approve agricultural loans to farmers who use these methods (435). Some growers worry that use of IPM and BBTs may be impeded by the new Worker Protection Standards recently issued by EPA that increase the amount of time after pesticide application during which agricultural workers are barred from reentering fields. The required delay will prevent growers and crop consultants from reentering fields shortly after spraying to scout for remaining or fresh pest populations; some growers argue the lack of immediate monitoring will force them back to calendar spray schedules (31).

Perhaps the most commonly discussed influence is cosmetic standards. Federal, state, and private grading standards for specific attributes such as the shape, color, and surface defects of fruits or vegetables may also drive certain pest control decisions. USDA grades for fresh fruits and vegetables, commonly specified in business contracts, are required under some federal marketing orders establishing minimum standards, as well as for produce sold to the federal government and for certain commodities imported and exported (380). Most retailers buy only produce of the highest USDA grades to ensure adequate appearance (297). In addition, some states have standards for certain crops, and many firms, such as Sunkist, have private standards for fresh produce. The failure to meet particular grading standards can lead to downgrading or to loss of access to the fresh market altogether, and consequently a substantial loss of income (298).

Produce standards in many fruit, vegetable and nut crops are also affected strongly by export markets. For example, about 40 percent of California citrus is destined for Asian and European consumers. Cosmetic standards for these markets are far higher than those in the United States, making use of conventional pesticides almost unavoidable for produce intended for export (18).

The extent to which growers use conventional pesticides to meet cosmetic standards remains controversial, however (189,298,380). Some studies suggest that a grading system which emphasizes external appearance may leave growers and packers little choice but to apply large amounts of conventional pesticides. Some surveys of apple and citrus growers report, for example, that for a majority of growers at least half of their pesticide usage is to attain a suitable cosmetic appearance (298). Although citrus is a crop that lends itself well to BBTs (18), in parts of California no BBT can fully control the thrip and red scale pests responsible for cosmetic blemishes. Fruit going to the processed market sometimes has been treated with the same amount of conventional pesticide as that going to the fresh market by growers hopeful that most of their fruit crop will be accepted in the fresh market (92,298).

Production arrangements vary in the extent to which they direct the grower to use particular pest management approaches; most only require that the final product meets certain standards, although some are quite specific (21,83). In general, processors are more likely than fresh commodity buyers to specify the desired pest control method in a grower agreement or contract (213). However, the degree of producer control can vary greatly, even within a particular crop for a particular use. The variation reflects differences among growers and firms in management skills, access to credit, and risk preferences (435). For example, three California firms handle more than 75 percent of US fresh carrot production. Their production arrangements with growers range from some that give virtually complete control over pest control, to others that cover only the purchase of output.

FROM RESEARCH TO IMPLEMENTATION

Chapter 5 has shown that the federal government supports sizable efforts on the research and implementation of BBTs, funded annually around $210 million. Despite these efforts, applications of BBTs in the field are relatively few (chapter 3). And a significant gap lies between the research on BBTs and its use—a gap referred to by some long-time observers as the "valley of death." The problem characterizes BBTs in other countries as well (e.g., box 5-5). Here OTA identifies some of the major reasons for this chasm and suggests options that might help provide solutions.

Coordination Is Needed to Enhance Delivery to the Field

A lack of necessary coordination between research and implementation was the most prominent problem identified by every workshop and advisory panel convened during the OTA assessment, and by dozens of scientists and representatives of federal agencies. The issue is not simple;

BOX 5-5: Connection between Research and Implementation in Australia

U.S. scientists often point to Australia as a potential model for the United States to emulate in the regulation of biological control. It is unclear, however, whether differences between the U.S. and Australian regulatory systems have had a significant impact on the relative adoption and success rates of biological control or other BBTs. Although Australia is thought to be several steps ahead of the United States, both its research and its implementation efforts appear to confront many of the same obstacles plaguing U.S. programs—most notably, low rates of success, adoption, and commercialization. Despite regulatory developments, discontent about the screening and approval process for introductions remains prevalent.

The Australian government has instituted several national policy initiatives that have removed some of the regulatory obstacles that American scientists and natural enemy companies claim inhibit the success of biological control in the United States. The result, however, has not been greater use or commercialization of BBTs. A series of complete and partial successes have kept BBTs in the public eye and in demand, but private-sector involvement remains minimal. Research results are not getting into the community for widespread use, and the Australian government has been ambivalent in its attempts to improve the situation.

In 1989 the Australian government spent only a small percentage of its pest control research budget on BBT research and implementation—$20 million, an amount equivalent to approximately 2 percent of the funds spent on chemical research. Although there is widespread acceptance of the need to encourage BBTs, there is little in the way of explicit directives, and resources are still limited. The government does not give any subsidies to encourage BBT use, and support for redistribution of biological control agents and implementation projects and resources is still inadequate. The only potential government incentive for growers to adopt BBTs is the increasing restriction on conventional chemical pesticides. This incentive may eventually become strong, but it has not yet had much impact on growers.

The Australian government has several policies that help link research to implementation. One of the conditions of government funding is that recognition be given to the importance of long-term research and research for public benefit. Consequently, Australian scientists often integrate the implementation phase with the initial research. Both the central government and the state governments encourage research agencies to promote their work on BBTs more publicly. Nevertheless, farmers and researchers alike realize that the results are not getting out to the field.

SOURCE: J.M. Cullen, and T.E. Bellas, Division of Entomology, CSIRO, Canberra, Australia, "Australian Laws, Policies, and Programs Related to Biologically Based Technologies for Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1995.

this need for coordination occurs on several levels. In general, ad hoc interactions among scientists from various government agencies and universities working on BBTs have been quite good. Problems arise, however, when institutional coordination is necessary.

Interdepartmental Coordination

In the 1990 Farm Bill, Congress directed EPA to coordinate with USDA in identifying pressing national needs where shortages in pest control methods are likely to occur through the loss of conventional pesticides. The most obvious causes of such shortages are the lack of reregistration of chemicals for minor use crops and pesticide resistance (see chapter 2). USDA was instructed to address these priorities through its research and extension programs.[13] In 1994, the Secretary of Agriculture and the Administrator of EPA signed a memorandum of understanding belatedly agreeing to collaborate in exchanging necessary information on upcoming pesticide losses (403).

OTA has not been able to identify any clear mechanism by which such priorities are consistently identified and acted upon in the development of the portfolio of USDA-funded research on BBTs. The first step would be to improve the information exchange between USDA and EPA.

OPTION *Congress could, through its oversight functions, encourage USDA and EPA to act on their recent memorandum of understanding.*

OPTION *Congress could specify and provide direct appropriations (perhaps as a proportion of the funds requested for the USDA IPM Initiative) for USDA and EPA to collaborate in developing and maintaining a database on upcoming pest control needs (resulting from pesticide loss and resistance) and available alternatives for filling these needs. Careful consideration would need to be given to the appropriate institutional site for this function; the database would require sustained support. It should be constructed to ensure universal accessibility and also so that it can provide guidance for the funding decisions of research agencies.*

In December 1994, Argonne Laboratories, under contract with the Cooperative State Research, Education, and Extension Service began developing the software for a database that would incorporate state information on the use of various pest control methods and EPA data on pesticide reregistration (289). CSREES hopes the database will one day include information on pesticide resistance and USDA research, and that it will eventually be supported by states and users. Should Congress decide to designate this database as the national repository of information on pending pest control needs, some early adjustment might be needed to make sure it fulfills the criteria just discussed. For example, CSREES should consult with the Agricultural Research Service and other agencies to ensure that the database is constructed so that it can inform their decisionmaking regarding research priorities.

Providing for Follow-Through in the Research

The Agricultural Research Service (ARS) and the State Agricultural Experiment Stations fund most of the research on BBTs. In both cases, the science usually is generated "bottom up." National goal-setting mechanisms lack funding authority and therefore have little direct influence over the research agenda. The decision processes of ARS and the State Agricultural Experiment Stations have the advantage of keying research to regionally identified problems. Where they fall down, however, is in their ability to address externally identified strategic needs. This is particularly a problem for work on BBTs. A vast array of pest management questions deserve scientific investigation. The diffuse mechanisms for generating research projects and the limited funds available cannot help but result in a research portfolio that is dispersed and lacks coordination.

One consequence of the scatter is that some of the research components necessary to enable the practical uses of BBTs are not addressed. The application of any given BBT against a specific pest problem results from research ranging from

[13] Under the Conservation and Research Titles of the 1990 Farm Bill.

fundamental aspects of the pest problem to details of how the BBT is applied. The latter has consistently been underemphasized. OTA fully acknowledges the value of more fundamental research and is not addressing whether the current allocation here is appropriate. But it is clear that not enough attention has been given to the essential research to take BBTs out of the hands of scientists and into those of farmers and other users. Historically, no research agency has identified this function as its responsibility. Extension scientists might have been logical candidates but have not assumed this role (84).

Another consequence of the funding processes of the ARS and the State Agricultural Experiment Stations is that the agencies have difficulty responding to externally generated research needs, such as those identified by operations agencies. Despite clear-cut institutional responsibilities, ARS has not always delivered solutions that are field-ready to APHIS; as a result, APHIS has developed its own research capabilities for adapting BBTs originally identified by ARS and others for larger-scale field use. Similarly, the needs of the land management agencies for BBTs to use in weed control have been met only by a small scale effort at ARS, even though weed-infested lands are extensive and represent a significant national problem. In part, this reflects the fact that agencies within the Department of the Interior (DoI)—the Bureau of Land Management in particular—lack pass-through funds that they could allocate to ARS for the related work. Future needs of the DoI agencies may be particularly acute because their research agency, the National Biological Service, lacks support in the current Congress and has been targeted for downsizing, elimination, or merger.

The difficulty that USDA's major research agencies have in responding to externally identified priorities does not bode well for how the agencies will deal with impending pesticide losses through reregistration or pesticide resistance, even if this information is made readily available through better coordinated efforts with EPA. This has special significance for BBTs because these technologies are most likely to be adopted where conventional pesticides disappear (see chapters 3 and 6).

Experience has shown that research flows more expeditiously into applications of BBTs when directed funds circumvent the normal, highly structured, institutional processes. OTA's options attempt to build on this experience.

OPTION *Congress could direct the Agricultural Research Service to allocate a proportion of its BBT funds to a targeted competitive grants program within the agency. These funds would be available for collaborative research projects that provide the follow through into field applications. Evaluation of the needs of farmers or other users at the inception of the research and of ways in which the BBT would meet this need would be essential to ensure real-world applicability. The size of this effort would need to be balanced against its potential effects on the agency's capability to conduct longer-term studies.*

OPTION *Proposed research funding for fiscal year 1996 provided through CSREES under the USDA IPM Initiative has taken this approach to ensure "buy in" by researchers, farmers, and others involved in all phases of the development and implementation of IPM programs (see box 5-1). Congress could fund this research initiative. Its potential influence on BBT research is unclear, however, because the role of BBTs in the IPM Initiative has not been explicitly stated. Hence, funding of the research component of the IPM Initiative would affect BBTs only if Congress instructed USDA to identify the role of BBTs or to allocate a proportion of the program for IPM research that incorporates biologically based approaches (i.e., bio-intensive IPM).*

OPTION *Congress could increase the accountability of the Agricultural Research Service to the operations and land management agencies by designating funds within these agencies for pass-through to ARS for meeting their operational needs. Because new funding is unlikely in the current fiscal climate, these funds would have to be derived from the current budgets of these agencies.*

OPTION *Alternatively, Congress could allocate to the operations and land management agencies "redeemable credits" toward research that targets* *their needs by the USDA research agencies. These credits would obligate the research agencies to conduct a specified amount of research to meet the needs of the operations and land management agencies, but no exchange of funds would occur (i.e., funds would remain in the research agencies). The research agencies would have to be informed, during their appropriations processes, of their obligations, and some tracking mechanism might be necessary to assure accountability for conducting the work and producing results according to the agreed priorities.*

OPTION *Congress could improve the match between ongoing research and the needs of farmers by requiring research agencies to seek input from farmers and other users into funding decisions. For example, representatives of user groups, commodity groups, etc., could sit on funding panels or make recommendations to the Deputy Administrator of the National Program Staff of the Agricultural Research Service.*

OPTION *Congress could create a competitive grants program specifically targeted toward BBTs that are well researched but not yet in practical use. The goal would be to invest in bringing research discoveries that currently lie unused into the field, particularly those of high technical merit but likely to yield profits too low to be of commercial interest. Such funds might be administered through CSREES, perhaps as a part of its extension functions. Although new money would be required to set up the program, it would be very cost-effective, because only technologies on the verge of application would be funded. The same type of targeted funding mechanism currently underlies the Cooperative Research and Development Agreements under which private-sector companies invest in government research (see also chapter 6 for further options related to CRADAs). However, those agreements primarily address research that is amenable to commercial development.*

Coordination of Biological Control

Coordination of biological control research poses separate but related problems. Researchers point to dwindling resources and institutional obstacles as significant reasons why current rates of success in classical biological control are low (58) (see chapter 3). At the same time, the numbers of people and organizations conducting biological control are growing ever larger. Numerous small companies also rear and sell natural enemies (see chapter 6). In the past, scientists at the Agricultural Research Service and universities conducted most biological control introductions. Today, federal, state, and county government agencies responsible for pest control carry out their own programs, often in the rush of addressing a new, high-cost pest, such as the Russian wheat aphid.

Research scientists worry that the quality of biological control work will suffer as it becomes increasingly dispersed. The consequences might include increased introduction of ineffective agents, greater potential for introduced agents to interfere with one another, and a further lack of adequate monitoring to evaluate effectiveness and nontarget impacts. Moreover, poor coordination of biological control programs among government agencies can result in replication of effort; conversely, the agencies sometimes end up working at cross purposes (see box 5-2).

Better coordination of biological control work would increase the potential for success and reduce the costs and risks (82). Biological control is worth supporting because of the high potential payoffs when it succeeds. By coordination, researchers usually mean disseminating information about ongoing work, enabling collaborative efforts, making research findings readily available, and maintaining good databases of biological control introductions and their results. Good databases are essential to develop biological control into a more predictive science (see chapter 3). In addition, good research in biological control requires support over a period of years, far longer than is the norm in most funding cycles. What biological control workers seek is a centralized administration that would coordinate the various sequential and interdependent activities required for a biological control program, including assistance with satisfying regulatory requirements. Such coordination could incorporate private sector involvement in the production and dissemination of natural enemies (see chapter 6 options). It might also deal with use of biological control in non-agricultural habitats, such as in wilderness preserves and aquatic ecosystems. The coordinating mechanism might range from an organization that simply coordinates information and needs to a single entity responsible for all aspects of biological control research and implementation.

The harshest critics say that the necessary coordination is virtually nonexistent today (58). In fact, two USDA entities, the National Biological Control Institute (in APHIS) and the Interagency Biological Control Coordinating Committee (IBC^3) were designed for this function. Neither fulfills it perfectly—the institute because it is located within an operations agency and lacks funds and authority; the committee because it has largely ceased to function.

Representatives of the Agricultural Research Service suggest that their agency, through its National Program Staff, should be the coordinating site (320). However, ARS has not shouldered this responsibility under its existing structure, and this option would suffer the same (real or perceived) problem as the National Biological Control Institute—it would place responsibilities for coordination within a single agency having its own vested interests.

OPTION *Congress could select either the National Biological Control Institute, the Interagency Biological Control Coordinating Committee, or a new unit (perhaps incorporating both organizations) as the institutional site for national coordination of biological control. Selection of the National Biological Control Institute would require its elevation to a higher level within USDA, because its current position makes it accountable to the priorities of one agency (APHIS). Selection of the Interagency Biological Control Coordinating Committee would require revitalizing the now inactive committee. Specific coordinating responsibilities and appropriations would need to be assigned to whatever organization is selected.*

OPTION *Alternatively, Congress could create a centralized agency responsible for all federal activities related to biological control. This option seems only remotely feasible today, because biological control programs are dispersed throughout at least eight agencies, in many cases related directly to their pest control responsibilities.*

OPTION *Congress could strengthen and stabilize the new biological control program within the National Research Initiative, and also make provisions so that CSREES could fund some projects of long duration rather than the five-year grants the agency says are mandated by current law. Note that the National Research Initiative program on biological control has not received strong support from the current Congress and might be eliminated in fiscal year 1996.*

OPTION *Should Congress choose to fund the USDA IPM Initiative, it could stipulate that the designated organization for coordinating biological control be a participant. Even without designating a coordinating organization, Congress could require that the National Biological Control Institute be involved in the initiative to help integrate biological control and IPM programs (see also chapter 3 for discussion of problems related to a lack of coordination between biological control and IPM).*

OPTION *Congress could direct USDA to maintain a consistent and comprehensive database on biological control introductions. Several different institutional sites might be possible. Previous attempts at developing such a database in the Agricultural Research Service suffered from erratic support. The history of poor documentation and recordkeeping by the APHIS regulatory unit that permits biological control introductions (see chapter 4) makes it seem an equally problematic site at this time; although whatever data are developed by APHIS via the permitting process should be incorporated into the biological control database. Other possibilities include the National Agricultural Library or the National Germplasm Program. Development of a biological control database could occur even if no coordinating structure for biological control is designated.*

Addressing Currently Unmet Research Needs

Although this report does not seek generally to address details of what specific BBT research should be conducted,[14] gaps in two areas have

[14] In part this is because the upcoming report from the National Research Council should do a thorough analysis of this topic.

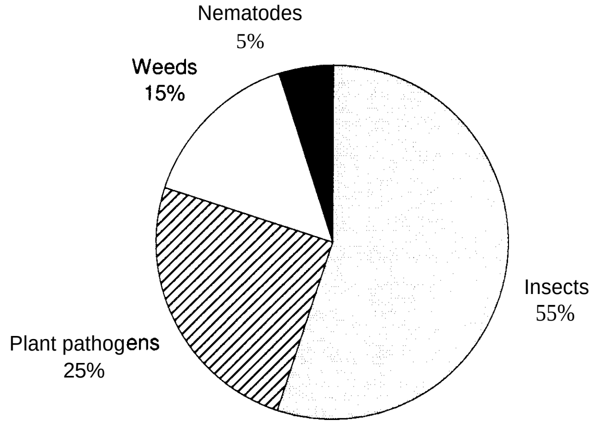
become particularly obvious during the course of the assessment. First, examination of the proportion of federal funds going to research on various categories of pests shows an obvious slant towards insect pests (figure 5-3), Weeds receive a disproportionately small allocation, even though herbicides represent the single greatest category of pesticide use in the United States, accounting for approximately 59 percent of pesticides used in agriculture and 57 percent of overall pesticide use[15] (399). The emphasis on insects may be a historical artifact of when BBT research developed, because the widespread use of herbicides is a relatively recent practice in U.S. agriculture. Nevertheless, it means that a significant category of pests currently receives relatively little attention. In the absence of any action, this pattern is likely to continue; the executive branch's budget proposal for fiscal year 1996 eliminated funding for the ARS biological control of weeds project in California and the Army Corps of Engineers program for biological control of aquatic weeds.

A second major gap is the followup and monitoring of BBTs, especially biological control. Very little of this type of work is conducted in the United States. According to biological control workers, such research will be essential to develop better predictive capabilities and therefore streamline biological control projects (see chapter 3). The lack of followup has another important consequence. It makes evaluation of the potential nontarget impacts of BBTs exceptionally difficult to assess, resulting in a regulatory system based more on assumptions about safety rather than on documentation to that effect (see chapter 4).

OPTION: *Congress could direct the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service to allocate a greater proportion of their research funding toward control of weeds,*

OPTION: *Congress could direct all federal agencies that conduct or fund biological control programs to initiate or fund monitoring projects, especially for higher risk categories (see chapter 4 for discussion of risk categories). One way this might be accomplished is to give higher priority to research projects that include a monitoring component.*

FIGURE 5-3: Distribution of Federal BBT Research According to Pest Type (1994)



SOURCES: D.M. Gibbons, The EOP Foundation, Inc., Washington, DC, Report on the Role of the USDA in Biologically-Based Pest Control Research, " unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995; J.R. Nechols and J.J. Obrycki, Kansas State University and Iowa State University, "OTA Preliminary Assessment of Biological Control Current Research, " unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994,

NOTE. EPA, APHIS, and states are not included because research and development could not be identified by pest type

■ Maintaining the Necessary Level of Technical Expertise

At a nationwide scale, technical expertise is lacking in certain key areas for the development and implementation of BBTs. For example, two significant obstacles to increased use of BBTs are the lack of adequate incorporation into 1PM programs (see chapter 3) and the paucity of related information about BBTs available to users. Part of the problem lies with the lack of staff adequately trained in BBTs and 1PM within the Cooperative Extension System.

15 Percentages calculated according to weight of active ingredient.

A second area where adequate expertise is disappearing is the field of taxonomy and systematics. The number of qualified taxonomists is shrinking; yet the discovery and development of new biological control agents, because of their specific nature, relies on accurate taxonomy—the identification and classification of living organisms (142,186).[16] Funds and resources for taxonomy and biosystematics are difficult to obtain, and critics say the science is considered to have relatively low priority among ARS administrators (58). According to the natural enemy industry, only one U.S. scientist can identify various species of *Trichogramma* wasps that are among the most commonly sold natural enemies in the United States. Incorrect identifications can lead to a mismatch of biological control agents with their pest targets, or to poor control agents unintentionally being sold as natural enemies. Moreover, an accurate and knowledge-rich classification is essential to enable a more predictive approach to biological control (186).

OPTION *Congress could support education in IPM through the Land Grant University system. Various approaches might be possible, for example, funding graduate fellowships in IPM.*

OPTION *Congress could direct the Agricultural Research Service to increase resources and staff slots allocated to the Biosystematics Laboratory for work related to biological control.*

OPTION *Postdoctoral fellowships from APHIS's National Biological Control Institute have been used successfully to support U.S. taxonomic work. Congress could direct APHIS to allocate a larger share of its biological control funding for this purpose.*

Educating and Influencing Users

A significant weak link in the implementation of BBTs is getting farmers to experiment with these technologies. Many lack sufficient information to make informed decisions, and the available technical support may be strongly biased in favor of conventional approaches. Today, extension's direct role in educating farmers about pest control has been dwarfed by that of private consultants. Congress could help improve access of private consultants to information on BBTs and IPM in several ways.

OPTION *The Federal Insecticide, Fungicide, and Rodenticide Act prohibits the federal government from requiring training in IPM for certification of pesticide applicators. Congress could amend the act to rectify this situation and require that pesticide applicators be knowledgeable in the full range of pest control options, including BBTs.*

OPTION *Several different types of consultants affect pesticide use decisions. Several professional associations influence the types of information these consultants provide through training programs and certification standards. Extension has worked with at least one society, the Agronomy Society, to help integrate IPM into their certification program. Congress could encourage similar efforts through the Cooperative Extension System, perhaps by providing targeted competitive funds for projects that involve collaboration between extension personnel and professional societies to integrate BBTs and IPM into training programs or certification standards.*

Certain financial incentives are thought to sway farmers' decisions in favor of conventional pesticide-based methods, such as cosmetic standards. In addition, constraints on the availability or cost of conventional pesticides affect the array of affordable pest control options available to farmers. Several agricultural economists have suggested that markets for BBTs could be expanded by creating incentives for farmers to use these approaches or disincentives to use conventional approaches (e.g., taxing conventional pesticides).

One problem with this approach is it assumes the availability of BBTs is directly driven by market forces. However, BBT research, especially in certain areas, is primarily publicly funded at this time. OTA has found that clear

[16] Taxonomy is part of the larger field of biosystematics that examines broad aspects of the relationships among living organisms (species and higher taxonomic categories like families).

mechanisms have not existed to match this research to the needs of farmers or other users. Policy changes that increase the demand for BBTs, but neglect to improve the supply of BBTs coming through the pipeline, might be a set-up for failure. Adjusting the research agenda to better ensure that BBTs make it into the hands of farmers and other users will be an important part of policies that seek to decrease pesticide use.

Commercial Considerations 6

Industry involvement in the production of biologically based pest control products is something of a mystery to outsiders. Misinformation—especially gross under- and overestimates of the current and potential future significance of the private sector role—abounds. For example, some researchers unrealistically expect that the private sector will pursue every promising technology, ignoring the fact that investment makes sense only if a company stands to make a profit. At the opposite extreme, others equally incorrectly believe that biologically based pest control should be left entirely to the public sector—that there is no appropriate role for the private sector. This view ignores the tremendous vested interest of the private sector in conventional pesticides, which must be incorporated into planning for the future of the nation's pest management practices.

This chapter explores the commercial production of biologically based pest control products. It identifies the size and structure of the industry, its relationship to the production of conventional pesticides, industry trends, and the ways that all of these elements influence the extent of future adoption of biologically based methods. The chapter concludes by discussing the numerous direct and indirect influences that the federal government exerts over producers of biologically based technologies for pest control (BBTs) products and by suggesting ways that the government could encourage commercial activity in this area.

Only certain biologically based technologies lend themselves to commercial production of a marketable product. These include: augmentative releases of natural enemies; deployment of pheromone-based traps and mating disrupters; and applications of microbial pesticides. In contrast, no commercial involvement occurs in classical biological control where the agent becomes established, reproduces itself, and provides continuing pest control without further intervention (options to contract out production of natural enemies to commercial insectaries, however, are discussed later in this chapter). Only government agencies thus far have used sterile male approaches; some companies that have examined the commercial potential of the method have concluded that there are significant technical impediments. Conservation of natural enemies through cultural practices or choice of pesticide type also occurs without purchase of any biologically based product (317).

Chapter 6 Findings

- Biologically based products now make up about 2 percent of the market for pest control in the United States and 1 percent or less of the international market, with annual worldwide sales of $180 million to $248 million. These products, however, represent one of the fastest growing sectors of the pest control industry.
- Almost all of the biologically based products sold commercially to date have been for control of insect pests. Because only about 29 percent of the conventional pesticide market is aimed at insect control, however, biologically based technologies for pest control (BBTs) are likely to capture a significant proportion of this market in the near term.
- The industry that produces natural enemies for pest control is small but growing, with annual U.S. sales estimated at $8 million and worldwide sales at $40 million. The industry faces substantial hurdles to expanded sales. Some reflect technical aspects of product development, manufacture, quality control, and distribution. Others occur because natural enemies do not fit easily into conventional pest control systems or measure up to farmers' expectations for product efficacy based on their experience with conventional pesticides.
- Venture capital is the foundation of the midsize biotechnology companies that have been the nation's laboratories for the discovery of new microbial pesticides. Because companies have been slow to realize profits from biologically based pest control products, their future is somewhat uncertain. The financial instability has contributed to numerous mergers and acquisitions or agreements with larger agrochemical companies.
- The conventional pesticide industry has shown some interest in biologically based pest control products, with even the largest companies like Ciba-Geigy developing related product lines. Overall investment for research in this area, however, remains only a small fraction of that devoted to conventional pesticides. Big agrochemical and pharmaceutical companies seek products with large markets and sizable returns on investment—criteria satisfied by none of the BBTs now sold commercially. Some believe that genetically engineered microbes hold the greatest promise. The big companies are poised to acquire smaller biotechnology and natural enemy companies if technical breakthroughs or other factors should result in significant market growth for BBTs.
- Today's pesticide industry has developed around the research, development, and marketing of conventional pesticides, and biologically based products do not move smoothly through this structure. Various other factors, some having little relationship to federal policies or programs, also will influence the commercial future of BBTs. Development of favorable federal policies could enhance R&D of BBT products and speed up growth of their markets, but even under the most favorable conditions, biologically based products will not replace a significant proportion of conventional pesticides over the next 10 to 15 years.

STRUCTURE OF THE BBT INDUSTRY

Biologically based products are a small but growing part of the pest control industry in the United States and worldwide. The market for BBTs is unevenly distributed geographically and also across pest control sectors. The companies involved range from small owner-operated firms to large multinational corporations. The products also are diverse, although various Bt-based insecticides account for the majority of sales at present.

Market Share

BBTs currently command only minute fractions of the $6 billion to $7 billion U.S. market and the $24 billion to $25 billion worldwide retail market for crop protection (table 6-1). The available estimates of market share for BBTs are imprecise and probably err on the side of optimism. Nevertheless, even the most conservative analysts predict that the market for BBTs will grow more rapidly than the market for conventional pesticides which is expected to expand only 2.5 to 3 percent annually over the next five years (149,150). Estimated annual growth rates for global sales of BBTs in general and for each major category of BBTs in particular (natural enemies, pheromones, microbial pesticides) range from 5 to 30 percent, with most predictions around 10 percent (301,14,150,294,413).

Almost all sales to date have been of products to control insect pests (figure 6-1) (149). According to some sources, Bt-based products accounted for more than 90 percent of worldwide microbial pesticide sales in 1990 (294). All pheromone-based products and most natural enemy products currently on the market are for control of insect pests. BBTs now account for 2.5 to 3.5 percent of worldwide insecticide sales. Some experts predict that growth of BBT sales in the immediate future will be unevenly distributed across the pest control market, occurring primarily in the insect control sector where product R&D and a track record of field efficacy are best established for Bt (149). Others assert that the Bt market has reached a plateau and that future growth will result from types of products based on viruses and fungi (e.g., the use of fungi to control household pests like termites and cockroaches) (233).

The geographic distribution of BBT sales also is uneven. North America and Europe accounted for approximately 60 percent of the total Bt market in 1991 (287). The United States accounted for an estimated 55 percent of all worldwide sales of microbial pesticides and natural enemies (294). The Far East represents a potentially significant but poorly understood market of about $47 million annually (287,149). While natural enemy sales occur primarily in North America and Europe, augmentative uses in developing

TABLE 6-1: Estimated Market Value of Biologically Based Pest Control Products (millions of dollars annually: 1990, 1991, or 1992)

	Natural enemies	Pheromones[a]	Microbial pesticides	All BBTs	% Total market[b]
United States	$8	$30 to $42	$56.7 to $97	$94.7 to $147	1.3% to 2.4%
Worldwide	$40	$60	$104.5 to $147.5	$180 to $247.5	0.7% to 1.0%

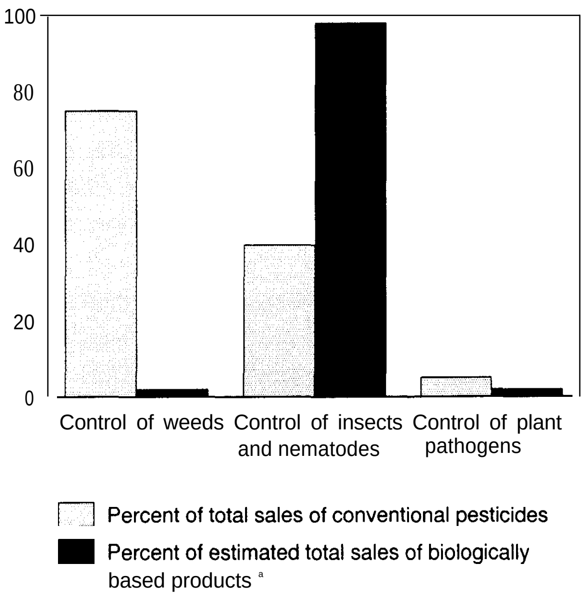
[a] Pheromones may include some products for pest monitoring as well as control. Sources do not report the data in a way that would allow this level of discrimination.

[b] Percentage of total worldwide market for pest control products based on an estimated total retail market of $24 to $25.2 billion.

SOURCES: Compiled from M.G. Banfield, *An Analysis of the Semiochemical Industry in North America,* 1991; J. Houghton, Houghton and Associates, St. Louis, MO, "The View of Biological Pest Control From the Pesticide Industry," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1993; J. Houghton, "Biologically-Based Technologies For Pest Control: Workshop on the Role of the Private Sector," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 20–21, 1994; P.B. Rodgers, "Potential of Biopesticides in Agriculture," *Pesticide Science*, 39(2): 117–129, 1993; "Sales of Biopesticides Expected to Rise at the Expense of Chemically-Based Pesticides," *Pesticide Outlook*, 4–5, February 1994; K.R. Smith, Henry A. Wallace Institute for Alternative Agriculture, Hyattsville, MD, "Biological Pest Control: An Assessment of Current Markets and Market Potential," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994; G. Voss and B. Miflin, "Biocontrol in Plant Protection: CIBA's Approach," *Pesticide Outlook* 29–34, April 1994.

NOTE: Numbers presented are composites of annual data for 1990, 1991, or 1992 and show the full range of estimated values obtained by OTA. Estimated market values for biologically based pest control products are difficult to obtain, vary greatly with the source, and should be viewed with skepticism. Those involved in the developing or producing of biologically based pest control products tend to provide optimistic numbers. The most widely cited estimates come from consulting firms that summarize market trends and then sell their analyses to the private sector. Accuracy of these analyses is difficult to judge because the sources and data are proprietary. Despite the inexactitude, experts agree that the relative magnitudes of commonly reported numbers are correct.

FIGURE 6-1: Comparison of BBT and Conventional Pesticide Sales According to Type of Pest



SOURCES: Office of Technology Assessment, 1995; (data on pesticide sales) A. Aspelin, "Pesticide Industry Sales and Usage: 1992 and 1993 Market Estimates, " U.S. Environmental Protection Agency, EPA Report No. 733-K-94-001 (Washington, DC: June 1994).

[a]Levels for BBTs estimated by OTA based on known product types and relative sales,

countries like Colombia and China are thought to be high but traditionally supplied by government rather than sources in the private sector. However, South and Central America have witnessed rapid movement toward privatization of the industry within the past three to five years; some 7 to 10 percent of the natural enemies produced in the United States are sold in Latin America (28). The Japanese government has also taken a noncommercial approach to control of *Fusarium* wilts (plant diseases) by distributing a microbial control agent (22).

Most sales of BBT are to users in agriculture and forestry; only a small fraction of sales are for gardening and other uses (317). Major arable crops like corn and cotton account for only a small proportion of the market (e.g., 7 percent of the Bt market in 1992) (294).

Companies and Products

Companies that produce biologically based pest control products have total annual sales that range from less than $50,000 to billions of dollars (including non-BBT product lines). The companies roughly break down into those marketing natural enemies, those marketing pheromone-based products, and those marketing microbial pesticides. However, the growing frequency of various acquisitions, partnerships, and agreements among companies increasingly blurs these distinctions. A few of the largest companies have entered markets for all types of products.

Natural *Enemies*

As many as 132 companies in North America produce or supply natural enemies (155); approximately 25 to 30 of these companies are commercial insectaries (37). A relatively few large companies dominate worldwide production. The two largest are Koppert, B. V., in the Netherlands which has annual revenues of about $20 million and distributors in more than 20 countries, and Bunting and Sons in Great Britain (317). Ciba-Geigy, the world's largest producer of agrochemicals, bought Bunting in 1993 (413). About half of all natural enemy companies are located in North America, where most are small and family operated. Only about a half-dozen U.S. companies have annual sales exceeding $1 million. Although the total number of North American companies is small, it is large relative to current market demand, and thus competition is intense (317).

The Association of Natural Bio-Control Producers (ANBP), founded in 1990, is a trade association of about 100 members representing the interests of North American natural enemy companies. Some 22 of the members of this organization are commercial producers, representing approximately 85 percent of North American commercial insectaries and more than 90 percent of the North American wholesale market of natural enemies (317). But only one-fifth of the roughly 100 distributors of natural enemies in

North America belong to ANBP (37). The International Organization of Biological Control (IOBC) is an active and long-standing international association that represents the industry as well as others engaged in researching or implementing biological control programs (317).

Natural enemy products marketed worldwide consist of more than 100 species, primarily of insects and mites that prey upon or parasitize pests (317). In addition, a handful of companies supply snails or vertebrate animals, such as the mosquito fish, *Gambusia affinis*, for biological control. The most widely used natural enemies are various species of the wasp *Trichogramma* that parasitize caterpillar pests (317). No industry analyses compile data on production or sales according to type of product (317). Box 6-1 lists the products that appear to be marketed most frequently.

Sales of natural enemies in the United States reportedly grew rapidly over the past five years (28), but significant hurdles to expansion exist. These are related to the nature of natural enemy products, production methods, and the industry's stage of development.

Natural enemies are shipped as live eggs, larvae, or adults. These living products have a short shelf life and require attentive (temperature-controlled) handling. Applications in the field must be carefully timed according to weather, pest abundance, and pesticide spray schedules. Current production techniques are hands-on, labor intensive, and expensive because natural enemies

BOX 6-1: Biologically Based Products for Pest Control

Types of natural enemies sold most frequently

Lacewings (Chrysoperla carnea, Chrysoperla rufilabris)

- Primarily for aphid control, but also for mealybugs, thrips, scales, and various other insects in fields or glasshouses

The parasitic wasp Encarsia formosa

- For control of whitefly

Various species of parasitic wasps in the genus Trichogramma

- For control of caterpillar pests such as European corn borers, corn earworms, boll worms, budworms, armyworms, and hornworms

Predatory lady beetles (primarily Hippodamia convergens *and* Cryptolaemus montrouzieri)

Various predacious and parasitic mites

- Primarily for control of thrips in glasshouses and spider mites

The aphid gall midge (Aphidoletes aphidimyza)

- For control of aphids in glasshouses

Pheromone products currently marketed or under development

For Disruption of Pest Mating:

- Products targeting 16 different insect pests

Lure and Kill (pheromone and insecticide combinations):

- 10 different products targeting five different insect pests

Microbial pesticides currently sold commercially

For Insect Control:

- Bt (*Bacillus thuringiensis*), at least eight different varieties of bacteria marketed under more than 17 different trade names
- One genetically engineered Bt product

(continued)

BOX 6-1: Biologically Based Products for Pest Control (Cont'd.)

- Three genetically engineered products consisting of Bt toxin genes inserted into a killed *Pseudomonas fluorescens*
- Bacterial milky spore disease of the Japanese beetle (*Bacillus popolliae*, *B. lentimorbus)*
- One fungal pathogen for cockroach control (*Metarhizium anisopliae*)
- Two fungal products for control of turf and ornamental pests (*Beauvaria bassiana*)
- Two viruses (gypsy moth NPV and beet armyworm NPV)
- A protozoan pathogen of grasshoppers (*Nosema locustae*)
- Four nematode species in the families *Steinermatidae* and *Heterorhabditidae*

For Weed Control:

- Two fungi that cause plant disease (both were taken off the market, but one has recently been reintroduced; see chapter 3)

For Control of Plant Diseases:

- Eight microbial antagonists of plant diseases, including: *Gliocladium virens* for use in soiless planting mixtures; *Trichoderma harzianum* for use in potting mixtures and as a golf course inoculant; *Agrobacterium radiobacter* for control of crown gall: *Bacillus subtilis* for seed treatment; *Candida oleophila* and *Pseudomonas syringae* for control of postharvest plant disease

SOURCES: J.O. Becker and F.J. Schwinn, "Control of Soil-Bourne Pathogens with Living Bacteria and Fungi: Status and Outlook," *Pesticide Science* 37:355-363, 1993; B. Cibulsky, Manager, Licensing and Business Development, Abbott Laboratories, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 18, 1995; G.E. Harman and C.K. Hayes, Cornell University, Geneva, NY, "Biologically-Based Technologies for Pest Control: Pathogens that are Pests of Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October, 1994; K. Smith, Henry A. Wallace Institute for Alternative Agriculture, Greenbelt, MD, "Biological Control: An Assessment of Current Markets & Market Potentials," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994; and R.G. Van Driesche et al., University of Massachusetts, Amherst, MA, "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, December, 1994.

NOTE: Table primarily reflects products marketed in the United States.

are reared on live hosts (commonly referred to as *in vivo* production).

Great interest centers on the development of better production, packaging, storage, shipping, application, and quality control techniques to reduce cost, enhance shelf life, and improve product efficacy (317). Industry analysts say that such improved production and handling would greatly decrease the cost of using natural enemies (table 6-2). Another lesser interest of the industry is improvement of breeding stock to enhance compatibility with conventional pesticides. Some companies already do this by selecting stock from regions where pesticide use is high, and academic researchers have begun experiments to select or to genetically engineer certain natural enemies (mites) for herbicide resistance.

Because most natural enemy companies are small and operate with a low profit margin, few can afford to invest significantly in R&D (317). The industry would like to see far greater public investment in research, for example, to develop artificial diets for rearing natural enemies (*in vitro* production). They assert that the current relationship between the industry and the USDA Agricultural Research Service (ARS) has much room for improvement (34). Much of the groundwork for commercial production of natural enemies was laid by past federal research that developed production techniques and identified potential biological control agents. Producers complain that this technology transfer pipeline began drying up some time ago and has hardly existed at all for the past six to seven years (270).

TABLE 6-2: Projection: How Improved Production and Handling Technologies Would Incrementally Increase the Scale and Decrease the Costs of *Trichogramma* Production

Improvement	Increase in production capacity (hectare per season)	Reduction in cost per hectare
University R&D	—	—
Industrial pilot plant (to scale-up production techniques)	× 15	50% reduction
Longer shelf life	× 5	No change
Improved techniques for field application	× 24	96% reduction
Artificial diets	× 22	88% reduction
Total change with all improvements	× 40,000	99.8% reduction

SOURCE: Adapted from G. Voss and B. Miflin, "Biocontrol in Plant Protection: CIBA's Approach," *Pesticide Outlook* 29–34, April 1994.

Although improved products and production methods might help natural enemies compete more effectively against other pest control products in the marketplace, other obstacles remain. Most important, natural enemies are highly specific, and suppress but do not locally eliminate a pest. Their performance profile differs significantly from that of conventional pesticides (see chapter 3). Industry representatives believe that better education of farmers—through extension personnel and pest control advisors with specific training in BBTs—will be essential for the development of larger markets (see chapter 5).

Perhaps equally important, the effectiveness of commercially available natural enemies under field conditions remains hotly debated, with some academic scientists claiming that the products have little utility except in glasshouse horticulture. The sources of differing views on effectiveness are difficult to untangle. There is too little information about how natural enemies should be applied to maximize their impact on pests (i.e., when, where, how, and how many per acre). Nor has the effectiveness of most natural enemies—and the extent to which that effectiveness is affected by care in product handling and use—been adequately evaluated (12).

Some scientists believe that the quality control of natural enemy products fluctuates widely among producers, although adequate documentation of this problem is lacking. Instructions on appropriate application rates also vary greatly among companies (59A). Some companies fear that poor products with improper use will destroy the industry's public image (285). The industry has been moving toward voluntary quality control standards through activities of the ANBP in the United States and of the IOBC internationally (12,157). Companies fear that the federal government will move to regulate the industry if they do not institute such voluntary controls.

The USDA Animal and Plant Health Inspection Service (APHIS) recently published draft regulations for the importation, interstate transit, and use of biological control agents[1] (see chapter 4). These regulations, which would have put significant new requirements in place, were withdrawn following negative public comment. Natural enemy producers now consider future federal regulation of their industry to be among their greatest challenges and wish to participate in the development of any new rules.

Finally, the market for natural enemies is highly volatile (317), fluctuating with production levels of those crops for which natural enemies are most commonly deployed. The market also depends on pest abundance, which, in turn, is greatly affected by the weather and other environmental variables. These problems would diminish if markets and types of crops serviced increased. For now, though, producers have great difficulty predicting the market for certain products and increasingly are turning to narrower product lines that have more consistent sales.

[1] Federal Register 60(116):31647, June 16, 1995.

Although this move reduces the companies' economic exposure, it provides fewer options for farmers and other users to experiment with natural enemies for suppressing a variety of pests.

Pheromones

Pheromone-based insect traps or mating disrupters are produced by 14 North American companies, including Ecogen, Consep Membranes, Hercon Environmental, and Troy Biosciences. Only two or three companies in the United States actually synthesize the pheromones used in pheromone-based products. These chemicals are then incorporated into dispensers and traps by the companies marketing those products.

Producers of semiochemicals[2] banded together in 1992 to form the American Semiochemicals Association (ASA). In part as a result of the association's efforts, the U.S. Environmental Protection Agency (EPA) moved to relax regulatory oversight of pheromone registration and sales in 1994, and the industry seems to have few complaints about the federal regulatory system currently in place.

Pheromone products include devices for monitoring pest populations, mass trapping of insects, mating disruption, and bait-and-kill combinations also containing a conventional pesticide or viral or fungal based pesticides. Mating disruption products have been developed for such well-known pests as the pink bollworm (*Pectinophora gossypiella*), Oriental fruitmoth (*Grapholita molesta*), and tomato pinworm (*Keiferia lycopersicella*). Current bait-and-kill products target the American cockroach (*Periplaneta americana*), and the boll weevil (*Anthonomus grandis*).

Pheromone products can be easily incorporated into current pest management practices because they are compatible with any pesticide spray schedule. For example, pheromones are now used widely in the western United States to disrupt mating by the codling moth (*Cydia pomonella*) in apple and pear orchards (259). They also play an integral part in integrated pest management (IPM) systems as tools for monitoring pest abundance.

Like natural enemies, pheromones used for suppressing pests are highly target specific and generally reduce, but do not locally eliminate, pests. Some have proven very effective at suppressing pests of high densities, however (39). Moreover, they are "adult-based" strategies and are most effective when deployed in concert with other pest control tools that attack larvae as well. The need to use pheromones as one of several components in a pest control system can confuse farmers more accustomed to "stand alone" pesticide products, leading to failures in the field and a lack of confidence in pheromone-based approaches.

Pheromone products vary in the amount and type of information included to instruct the user on proper use—for example, whether they address product strength, recommended handling, or expiration.[3] Research scientists worry that such inconsistent instructions can further undermine consumer confidence by contributing to incorrect use and poor performance. The Entomological Society of America (ESA), an organization of professional entomologists from academia, industry, and government, is working on a paper recommending that the industry adopt voluntary standards for including this type of information on the labels of monitoring products (87). Some industry representatives, however, question the need for such standards, arguing that poorly performing products will eventually be eliminated through diminished sales. In addition, some of the technical information that scientists would like to see displayed is proprietary information for the companies.

The federal research system historically was a significant source of new information on phero-

---

[2] Semiochemicals refers more generally to naturally occurring chemicals that mediate behavior between living organisms. Pheromones are a type of semiochemical.

[3] Such information would be in addition to the standard data required by EPA for labels of pest control products. No federal labeling requirements exist for pheromone products intended for monitoring pests.

mones. Industry representatives complain that the level of federal research in this area has declined substantially over the past 10 to 15 years, and that federal researchers have consequently ceased to provide enough new discoveries of potential commercial merit (126). The cost of such research is too high for the companies to shoulder on their own (116). The specific area in which federal scientists could now make the biggest contribution is in evaluating the field performance of formulations (persistence and rate of pheromone release) (39,1 16).

The Federal Technology Transfer Act of 1986 permits federal scientists to patent their discoveries and sell limited licenses for their use. This legislation has had mixed results. Whereas the licensing process has provided incentives for cooperation between federal researchers and industry, some discoveries have been lost when they have been licensed to companies that cannot or do not develop the product (126). In addition, some smaller companies have difficulty meeting the financial requirements for obtaining licenses for the products of federal research.

The gap in the discovery and development of new products also means that the industry is now crowded by a large number of companies competing for a small number of product types and uses (23). Industry representatives predict the ultimate result to be a reduction in the number of companies involved because of company mergers, acquisitions, and failures (23). This process is already under way; a number of pheromone companies have recently been purchased by agricultural biotechnology companies, for example, Agrisense by Biosys (136). Some pheromone producers worry that this consolidation may ultimately destabilize the industry because many of the biotechnology companies are not themselves in sound financial condition. The situation in Europe-where a number of large companies, like BASF, are involved in developing pheromone products-offers an interesting contrast. There, strong government policies to reduce the use of conventional pesticides have stimulated the involvement of larger companies (39).

Microbial Pesticides

More than 20 companies develop or produce microbial pesticides worldwide (317). A few are small companies that market only one or a few products with annual sales of less than $1 million. Some are midsize biotechnology companies like Biosys, Ecogen, and EcoScience, which produce a diverse mix of products. Numerous larger agrochemical and pharmaceutical companies, like Ciba-Geigy, Abbott Laboratories, and Sandoz also are involved. For these, microbial pesticides account only for a fraction of annual sales (317). The interest of the pharmaceutical companies has been driven by their easy access to the large-scale fermentation equipment necessary for production of microbial pesticides (150).

Most U.S. producers of microbial pesticides are members of the Washington-based Biotechnology Industry Organization (BIO). This trade association serves as both a lobbyist and a source of educational seminars for members of the biotechnology industry. In addition, BIO holds conferences five times a year where industry representatives gather to discuss the latest technologies and future directions for the industry (333).

Microbial pesticides are formulations of bacteria, fungi, nematodes, protozoa, or viruses for

Several *new microbial pesticides based on fungi, like this* Beauveria bassiana on *whiteflies, have just become commercially available.*

Agricultural Research Service, USDA

pest control. Although researchers have explored a large number of species from more than 20 taxonomic families of plant or animal pathogen for potential commercialization, far fewer species are available for commercial sale (box 6-1 presented earlier) (317). A total of 43 strains/species and 245 products are now registered with the Environmental Protection Agency (396). The industry's greatest focus, by far, has been on the identification and development of strains of the bacterium *Bacillus thuringiensis* (Bt) which contain insect toxins. As many as 40,000 different strains have been identified and archived.

Microbial pesticides may have achieved the greatest market share of BBTs today because Bt is easy to use and compatible with conventional pesticides. Farmers use the same equipment and methods to apply Bt-based products and conventional pesticides, and thus do not require substantial retraining to use them (317). Consequently, farmers' acceptance of Bt has been relatively high. An exception is fresh-produce farmers; some believe that use of Bt results in fruits with a lower quality appearance (99).

Other microbial pesticides vary in ease of use and compatibility with conventional chemicals. For example, unlike most fungal agents, most bacterial agents for plant pathogen control are compatible with fungicides (22). When Ocean Spray Cranberries personnel sought to use nematode products to control insect larvae in cranberry bogs, they had to work closely with the producer to adapt the nematode for application because the standard methods were too difficult (67).

According to industry analysts, the market for microbial pesticides today remains modest largely because of inherent deficiencies in the products. Most microbial pesticides have a short shelf life. Bt, for example, has a shelf life ranging from six months to two years, compared with a shelf life of two to four years for conventional pesticides (211). They also have a short field persistence, a narrow spectrum of activity, and a slow rate of action relative to conventional pesticides (150). An exception here may be some of the new seed treatments coming onto the market to control plant pathogens. These provide a longer period of control than similar chemical treatments (138A).

Some industry representatives believe that the greatest opportunities for microbial pesticides will result from genetic engineering to correct these flaws. Field tests of microbial pesticides created by genetic engineering have begun, and four products are currently on the market: Ecogen's Raven and Mycogen's M-trak, MVP and M-Peril. Genetically engineered microbes have the additional advantage of being clearly patentable. Whether naturally occurring strains are patentable is more ambiguous; the ability to obtain a patent depends on whether the strain has unique and novel qualities, such as the capability of producing a different protein or killing a different kind of insect (250).

Whether genetic engineering will provide a quick route to cheap, highly efficacious, microbial pesticides remains to be seen. Because R&D and registration costs are higher for genetically engineered microbes than for naturally occurring ones, genetically engineered products must be targeted at bigger markets to recover the R&D costs. But competition from conventional pesticides is likely to be most intense in those bigger markets. Moreover, the regulatory environment is ambiguous, and future public acceptance of commercial use is uncertain. Some of the very characteristics most desirable to engineer into a microbial pesticide—increased breadth of activity, faster kill rate, longer field persistence—are those most likely to generate greater ecological risks (see chapter 4).

In any case, expanded use of microbial pesticides will depend on their providing cost-effective pest control. Currently, the cost of using these products is relatively high. Companies have had difficulty achieving economies of scale by expanding production. Nevertheless, according to some estimates, biopesticide use costs are falling. For example, from 1990 to 1993, the cost of using Bt to control Colorado potato beetle (*Leptinotarsa decemlineata*) in the United States reportedly dropped from $20 to $10 per acre (294). And Bt products currently used for forest insect control are comparably priced to conventional pesticides registered for this use (49).

Economic factors may play the greatest role in determining the future of microbial pesticides. Biotechnology companies have been laboratories for the discovery of diverse microbes with commercial potential, and venture capital has been their foundation. However, most of the biotechnology companies have yet to make any profit from their products. Some have had difficulty breaking into the Bt market because of the intense competition and domination of larger companies like Abbott. Even the biggest and best-known biotechnology companies, like Ecogen and EcoScience, require continuous capital input to stay afloat. The venture capital is beginning to dry up, creating some volatility in the industry and a pullback from R&D investment. In the past 10 years, venture capitalists have developed a negative view of the agricultural biotechnology industry because it has spent large amounts of money on research with very little return. Few venture capitalists now fund biotechnology, except in the area of medicine (211). The result is a series of mergers and consolidations, such as the recently announced purchase of Crop Genetics International by Biosys (53).

A number of biotechnology companies have also formed alliances with larger agrochemical companies (150). Through these, the larger company may provide R&D funding in exchange for marketing rights and thereby gain entry to BBTs without the expense, time, and long-term commitment required to develop an in-house program. The biotechnology company, in return, may obtain much-needed cash and perhaps assistance with formulation, manufacturing, marketing, or other areas in which the company lacks expertise.

The shortage of people with the appropriate training in production and formulation engineering is one of the factors that make such an arrangement desirable. Industry members believe that this problem needs to be tackled by universities. Some are already doing so; for example, the University of California at Davis has just started a new area of study in fermentation engineering, an integral technology in the production of microbial pesticides (211).

VIEW FROM THE CONVENTIONAL PESTICIDE INDUSTRY

The conventional pesticide industry has an ambivalent view of biologically based pest control. Most major agrochemical companies have invested to some degree in BBTs, but this involvement generally is small and somewhat tentative. The ambivalence derives from several sources, including the companies' perceptions of the positive and negative attributes of biologically based products as well as the larger forces at play within the pesticide industry.

Participation by Agrochemical Companies

The top 10 companies within the agrochemical industry are responsible for approximately 72 percent of worldwide agrochemical sales (150). All of these companies have supported R&D of biologically based pest control products over the past decade through either internal programs or relationships with smaller biotechnology companies (150). Worldwide R&D investment by the industry is estimated at $2.6 billion annually, with approximately $100 million of this allocated to BBTs (149). Although agrochemical companies typically put only a fraction of the R&D money into BBTs, this amount is large relative to the R&D budget of midsize biotechnology companies (233).

A number of the top companies currently market biologically based products (table 6-3). Despite their dominance of the pest control market, agrochemical companies do not account for the lion's share of worldwide BBT sales. For example, about 70 percent of global Bt sales are attributable to Abbott Laboratories and Novo Nordisk,[4] producers primarily of pharmaceuticals and industrial enzymes (150,423).

[4] In 1995, Novo Nordisk began to sell its microbial pesticide division.

TABLE 6-3: Examples of Biologically Based Products Marketed by Major Agrochemical Companies or Their Partners

Company	Product	Description
Ciba Geigy	Agree	Bt *aizawai* and Bt *kurstaki* in a combined formulation for vegetable, fruit, corn, soybean, and tobacco uses
	Design	Bt *aizawai* formulation for cotton and soybean uses
	Through Ciba Bunting Ltd. markets:	
	12 natural enemies (including mites)	e.g., *Trichogramma brassicae* wasps, *Encarsia formosa*, *Phyoseiulus persimilis* for fruit, vegetable, and ornamental uses
	Bunting *Steinernema feltiae*	Nematode formulation for ornamental uses
	Bunting *Steinernema carpocapsae*	Nematode formulation for fruit and ornamental uses
	Bunting *Heterorhabditis megidis*	Nematode formulation for ornamental uses
	Bunting *Bacillus thuringiensis*	Bt formulation for vegetable and ornamental uses
Sandoz	Javelin WG	Bt *kurstaki* formulation for vegetable, fruit, and field crop uses
	Thuricide	Bt *kurstaki* formulation for ornamental, shade tree, and forest uses
	Vault WP	Bt *kurstaki* formulation for vegetable, fruit, and field crop uses
	Teknar	Bt *israelenis* for mosquito larvae control
Dupont	by agreement markets:	
	Novo Nordisk's Biobit	Bt *kurstaki* formulation
	Crop Genetics International Gypcheck	NPV virus formulation for forestry uses produced on contract for the U.S. Forest Service

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

Sandoz, ranked about number 12 in global sales of crop protection products, is the agrochemical company that is most closely associated with biologically based pest control both in the United States and worldwide (423). Sandoz has almost 25 years experience in this area. Sandoz currently markets pheromone-based products and microbial pesticides; it holds an estimated 25 percent of the global market in the latter (150).

The more recent movement of Ciba-Geigy into BBTs provoked considerable interest because of the company's status as the world's largest agrochemical producer (its sales of global crop protection products in 1991 were about $12.2 billion) (150). Ciba produces a Bt product and a pheromone product. It entered an agreement with Biosys to market that company's nematode-based biopesticides for turf and ornamental applications in 1992 (413). The U.S. component of that agreement was terminated in 1995 (79). As mentioned earlier, Ciba-Geigy bought Bunting and Sons, one of the world's largest producers of natural enemies, in 1993. The natural enemy company has not yet been integrated with Ciba's other crop protection units. Ciba attempted another entry into production of natural enemies in 1989 through a joint venture with the government of Ontario to develop a rearing facility for *Trichogramma* wasps to control spruce budworm (*Choristoneura fumiferana*). However, the company sold its interests in the project in 1994 because it decided the venture was unlikely to provide a sufficient return to justify further funding (413).

Industry Perceptions about Biologically Based Products

BBTs appeal to agrochemical companies because of the lower costs of bringing such products to market, swifter and cheaper registration, apparent environmental safety, and positive public relations value (150). Recent efforts by the EPA to streamline and speed registration of low-risk pest control products have resulted in reduced data requirements and quicker processing of registration applications for BBTs. Bringing a microbial pesticide to market now takes roughly three years and costs an estimated $1 million to $2 million, in comparison with eight to 10 years and $25 million to $80 million for an agrochemical. Costs of meeting registration requirements of $20 million for the agrochemical versus $200,000 for the microbial pesticide contribute significantly to the differential, as do the rising costs of new agrochemical discovery (294,317).

BBTs generally do not fare well when held up to the performance standards set by conventional pesticides, however (table 6-4). Most biologically based products generally are effective against only a few pests, whereas many chemicals are "broad spectrum"—providing simultaneous control of a wider pest array. Environmental conditions and methods of application can affect the efficacy of some biological products. Finally, many BBTs have shorter shelf lives and field persistence than most conventional pesticides. Agrochemical companies believe that farmers are accustomed to the ease of use and effectiveness of conventional pesticides and will be reluctant to try biologically based products if they cannot offer similar qualities (149,150).

Industry expectations for returns on new products have been set by conventional pesticides: revenue from a single product can reach $100 million annually in the largest markets (e.g., corn, soybean, wheat, and cotton) (150). Current biologically based products cannot compete in this arena; with the possible exception of Bt, their typical markets are minute in comparison. Some agrochemical companies believe that microbial pesticides genetically engineered for enhanced efficacy, broader spectrum effects, or longer field persistence might attain markets rivaling those of conventional pesticides (149,317). Such companies concentrate what R&D resources they allocate to BBTs on genetic engineering, anticipating greater returns over the long term than would be possible by investment into the types of BBTs on the market today.

Biologically based products do not fit easily into the extensive entrenched system for pesticide distribution, sale, and use (149). Consequently, even some products that are technical successes end up being failures in the marketplace. Pesticide sales representatives who are unfamiliar with BBTs do not adequately promote them, and users who have insufficient information about these products are hesitant to try them. This situation poses special problems because, according to industry representatives, some growers rely on sales representatives for advice more than on extension personnel (149).

Paradoxically, certain especially effective BBTs have proved to be commercial failures because they do not have the necessary characteristics for success. DeVine, a fungus formulation for weed control produced by Abbott Laboratories, provided such good control of its target pest that repeated applications were unnecessary. It could not sustain a large enough market to justify the company's production and sales costs, and the product was eventually withdrawn from the market. The product was brought back onto the market in 1995 through support of EPA (49).

Other Influences on the Industry

A number of well-performing, low-priced products dominate the relatively stagnant market for conventional pesticides (413). Market growth is slow, and profitability declined from 1980 to 1991 (150). New products have not been forthcoming despite significant growth in the industry's total R&D; major pesticide manufacturers spent an estimated $1.4 billion on research into

TABLE 6-4: Comparison of Biologically Based Products and Conventional Pesticides

	Natural enemies	Pheromones	Microbial pesticides	Conventional pesticides
Shelf life	Short (hours to days)[a]	Moderate (1 to 2 years)	Short to moderate (months)[b]	Long (years)
Field persistence	Short[c]	Short to moderate (days to weeks)	Short (less than one week)[d]	Variable (days to years)
Spectrum of activity	Narrow[e] (one pest per product)	Narrow (one pest per product)	Narrow to moderate[f] (one to several pests per product)	Moderate to broad (diverse classes of pests for certain products)
Ease of use	Low (careful handling and planning of use required)	Moderate to high	High[g] (same as for conventional pesticides)	High
Compatibility with conventional pesticides	Low (only in certain combinations)	High (not affected by conventional methods)	High	High
Cost of application	High	High[h]	Low to moderate	Variable, but generally low
Effectiveness[i]	Low to moderate	Moderate to high	Moderate to high	High
Adverse effects on human health and environment	Low	Very low	Low	Variable, but sometimes high

[a] Some insects can be kept for months if conditioned to remain dormant.
[b] Some Bt products are stable for more than three years if frozen or formulated in oil.
[c] Generally a season or less, although release of certain insects into a new area can last for years.
[d] Field persistence of microbial pesticides is usually considered to be short relative to that of conventional pesticides. Some, however, such as seed treatments, which will persist until the crop is harvested, provide more lasting control than comparable conventional pesticides.
[e] Certain predator species, however, may be effective against a variety of pests.
[f] Some newer viruses have a broader spectrum.
[g] Some viruses are harder to apply.
[h] Low to moderate, if cost is compared with the cost of custom pesticide application (equipment use and depreciation, labor, worker protection training, etc.).
[i] Effectiveness as judged against performance criteria of conventional pesticides.

SOURCE: Office of Technology Assessment, U.S. Congress, 1995.

new products in 1992, up 88 percent from six years earlier (294). Few newly discovered chemistries have matched the desired levels of environmental and toxicological safety (150). Also, between 1973 and 1993, rates of discovery of new agrochemical molecules dropped from one in 5,000 to one in 20,000 (294).

In this context, the rapid market growth and "green" aspects of BBTs have appeal. However, the declining profitability within the agrochemical industry has generated a trend toward consolidation of companies, and these typically target new products at the largest major-use markets,[5]

[5] *Major use* refers to larger pesticide markets (e.g., those serving corn or wheat).

rather than the smaller markets usually served by BBTs.

Some analysts predict that the appeal of BBTs will diminish further when the new chemicals currently poised for commercialization come onto the market, for some will compete directly with Bt (33). The agrochemical industry's annual R&D investment of more than $2.6 billion is not insignificant, especially in comparison with the estimated $100 million that goes to private sector R&D on BBT products (149). Some in the agrochemical industry believe that they are closing the gap with newer chemicals that are more environmentally acceptable and have better toxicological profiles. One example is Bayer/Miles' Imidicloprid described by company representatives as a "Goldilocks compound. It's not too hard, not too soft, but just right" (237). Another new product, fipronil (a nerve poison), was developed by analyzing soil for components that tend to deter pests.

Agrochemical companies are pursuing other new avenues to crop protection as well. Plants genetically engineered for pest, pathogen, or herbicide resistance are perhaps the best example. Many of these will be targeted at major crops that provide a potentially large market, such as cotton (96). Metabolites derived from microbes, like Avermectin, are another promising area (33).

Some representatives of the agrochemical industry thus believe that the opportunity for BBTs to enter the market in the 1980s and early 1990s was somewhat artificial (150). Farmers were pushed by a lack of alternatives to adopt "next best" methods for pest control, allowing Bt and other BBTs to flourish under unique circumstances. They believe, moreover, that this opportunity will disappear when the BBT products have to compete with the new chemicals and genetically engineered plants that are coming on line.

Implications

The ambivalent view of BBTs has not been lost on long-time participants in the area like the Sandoz Corporation. Such companies are struggling with whether to continue investment in this area when significant profits are not yet forthcoming.

Overall, agrochemical companies have come to see BBTs as having their greatest—perhaps their only—potential in niche markets not well served by conventional pesticides (413). Opportunities exist where conventional pesticides are lacking, market size cannot justify the expense of chemical R&D, highly selective pest control is desired, or consumers ask for pesticide-free agricultural products (413). These are not comparable to the "big ticket" markets afforded by conventional pesticides used in corn, wheat, and other major-use crops.

Industry analysts do not expect BBTs to compete directly with chemicals, but instead to support their "prudent use" (413). These products allow companies to maintain a market presence where their chemical product sales and distribution networks are already strong (150). Resistance management is one of the leading reasons agrochemical companies have moved to Bt products (150). Alternation of BBTs with chemical management, which slows the rate at which resistance develops, can prolong the useful life span of the chemical. For this reason, some producers of natural enemies optimistically predict a growing interest among agrochemical companies in the marketing of "pest control systems" that combine various pest control tools to achieve the desired level of pest suppression (28). However, few major agrochemical producers have yet developed resistance management as a significant marketing strategy for BBTs (box 6-2) (79).

Most agrochemical companies have hedged their bets by forming alliances with smaller biotechnology companies rather than developing their own R&D programs for BBTs. Through these relationships they will realize the benefits afforded by developing BBT products without making large-scale investments in the technologies. This approach also puts the agrochemical companies in a good position to take advantage of any major breakthroughs that would bring BBT performance profiles into line with conventional products. Such developments could greatly

BOX 6-2: How Ciba-Geigy Markets a Microbial Pesticide

Ciba-Geigy has targeted marketing of its Agree Bt-based product to address today's problems in pest management: pest resistance, environmental impact, and development of IPM systems. According to Ciba-Geigy's advertising material on Agree:

Use of Agree will allow the farmer to reduce the amount of neurotoxic insecticides used on a particular crop. Alternating Agree with neurotoxic insecticides will prolong the effectiveness of both in a resistance management strategy.

As a natural biological, Agree conforms to all IPM objectives: 1) it is host-specific and will not affect other biotic systems, thus preventing an increase of previously non-threatening pests, while maintaining the presence of beneficial insects; and 2) it is compatible with most other control methods as a resistance management tool.

SOURCE: Ciba-Geigy, "All about Agree," Greensboro, NC, 1995.

expand BBT markets and significantly change the cost equation for companies deciding where to invest their resources. Industry representatives believe the result would be rapid acquisition of smaller biotechnology companies by agrochemical companies (149).

ISSUES AND OPTIONS

Forces Shaping the Future

Future commercial involvement with biologically based pest control will depend on whether products placed on the market are effective and cost-competitive and whether they match the needs of growers and other users. Within these basic constraints, a wide array of factors will shape the future. Some are more predictable than others, and some are influenced by the federal government (table 6-5) (317).

Growth in the public's demand for organic produce would probably increase the use of BBTs, because BBTs are allowed under current organic produce certification standards, such as those promulgated by the California Department of Food and Agriculture Organic Program (37A). The Organic Foods Association of North America reported that sales of organic products totaled $2.3 billion in 1994, with annual growth exceeding 22 percent (226). Conversely, the public's basic fear of diseases and microbes could erupt into concern about use of microbial pesticides. For example, individual citizens have already tried to halt the spraying of Bt by the Maryland Department of Agriculture to control European gypsy moths (*Lymantria dispar*) on their property, despite attempts to educate the public about the virtual nonexistence of any risk to human health (329).

Genetically engineered microbial pesticides are a wild card in commercial involvement. The most important issue is whether genetic engineering will bring microbial pesticides within the performance standards of conventional pesticides. Public response to the technology also will play an important role. The release of genetically engineered ice-inhibiting microbes in California in 1987 caused a furor that has not been forgotten. Some industry analysts see the lack of publicity in response to the release of genetically engineered Bt in California in 1994, similar field tests in other states, and now marketing of Raven (a genetically engineered Bt), as a bellwether of abating public concern (95). Should scientists discover and widely publicize new risks of genetically engineered organisms, however, public opinion could easily turn against use of genetically engineered microbes (317).

Changes in the scope and rigor of national and state environmental policies and pesticide regulation could have significant impact. Increasing the information requirements for pesticide registration could drive up the cost of product regis-

TABLE 6-5: Examples of Factors Potentially Affecting the Future of the BBT Industry

Potential trend, event, or action	Predicted net effect	Federal action that could cause these effects
Public attitude or perception		
Demand for organic foods increases	Positive	
Public becomes increasingly fearful of diseases and microbes	Negative	
Public's suspicions of biotechnology diminish	Positive	
Media coverage of pesticide hazards increases	Positive	
Public's demand for greater food safety grows	Positive	
Public's demand for higher standards of environmental safety grows	Positive	
Industry changes		
Natural enemies industry implements voluntary quality control	Positive	USDA technology transfer or regulatory pressure
Agricultural biotechnology industry collapses under debt load	Negative	
New, environmentally safe, conventional pesticides are introduced	Negative	
Crop plants genetically engineered for pest resistance are widely successful	Negative	
Farmers increase their reliance on pest control advisors or extension agents knowledgeable about integrated pest management and BBTs	Positive	Training of extension agents; licensing/ training of pest control advisors
Growing numbers of food processing companies require low or no pesticide produce from farmers	Positive	Changes in food labeling
Farmers' insurance costs for using pesticides increases	Positive	
Technology innovations		
Cheap, reliable techniques are developed for rearing, packaging, shipping, storing and applying natural enemies	Positive	Research or funding via USDA
Production costs for microbial pesticides drop	Positive	Research or funding via USDA
New pheromone formulations, cheaper methods of synthesis, improved deployment strategies are developed	Positive	Research or funding via USDA
Genetic engineering of microbial pesticides results in broader spectrum of activity, enhanced field persistence, or other improvements	Positive	Research or funding via USDA
Rate of discovery of novel Bt strains slows down	Negative	
Natural phenomena		
More pests develop resistance to conventional pesticides	Positive	
Pest resistance to Bt toxins becomes widespread	Negative	
Public policy		
EPA pesticide reregistration process speeds up	Positive	Internal changes at EPA
Expense of registering or using conventional pesticides grows as a result of provisions in reauthorized Federal Insecticide, Fungicide and Rodenticide Act, Endangered Species Act, or Clean Water Act	Positive	Congressional action
More states institute California-type regulation of pesticide use	Positive	
Coordination between public-sector research and BBT industry increases	Positive	USDA or Congress moves to increase coordination

SOURCES: Office of Technology Assessment, U.S. Congress, 1995; A.S. Moffat, "New Chemicals Seek to Outwit Insect Pests," *Science,* 261(121):550–551, July 30, 1993; K.R. Smith, Henry A. Wallace Institute for Alternative Agriculture, Hyattsville, MD, "Biological Pest Control: An Assessment of Current Markets and Market Potential," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, D.C., January, 1994.

tration, and thereby further diminish the agrochemical industry's incentives to invest in new product R&D. Presumably, the result would be a further reduction in the number of conventional pesticides on the market and a lack of pesticide products for small-market crops like fruits and vegetables. Such changes would increase opportunities for biologically based products. Conversely, concern about the potential impacts on biodiversity from introducing biological control agents could translate into tightened regulation of the natural enemy industry and have a dampening effect.

Industry trends also will play a role. Growth in greenhouse agriculture would probably stimulate increased use of BBTs, because this is one of the most successful applications of these products. Changes in the capital market that positively or negatively affect the agricultural biotechnology industry could influence the development and availability of new microbial pesticides, including genetically engineered ones (317). The extent to which farmers and other users adopt BBT products will be a major determinant of market growth. Adoption of BBT products, in turn, may be affected by technical innovations that increase product efficacy and ease of use, or by the success of extension agents or pest control advisors in informing users about BBT products.

Visions of the Future from OTA's Workshop

On the theory that best predictions of the future come from those with the most experience in the field, OTA sought the opinions of 12 industry representatives during a workshop held in September 1994 (see appendix C). The participants represented the range of companies involved in the production of biologically based products. OTA asked each workshop member to speculate about two views of the future—one under the status quo and another under the assumption that the federal government would take action to support the BBT industry.

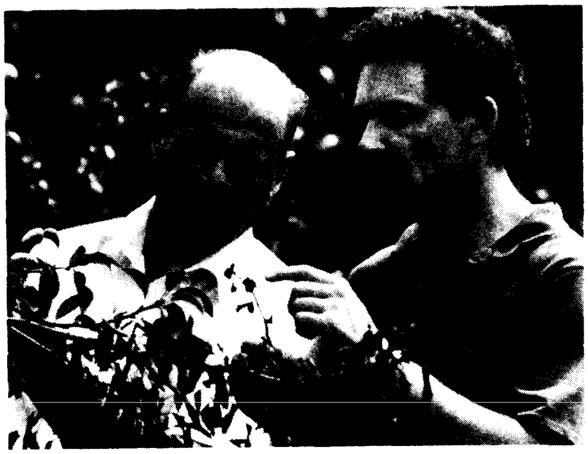
Under the Status Quo

The consensus of OTA's workshop participants was that, in the absence of any changes to federal programs or policies, biologically based products will experience a slow gain in number and uses. Technical improvement in product formulation and efficacy is likely to result gradually in increased spectrum of efficacy, better handling and use characteristics, and good incorporation into IPM programs. Nevertheless, the use of commercially available BBTs will increase primarily in high value crops such as fruits and vegetables and other niche areas (e.g., turf, ornamentals, lawn and garden) where current use is greatest. Members of the workshop estimated that BBTs might gain as much as 10 to 25 percent of those markets where biologically based products are effective (primarily in control of certain caterpillar pests).

Economic forces will cause agrochemical companies to continue to work toward "stand alone" solutions rather than pest control systems. Consequently, the successful conventional pesticides remaining on the market will most likely be broad-spectrum chemicals that fit poorly into integrated pest control systems like IPM because they may kill natural enemies as well as the target pest. Over time, it will be ever more difficult for BBTs to compete against the standards set by these chemicals. This situation, coupled with the incompatibility of the chemicals with integrated pest management, will provide strong incentives for farmers to continue with conventional chemically based pest management, especially for those crops where market size justifies R&D investment (i.e., major use).

An Alternative Future

OTA's workshop participants also foresaw a possible alternative future in which wider adoption of integrated pest management systems would increase use of BBTs and cause a corresponding decrease in the use of conventional pesticides. Simultaneously, a thriving BBT industry would be better able to support these IPM systems by bringing to market a greater diversity of BBT products with improved charac-



Commercial development is well advanced for microbial pesticides to combat fire blight, a destructive disease of pear and apple trees caused by the bacterium Erwinia amylovora.

Agricultural Research Service, USDA

teristics, such as increased shelf life, ease of use, and efficacy. The driving force behind these changes to the status quo would be various federal actions related to regulation, research, technology transfer, and extension.

The workshop's alternative scenario did not represent a radical departure from events under the status quo. Although participants predicted as much as a doubling of market growth rates, under even the most optimistic scenarios BBTs would still amount to only a fraction of the total market by the year 2005 because their present share of the pesticide market is so small. Also, the greatest use of BBTs will continue to be outside the major use crops, which will remain well served by the development of new conventional pesticides.

Nevertheless, the workshop participants saw such changes as an integral component of the government's role in expanded applications of IPM. In the absence of change, incentives for the pesticide industry will continue to be stacked in favor of the development and marketing of broad-spectrum chemicals that are incompatible with IPM. And the future of the agricultural biotechnology companies, whose R&D has fueled development of diverse BBT products, will remain uncertain.

Options to Enhance Commercial Involvement

The essential choice before Congress, then, is whether to nurture the BBT industry. Congress could choose to do this in a number of ways. The federal government exerts many subtle and direct effects on the BBT industry (table 6-5 presented earlier). In this section, OTA identifies a wide range of areas where Congress could adjust the federal role. These options, by and large, are not linked; most could be implemented independently. Because each has an incremental impact, the greatest effect would be felt if a number were put in place simultaneously.

Regulation has a major impact on BBT companies; it determines which products can be sold and for what uses, as well as the relative costs of BBT product development and marketing. Chapter 4 of this report assesses and presents options related to the appropriate level, standards, and content of regulatory review. That analysis incorporates considerations related to the commercial impacts of the regulatory system. Its critical features to the private sector are cost, fairness, and predictability. Industry representatives do not view all regulation as undesirable—it can remove poor products from the marketplace and address legitimate public concern about risks (121A,149). However, the current system for BBTs falls down in a number of places. Costs of meeting the information requirements of regulatory review have a significant effect on the decisions or ability of companies to pursue specific technologies, especially for small companies that produce natural enemies and for midsize biotechnology firms. In addition, future regulatory requirements are uncertain with respect to interstate distribution of natural enemies and to registration of microbial pesticides that have been genetically engineered.

Fashioning Public-Private Partnerships in Research

A lack of dedicated in-house research capabilities in the private. sector currently limits R&D of new products, production and packaging technologies, and delivery systems for certain BBTs. The federal government supports significant related research that historically has made important contributions to the identification of technologies now marketed by the private sector. The level of technology transfer has slowed, however, especially in the areas of natural enemies and pheromone products.

Some of the ongoing federal research that might be of commercial merit seems curiously out of sync with the structure of the BBT industry. For example, the USDA Agricultural Research Service (ARS) and Department of Energy scientists recently collaborated on a major research project to develop ways to mechanize the rearing of natural enemies (126). The result was a series of designs for prototype machinery that would cost millions of dollars more to produce than the total combined annual sales of all natural enemy companies in the United States.

Cooperative Research and Development Agreements (CRADAs) between companies and ARS are the major existing mechanism by which the private sector buys into ARS efforts (see discussion of ARS in chapter 5). Companies usually contribute funds for the research, while ARS provides the scientists and the infrastructure. Under provisions of the Technology Transfer Act,[6] ARS scientists can patent discoveries resulting from their work, including research conducted under a CRADA. Patented discoveries can then be licensed for a fee to companies for commercialization.

According to representatives of smaller BBT companies, the system allows most benefits of public-sector research to accrue to those companies having the greatest financial resources. Paradoxically, these are also the big agrochemical companies having the best access to research resources of biotechnology companies through a variety of contractual arrangements. Few past CRADAs have involved the smaller natural enemy and pheromone companies (300) because they lack financial resources to invest in research. Although funding by the private sector partner is not required for a CRADA, companies usually provide anywhere from several to over a hundred thousand dollars per agreement (300). In addition, representatives of the smaller companies assert that licensing of patented federal discoveries has a significant drawback: Some discoveries have never been developed by the licensees, although ARS does have the option of revoking licenses when this occurs.

ARS announces the availability of opportunities to license new technologies in the *Federal Register* and the *Commerce Business Daily*. The agency has also just begun to post this information on the Internet. Nevertheless, small BBT companies say they have not had good access to such information in the past (17). ARS has recently begun to explore additional ways to increase the frequency with which ARS discoveries are commercialized by U.S. companies (417A). Posting announcements in information sources more directly connected to the industry might improve dissemination to the widest range of interested companies.

OPTION *Congress could instruct ARS to make all discoveries related to development and commercialization of certain BBTs public property (i.e., not allow ARS scientists to patent their discoveries). Areas of particular significance to industry are the development of artificial diets for natural enemies and of new pheromone formulations. The ARS scientists involved might need additional incentives to continue research in these areas. This approach would not be desirable for microbial pesticides, however, because larger companies view the licensing arrangement as vital protection of intellectual property.*

OPTION *Congress could instruct ARS to encourage the development of CRADAs even with companies that cannot provide funding for the research. The agency would need to provide internal incentives and support for scientists that engaged in such projects.*

OPTION *Through its oversight functions, Congress could encourage ARS to communicate discov-*

[6] Federal Technology Transfer Act, P.L. 99-502.

cries of relevant technologies and opportunities for collaborative ventures more effectively to all members of the BBT industry. Better communication, perhaps via joint conferences or meetings, might have the additional benefit of better informing ARS scientists of the potential end uses of their discoveries (see chapter 5).

Enhancing Opportunities for New Products

These are financially troubled times for many of the companies that develop and sell BBT products. Many relatively small companies operate at a low profit margin and have difficulty investing in product discovery or production technologies. Agricultural biotechnology companies—the originators of many innovations in microbial pesticides--depend on a supply of venture capital that is rapidly dwindling. Some of these companies are entering a critical period when their need for funding will jump, as products long under development reach the market. The investment algorithm of larger agrochemical companies works against BBT products, with their niche markets and performance characteristics that differ greatly from those of conventional pesticides. Small-scale infusions of capital through loans, grants, or tax credits might significantly enhance companies' ability to profitably bring new products to market.

OPTION Congress could support research, development, and launching of new BBT products by providing tax credits or targeted small-business loans.

OPTION Congress could enhance market opportunities for BBT products by punitive regulation of conventional pesticides or by progressive incentives directed toward farmers and other users (see chapter 5). Note that the private sector views losses of conventional pesticides through regulation and pest resistance as "windows of opportunity" for entry of biologically based products into the market. Members of the industry, however, generally oppose artificial inflation of these opportunities through overly stringent regulation of conventional pesticides. They prefer policy actions that would affect market size through education and incentives for growers.

Many microbial agents have been registered by EPA, but are not presently on the market. The celery looper virus is one that is effective against a number of pests like this cabbage looper (Trichoplusia ni).

Agricultural Research Service, USDA

OPTION Congress could increase the options for the industry to protect its discoveries as intellectual property. Possibilities might include creating new statutory mechanisms to patent microbial pesticides (similar to the Plant Variety Protection Act), changing the timing of protection so that it starts at product registration rather than discovery, and financially supporting patent applications.

OPTION Congress created the Inter-regional Project No. 4 (IR-4) to support research that develops data for registration of minor use pesticides. Since the scope of IR-4 was expanded in 1982 to cover "biorational" pesticides, only a small part of the program's funding has gone towards work on BBTs (see chapter 5). Congress could specify that a larger portion of the IR-4 program funds should be designated to help meet the data requirements for registration of microbial pesticides and pheromone-based products.

To a significant extent, the instability of the BBT industry stems from uncertain or volatile markets. Better education of users about BBTs might help expand more predictable markets for biologically based products, as might greater consistency of product performance (especially for natural enemies). Options related to user education are covered in chapter 5.

OPTION *The quality and purity of natural enemy products is thought to vary. Some scientists have suggested that APHIS should regulate this area to improve the consistency of product performance. However, APHIS currently lacks jurisdiction to issue such standards. Industry organizations such as the Association of Natural Bio-Control Producers and the International Organization for Biological Control have begun to examine issues related to quality control, and the industry is moving toward voluntary standards. Congress could instruct APHIS to work with the natural enemy industry to develop such standards and to further assist in these efforts by providing access to the scientific resources of USDA.*

The federal government itself could provide a major market for BBTs—especially natural enemies—through its pest management programs. Recent experience in Canada has shown that creation of significant potential markets can spur private-sector investment. Banning of aerial pesticide application in Ontario forests in 1986 may have been the impetus for large companies to invest in the development of Bts for spruce budworm control (Nova Nordisk, Zeneca) and mass rearing facilities for *Trichogramma* production (Ciba-Geigy) (318).

OPTION *Congress could provide market opportunities for the natural enemy industry by contracting out the production of biological control agents used in federal pest control programs conducted by APHIS and the land management agencies. These agents are currently produced by federal laboratories.*

Appendix A: List of Boxes, Figures, and Tables

A

Chapter 2: The Context

Chapter 3: The Technologies

Chapter 4: Risks and Regulations

Chapter 5: From Research to Implementation

Chapter 6: Commercial Considerations

Appendix B: List of Acronyms

B

ANBP: Association of Natural Bio-Control Producers
APHIS: Animal and Plant Health Inspection Service
ARS: Agricultural Research Service
ASA: American Semiochemicals Association
BATS: Biological Assessment and Taxonomic Support (APHIS)
BBTs: Biologically Based Technologies (for pest control)
BIO: Biotechnology Industry Organization
BPPD: Biopesticides and Pollution Prevention Division (EPA)
Bt: *Bacillus thuringiensis*
CRADA: Cooperative Research and Development Agreement
CSREES: Cooperative State Research, Education, and Extension Service
DALs: Defect Action Levels
DoI: U.S. Department of the Interior
EPA: U.S. Environmental Protection Agency
ESA: Entomological Society of America
FACA: Federal Advisory Committee Act
FDA: U.S. Food and Drug Administration
FFDCA: Federal Food, Drug and Cosmetic Act
FHP: Forest Health Protection (U.S. Forest Service)
FIDR: Forest Insect and Disease Research (U.S. Forest Service)
FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
FWS: U.S. Fish and Wildlife Service
GRAS: Generally Recognized As Safe
IBC^3: Interagency Biological Control Coordinating Committee
IOBC: International Organization of Biological Control
IPM: Integrated Pest Management
IR-4: Interregional Research Project No. 4
NBCI: National Biological Control Institute (APHIS)
NPV: Nuclear Polyhedrosis Virus
NRI: National Research Initiative
OPP: Office of Pesticide Programs (EPA)
OTA: Office of Technology Assessment
PPQ: Plant Protection and Quarantine (APHIS)
TAG: Technical Advisory Group on the Introduction of Biological Control Agents of Weeds
USDA: U.S. Department of Agriculture

Appendix C: Background Reports, Workshops, and Workshop Participants

C

BACKGROUND REPORTS:

W. Cranshaw, Colorado State University Fort Collins, CO. *Biologically Based Technologies For Pest Control: Urban and Suburban Environments*

J.M. Cullen and T.E. Bellas, CSIRO, Canberra, Australia. *Australian Laws, Policies and Programs Related to Biologically Based Technologies For Pest Control*

M.L. Flint, University of California, Davis, CA. *Biological Pest Control: Technology and Research Needs*

G. Georghiou, University of California Riverside, CA. *Insecticide Resistance in the United States*

D.M. Gibbons, The EOP Foundation, Inc., Washington, DC. *Report on the Role of the USDA in Biologically Based Pest Control Research*

G.E. Harman and C.K. Hayes, Cornell University, Ithaca, NY. *Biologically Based Technologies For Pest Control: Pathogens That Are Pests of Agriculture*

J.M. Houghton, Houghton and Associates, St. Louis, MO. *Biologically Based Technolgies For Pest Control: Workshop on the Role of the Private Sector*

J. M. Houghton, Houghton and Associates, St. Louis, MO. *The View of Biological Pest Control From the Pesticide Industry*

A. Kuris, University of California, Santa Barbara, CA. *A Review of Biologically Based Technologies For Pest Control in Aquatic Habitats*

P.B. McEvoy, Oregon State University, Corvallis, OR. *Testing Biocontrol Agents and Microbial Pesticides For Host Specificity*

W.W. Metterhouse, Cream Ridge, NJ. *The States' Roles in Biologically Based Technologies For Pest Control*

J.R. Nechols and J.J. Obrycki, Kansas State University and Iowa State University, Manhattan, KS, and Ames, IA. *OTA Preliminary Assessment of Biological Control: Current Research*

P.J. Nowak, University of Wisconsin, Madison, WI. *Educating Users About Biologically Base Methods of Pest Control*

J. Randall and M. Pitcairn, The Nature Conservancy, Galt, CA, and the Biological Control Program, California Department of Food and Agriculture, Sacramento, CA. *Biologically Based Technologies For Pest Control in Natural Areas and Other Wildlands*

K. Reichelderfer Smith, Henry A. Wallace Institute for Alternative Agriculture, Hyattsville, MD. *Biological Pest Control: An Assessment of Current Markets and Market Potential*

D. Simberloff and P. Stiling, Florida State University, Tallahassee, FL, and University of Southern Florida, Tampa, FL. *Biological Pest Control: Potential Hazards*

R.G. Van Driesche, T.G. Bellows, O. Minkenburg, M. Adang, B. Federici, C. McCoy, J. Maddox, H. Kaya, J. Lewis, R. Cardé, and E.S. Krafsur, University of Massachusetts, Amherst, MA (Van Driesche, only). *Report on Biological Control of Invertebrate Pests of Forestry and Agriculture*

A.K. Watson, McGill University, Quebec, Canada. *Biologically Based Technologies For Pest Control: Agricultural Weeds*

D. Zilberman and C. Yarkin, University of California, Berkeley, CA. *The Economics of Development and Adoption of Pest Control Products With Emphasis on Biologically Based Controls*

WORKSHOPS:

Preliminary Planning Workshop, December 20–21, 1993

Participants:

Mary Louise Flint
California Statewide IPM Program
Davis, CA

John Houghton
Houghton Associates
St. Louis, MO

James Nechols
Kansas State University
Manhattan, KS

Katherine Reichelderfer Smith
Henry A. Wallace Institute for Alternative Agriculture
Greenbelt, MD

Daniel Simberloff
Florida State University
Tallahassee, FL

Role of the Private Sector in Biologically Based Technologies for Pest Control, September 20–21, 1994

Participants:

Jake Blehm
Buena Biosystems, Inc.
Ventura, CA

Robert Cibulsky
Abbott Laboratories
North Chicago, IL

Stephen Dumford
Ciba-Geigy Corporation
Greensboro, NC

Janice Gillespie
Technology Concep, Inc.
Bend, OR

Louie T. Hargett
Sandoz Agro, Inc.
Des Plains, IL

William Heilman
American Cyanamid Co.
Princeton, NJ

Paul Koppert
Koppert B.V.
The Netherlands

Pamela G. Marrone
Novo Nordisk Entotech, Inc.
Davis, CA

John McIntyre
Ecogen, Inc.
Doylestown, PA

Sinthya Penn
Beneficial Insectary
Oak Run, CA

Edwin Quattlebaum
Biosys
Palo Alto, CA

Todd Taylor
Crop Genetics International
Columbia, MD

Appendix D: Reviewers D

REVIEWERS OF THE FULL ASSESSMENT

Janet Anderson
U.S. Environmental Protection Agency
Alexandria, VA

David Andow
University of Minnesota
St. Paul, MN

Paul A. Backman
Auburn University
Auburn, AL

Ring T. Cardé
University of Massachusetts
Amherst, MA

Robert J. Cibulsky
Abbott Laboratories
North Chicago, IL

Ernest S. Delfosse
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Hyattsville, MD

Willard A. Dickerson
North Carolina Department of Agriculture
Raleigh, NC

Patricia J. Durana
Office of Technology Assessment
Environment Program

Roger C. Funk
The Davey Tree Expert Company
Kent, OH

Harry J. Griffiths
Entomological Services Inc.
Corona, CA

Judith A. Hansen
Cape May County Mosquito Extermination Commission
Cape May, NJ

Dennis L. Isaacson
Oregon Department of Agriculture
Salem, OR

Tobi L.Jones
California Environmental Protection Agency
Sacramento, CA

Peter M. Kareiva
University of Washington
Seattle, WA

Allen E. Knutson
Texas Agricultural Extension Service
College Station, TX

David W. Miller
EcoScience Corp.
Northborough, MA

Timothy L. Nance
Gro Technics Consulting
Naples, FL

Katherine Reichelderfer Smith
Henry A. Wallace Institute for Alternative Agriculture
Greenbelt, MD

David O. TeBeest
University of Arkansas
Fayetteville, AR

Jeffrey K. Waage
International Institute of Biological Control
Ascot, Berks, UK

Michael E. Wetzstein
University of Georgia
Athens, GA

David M. Whitacre
Sandoz Agro, Inc.
Des Plaines, IL

REVIEWERS OF A PORTION OF THE ASSESSMENT OR BACKGROUND REPORT

Janet Anderson
U.S. Environmental Protection Agency
Alexandria, VA

David Andow
University of Minnesota
St. Paul, MN

Gregory H. Aplet
The Wilderness Society
Washington, DC

William Beck
Novo Nordisk Bioindustrials, Inc.
Danbury, CT

Fred Betz
Jellinek, Schwartz & Connolly, Inc.
Washington, DC

Tom Bewick
University of Florida
Gainesville, FL

Larry G. Bezark
California Department of Food and Agriculture
Sacramento, CA

Jake Blehm
Buena Biosystems
Ventura, CA

Neal J. Briggi
Novo Nordisk Bioindustrials, Inc.
Danbury, CT

Ring T. Cardé
University of Massachusetts
Amherst, MA

Gerald A. Carlson
North Carolina State University
Raleigh, NC

James R. Cate
Cooperative State Research Service
U.S. Department of Agriculture
Washington, DC

Robert J. Cibulsky
Abbott Laboratories
North Chicago, IL

Whitney Cranshaw
Colorado State University
Fort Collins, CO

James Cullen
CSIRO
Canberra, Australia

Donald L. Dahlsten
University of California
Berkeley, CA

Ernest S. Delfosse
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Hyattsville, MD

Willard A. Dickerson
North Carolina Department of Agriculture
Raleigh, NC

L.E. Ehler
University of California
Davis, CA

Raymond Eid
Wilmington, DE

David A. Fischhoff
Monsanto Company
St. Louis, MO

Mike Fitzner
Cooperative State Research, Extension, and Education Service
U.S. Department of Agriculture
Washington, DC

Mary Louise Flint
University of California
Davis, CA

Lyle B. Forer
Pennsylvania Department of Agriculture
Harrisburg, PA

J. Howard Frank
University of Florida
Gainesville, FL

James R. Fuxa
Louisiana State University
Baton Rouge, LA

Ramon Georgis
Biosys
Palo Alto, CA

Harry J. Griffiths
Entomological Services Inc.
Corona, CA

Philip J. Hamman
Texas A&M University
Austin, TX

Judith A. Hansen
Cape May County Mosquito Extermination Commission
Cape May, NJ

Louie T. Hargett
Sandoz Agro, Inc.
Des Plaines, IL

Gary Harman
Cornell University
Ithaca, NY

Peter Harris
Agriculture and Agri-Food Canada
Lethbridge, Alberta, Canada

William P. Heilman
American Cyanimid Company
Princeton, NJ

Michael Hoffman
Cornell University
Ithaca, NY

John M. Houghton
J.M. Houghton and Associates
St. Louis, MO

Francis G. Howarth
Bishop Museum
Honolulu, HI

Charles R. Howell
Agricultural Research Service
College Station, TX

Marjorie A. Hoy
Unversity of Florida
Gainesville, FL

John W. Impson
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
Washington, DC

Dennis L. Isaacson
Oregon Department of Agriculture
Salem, OR

Barry Jacobson
U.S. Department of Agriculture
Washington, DC

Wojciech Janisiewicz
Agricultural Research Service
U.S. Department of Agriculture
Kernsville, WV

Tobi Jones
California Environmental Protection Agency
Sacramento, CA

Erik D. Kiviat
Husonia
Annandale, NY

W. Klassen
University of Florida
Homestead, FL

Allen E. Knutson
Texas Agricultural Extension Service
College Station, TX

Karen Koltes
National Biological Service
Washington, DC

James L. Krysan
Agricultural Research Service
U.S. Department of Agriculture
Beltsville, MD

P.J. Kuch
Agriculture Policy Branch
U.S. Environmental Protection Agency
Washington, DC

Armand Kuris
University of California
Santa Barbara, CA

Norman Leppla
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Beltsville, MD

Anne R. Leslie
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, DC

Hiram Li
Oregon State University
Corvallis, OR

Jeffrey A. Lockwood
University of Wyoming
Laramie, WY

Michelle C. Marra
North Carolina State University
Raleigh, NC

Pamela G. Marrone
Novo Nordisk Entotech, Inc.
Davis, CA

Arthur H. Mason
Minnesota Department of Agriculture
St. Paul, MN

Peter McEvoy
Oregon State University
Corvallis, OR

John McIntyre
Doylestown, PA

Robert L. Metcalf
University of California
Riverside, CA

William Metterhouse
Cream Ridge, NJ

Dale Meyerdirk
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Beltsville, MD

David W. Miller
EcoScience Corp.
Northborough, MA

James R. Nechols
Kansas State University
Manhattan, KS

John J. Obrycki
Iowa State University
Ames, IA

Eldon E. Ortman
Purdue University
West Lafayette, IN

Sinthya Penn
Beneficial Insectary
Oak Run, CA

Carol G. Peterson
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC

P.C. Quimby, Jr.
Agricultural Research Service
U.S. Department of Agriculture
Bozeman, MT

John Randall
The Nature Conservancy
Davis, CA

Tom Roberts
Bureau of Land Management
U.S. Department of the Interior
Washington, DC

Sally J. Rockey
Cooperative State Research, Education, and Extension Service
U.S. Department of Agriculture
Washington, DC

Matthew Royer
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Beltsville, MD

J. Thomas Schmidt
Novo Nordisk Bioindustrials, Inc.
Danbury, CT

Esther Schneider
National Biological Service
U.S. Department of the Interior
Washington, DC

Milton N. Schroth
University of California
Berkeley, CA

Jeffrey G. Scott
Cornell University
Ithaca, NY

Daniel Simberloff
Florida State University
Tallahassee, FL

R.D. Sjoblad
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC

Robert D. Sjogren
Meridian Precision Release Technologies
Minneapolis, MN

Katherine Reichelderfer Smith
Henry A. Wallace Institute for Alternative Agriculture
Greenbelt, MD

Judith B. St. John
Agricultural Research Service
U.S. Department of Agriculture
Beltsville, MD

David O. TeBeest
University of Arkansas
Fayetteville, AR

Jay Troxel
Fish and Wildlife Management Assistance
U.S. Fish and Wildlife Service
Arlington, VA

Charles E. Turner
Agricultural Research Service
U.S. Department of Agriculture
Albany, CA

Roy G. Van Driesche
University of Massachusetts
Amherst, MA

Mike Wallace
Texas Pest Management Association
Austin, TX

William S. Wallace
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Washington, DC

Lewis Waters
Bureau of Land Management
U.S. Department of the Interior
Washington, DC

Pat W. Weddle
Weddle, Hansen and Associates, Inc.
Placerville, CA

David M. Whitacre
Sandoz Agro, Inc.
Des Plaines, IL

H. Alan Wood
Boyce Thompson Institute for Plant Research, Inc.
Ithaca, NY

References

1. "Adulterated Food" (342(a)(3)), *Title 21 (Food and Drugs 1 to 800) U.S. Code,* 1972 ed.
2. "Agricultural Experiment Stations" (361(a) to 361(i)), *Title 7 (Agriculture 281 to 1099) U.S. Code,* 1980 ed.
3. "Agricultural Research Program" (450(i)), *Title 7 (Agriculture: 281 to 1099) U.S. Code,* 1980 ed.
4. Aldhous, P., "Malaria: Focus on Mosquito Genes," *Science* 261(121):646–648, July 30, 1993.
5. Alms, M.J., National Alliance of Independent Crop Consultants and Blue Earth Agronomics, Inc., Lake Crystal, MN, personal communication, August 15, 1995.
6. Alms, M.J., "Challenges for IPM in the Future: An Independent Crop Consultant's Perspective," *Second National Integrated Pest Management Symposium/Workshop—Proceedings* (Raleigh, NC: University Graphics, 1994).
7. American Society of Agronomy, *National Certified Crop Advisor—Performance Objectives,* 1995.
8. Andow, D., Associate Professor, Department of Entomology, University of Minnesota, St. Paul, MN, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 14, 1995.
9. Andow, D., Associate Professor, Department of Entomology, University of Minnesota, St. Paul, MN, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, March 9, 1995.
10. Aplet, G., Forest Ecologist, The Wilderness Society, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, June 21, 1994.
11. Association of Natural Bio-control Producers, letter to U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC, March 7, 1995.
12. Association of Natural Bio-control Producers, "Draft Policy Statement on Quality Control," 1995.
13. Baker, B., California Certified Organic Farmers,CA, letter to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Riverdale, MD, May 1995.
14. Banfield, M.G., *An Analysis of the Semiochemical Industry in North America,* unpublished master's thesis, 1991.
15. Barbosa, P., and Braxton, S., "A Proposed Definition of Biological Control and Its Relationship to Related Control Approaches" *Pest Management: Biologically Based Technologies,* R.D. Lumsden and J.L. Vaughn (eds.) (Washington, DC: American Chemical Society, 1993).
16. Barnes, R., Executive Vice President, American Society of Agronomy, Madison, WI, personal communication, August 15, 1995.
17. Bassari, J., Vice President, Rincon Vitova, Ventura, CA, personal communication,1995.
18. Batkin, T., Manager, California Citrus Research Board, Visalia, CA, personal communication, August 16, 1995.
19. Beard, A., Acting Head, Emergency Response and Minor Use Section, U.S. Environmental Protection Agency, Washington, DC, personal communication, May 5, 1995.

20. Beard, J.D., “Bug Detectives Crack the Tough Cases,” *Science* 254(38):1580–1582, December 13, 1991.
21. Beasley, C., Executive Vice President, Florida Citrus Processors’ Association, Winter Haven, FL, personal communication, August 16, 1995.
22. Becker, J.O., and Schwinn, F.J., “Control of Soil-Bourne Pathogens With Living Bacteria and Fungi: Status and Outlook,” *Pesticide Science* 37:355–363, 1993.
23. Bedoukian, R., President, American Semiochemicals Association, Danbury, CT, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 15, 1994.
24. Bellows, T., Professor, Department of Entomology, University of California, Riverside, CA, personal communication, August 1, 1993.
25. Benbrook, C.M., and Marquart, D.J., *Challenge and Change: A Progressive Approach to Pesticide Regulation in California,* contractor report prepared for the California Environmental Protection Agency, Department of Pesticide Regulation (Sacramento, CA: April 1993).
26. Bengston, D., Agricultural Commissioner, County of Mendocino, Department of Agriculture, Ukiah, CA, letter to Richard Rominger, Deputy Secretary of Agriculture, U.S. Department of Agriculture, Washington, DC, February 21, 1995.
27. Birdsall, S.L. and Ritter D., Imperial Valley Agricultural Commissioner and Whitefly Program Coordinator, unpublished report on the economic impact of the silverleaf whitefly in Imperial Valley, Imperial Valley, CA, 1994.
28. Blehm, J., President, Buena Biosystems, Ventura, CA, personal communications, August 3, 1993, October 13, 1994, and May 9, 1995.
29. Bolkan, H.A., “Campbell Soup Company Integrated Pest Management,” *IPM Monitor,* Summer 1994.
30. Bolkan, H.A., and Reinert, W.R., “Developing and Implementing IPM Strategies to Assist Farmers: An Industry Approach,” *Plant Disease* 78(6): 545–550, June 1994.
31. Bonanno, A.R., “Grower Needs and Involvement in IPM,” *Second National Integrated Pest Management Symposium/Workshop Proceedings* (Las Vegas, NV: ESCOP Pest Management Strategies Subcommittee, ES IPM Task Force, April 19–22, 1994).
32. Bridges, D.C. (ed.), *Crop Loses Due to Weeds in the United States—1992* (Champaign, IL: Weed Society of America, 1992).
33. Briggi, N., Director of Marketing, Novo Nordisk America, Davis, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 22, 1994.
34. Brooks, H., et al., Acting Associate Administrator, Agricultural Research Service, U.S. Department of Agriculture, Washington, DC, “Biologically Based Pest Control Products,” unpublished paper prepared for H. Brooks by industry representatives for a meeting on cooperation between ARS and the pest control industry and on ARS support of related APHIS activities, Washington, DC, August 8, 1994.
35. Browning, H., State Agricultural Experiment Station, University of Florida, Gainesville, FL, personal communication, August 1995.
36. Bunn, D., et al., “Consumer Acceptance of Imperfect Produce,” *The Journal of Consumer Affairs* 24(2):268–279, 1990.
37. Burt, M., Executive Officer, Association of Natural Bio-control Producers, personal communication, July 21, 1995.
37A.California Department of Food and Agriculture, Organic Program, “Producing, Handling, and Processing Organic Products in California,” Sacramento, CA, 1994.
38. Campbell Soup Company, Integrated Pest Management Research and Implementation, “Economic Profitability and Environmentally Compatible Alternatives,” *Products and Progress Report,* 1994–1995.

39. Cardé, R., Professor, Department of Entomology, University of Massachusetts, Amherst, MA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 16, 1995.
40. Cardé, R.T., Professor, Department of Entomology, University of Massachusetts, Amherst, MA, remarks made at the Advisory Panel meeting on Biologically Based Technologies for Pest Control, Office of Technology Assessment, U.S. Congress, Washington, DC, July 13, 1995.
41. Cardé, R., and Minks, A., "Control of Moth Pests By Mating Disruption: Successes and Constraints," *Annual Review of Entomology* 40:559–585, 1995.
42. Cardineau, G.A., Director, Molecular Biology, Mycogen Corporation, San Diego, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 7, 1995.
43. Carruthers, R.I. and Onsanger, J.A., "Perspective on the Use of Exotic Natural Enemies for Biological Control of Pest Grasshoppers (Orthoptera: Acrididae)," *Environmental Entomology* 22(5): 885–903, October 1993.
44. Cate, J.R., and Hinkle, M.K., *Integrated Pest Management: The Path of a Paradigm*, National Audubon Society (Alexandria, VA: Weadon Printing, Inc., July 1994).
45. Centre For Agriculture and Biosciences International, *Using Biodiversity to Protect Biodiversity: Biological Control, Conservation and the Biodiversity Convention* (Wallingford, Oxon, UK: 1994).
46. Charudattan, R., and Browning, H.W. (eds.), *Regulations and Guidelines: Critical Issues in Biological Control—Proceedings of a USDA/CSRS National Workshop* (Gainesville, FL: University of Florida, 1992).
47. Chow, F., Supervisory Chemist, Biopesticides and Pollution Prevention Division, U.S. Environmental Protection Agency, Washington, DC, memorandum to the Office Technology Assessment, U.S. Congress, Washington, DC, May 19, 1995.
48. Ciba-Geigy Corporation, "All About Agree," advertising brochure, Greensboro, NC, 1995.
49. Cibulsky, R., Manager, Licensing/Business Development, Abbott Laboratories, North Chicago, IL, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 18, 1995.
50. Cofrancesco, A., Research Entomologist, U.S. Army Corps of Engineers, Vicksburg, MS, personal communication, May 12, 1995.
51. Cofrancesco, A., Research Entomologist, U.S. Army Corps of Engineers, Vicksburg, MS, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 1995.
52. Community Alliance with Family Farmers Foundation, "BIOS: A New Project Promoting Biological Almond Farming," Davis, CA, 1995.
53. "Company News," *Biotech Reporter* 12(1):8, January 1995.
54. "Control and Eradication of Plant Pests" (147), *Title 7 (Agriculture: 1 to 280) U.S. Code*, 1980 ed.
55. Cooper, K., "Effects of Pesticides on Wildlife," *Handbook of Pesticide Toxicology Volume I*, W.J. Hayes Jr. and E.R. Laws Jr. (eds.) (San Diego, CA: Academic Press, Inc., 1991).
56. Coulson, J.R., "The TAG: Development Functions, Procedures, and Problems," *Regulation and Guidelines: Critical Issues in Biological Control: Proceedings of a USDA/CSRS National Workshop*, R. Charudattan and H.W. Browning (eds.) (Gainesville, FL: University of Florida, 1992).
57. Coulson, J.R., and Soper, R.S., "Protocols For the Introduction of Biological Control Agents in the U.S.," *Plant Protection and Quarantine, Volume III*, R.P. Kahn (ed.) (Boca Raton, FL: CRC Press, Inc., 1989).
58. Coulson, J.R., et al. (eds.), *110 Years of Biological Control Research and Development in the United States Department of Agriculture, 1883–1993* (In press).

59. Coxwell, M., Production Manager, NTGargiulo L.P., Watsonville, CA, personal communication, August 3, 1995.

59A. Cranshaw, W., Professor and Extension Entomologist, Department of Entomology, Colorado State University, Fort Collins, CO, personal communication, August 1994.

60. Cranshaw, W., Department of Entomology, Colorado State University, Fort Collins, CO, "Biologically Based Technologies For Pest Control: Urban and Suburban Environments," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.

61. Croft, B.A., *Arthropod Biological Control Agents and Pesticides* (New York, NY: John Wiley and Sons, 1990).

62. Croft, B.A., Professor, Department of Entomology, Oregon State University, Corvallis, OR, personal communication, May 1995.

63. Cullen, J.M., and Bellas, T.E. Division of Entomology, CSIRO, Canberra, Australia, "Australian Laws, Policies and Programs Related to Biologically Based Technologies For Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1995.

64. Curtis, R.K., Manager, Integrated Pest Management Programs, Campbell Soup Company, Sacramento, CA, personal communications, June 26, 1995; June 27, 1995 and August 18, 1995.

65. Curtis, R.K., Campbell Soup Company, Sacramento CA, letter to Edurdo Martinez Curiel, Consul of Mexico, February 1, 1994.

66. Dahlsten, D., Professor, Division of Biological Control, University of California, Berkeley, CA, personal communication, August 9, 1993.

67. Dapsis, L., Senior Agricultural Scientist, Ocean Spray Cranberries, Inc., Lakeville-Middleboro, MA, speech to the Entomological Society of America's workshop on Natural Enemies, December 1993.

68. Davies, W.P., "Prospects For Pest Resistance to Pesticides," *Pest Management and the Environment in 2000*, A. Aziz, S.A. Kadir and H.S. Barlow (eds.) (Wallingford, Oxon, UK: CAB International, 1992).

69. Debach, P. (ed.), *Biological Control of Insect Pests and Weeds* (New York, NY: Reinhold Publishing Corporation, 1964).

70. Defazio, S., Owner, Praxis Integrated Biological Cybernetics, Allegan, MI, personal communication, December 12, 1994.

71. "Definitions" (150aa et seq.), *Title 7 (Agriculture 281 to 1099) U.S. Code*, 1980 ed.

72. Delfosse, E., Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.

73. Delfosse, E., Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 18, 1995.

74. Delfosse, E., Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.

75. Delfosse, E., Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, July 18, 1995 and August 3, 1995.

76. Delfosse, E., Director, National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, unaddressed letter, July 11, 1995.

77. Denholm, I., and Rowland, M.W., "Tactics For Managing Pesticide Resistance in Arthropods: Theory and Practice," *Annual Review of Entomology* 37:91–112, 1992.

78. Dickerson, W., Plant Pest Administrator, North Carolina Department of Agriculture, Raleigh, NC, personal communication, July 1995, and August 1995.
79. Dumford, S.W., Director, New Technology and Basic Research, Ciba-Geigy Crop Protection, Ciba-Geigy Corporation, Greensboro, NC, personal communication, February 13 and August 3, 1995.
80. Dumford, S.W., "IPM and the Plant Pest Control Business," *Second National Integrated Pest Management Symposium/Workshop Proceedings* (Las Vegas, NV: ESCOP Pest Management Strategies Subcommittee, ES IPM Task Force, April 19–22, 1994).
81. Eckert, J., "Role of Chemical Fungicides and Biological Agents in Postharvest Disease Control," *Biological Control of Postharvest Diseases of Fruits and Vegetables—Workshop Proceedings*, (Shepherdstown, WV: U.S. Department of Agriculture, Agricultural Research Service, June 1991).
82. Ehler, L.E., "Revitalizing Biological Control," *Issues in Science and Technology* :91–96, Fall 1990.
83. Elkins, R., Farm Advisor, CA, personal communication, August 18, 1995.
84. Elworth, L., Special Assistant for Pesticide Policy, U.S. Department of Agriculture, Washington, DC, personal communication, May 10, 1995.
85. "Engineered to Be Deadly," *Bioscience* 43(10):674, 1995.
86. Engle, T., Budget and Accounting Office, Animal and Plant Health and Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 21, 1995.
87. Entomological Society of America, *Entomological Society of America Newsletter*, October 1994.
88. Environmental Section, *Biotech Reporter* 11(8):10, August 1994.
89. Environmental Law Institute, *Using Pollution Control Authorities to Protect Threatened and Endangered Species and Reduce Ecological Risk*, unpublished contractor report prepared for the U.S. Environmental Protection Agency, Washington, DC, 1993.
90. Experiment Station Committee on Organization and Policy, *Opportunities to Meet Changing Needs: Research on Food, Agriculture, and Natural Resources* (Dallas, TX: January 1994).
91. Faust, R.M., National Program Leader, Agricultural Research Service, U.S. Department of Agriculture, Washington, DC, letter to participants in Area-Wide Pest Management Systems Meeting, November 17, 1993.
92. Faxon, G.R., Manager, Processing Strawberry Advisory Board, personal communication, August 16, 1995.
93. "Federal Advisory Committee Act" (1 to 15), *Title 5 (Government Organizations and Employees 8501 to end) U.S. Code*
94. "Fetzer Vineyards," *Tomorrow*, Global Environment Business, p. 12, November 1994.
95. "First Engineered Microbe to Be Field Tested in California in 7 Years," *Biotech Reporter* 11(11):3–4, November 1994.
96. Fischhoff, D.A., Manager, Technology Assessment, Monsanto Corporation, St. Louis, MO, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.
97. Fitzner, M.S., "The Role of Education in the Transfer of Biological Control Technologies," *American Chemical Society* 1993.
98. Fitzner, M.S. and Kopp, D.D., National Program Leader for Integrated Pest Management (MF), National Program Leader Pesticide Impact Assessment (DK), Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, remarks at a briefing for the Office of Technology Assessment, U.S. Congress, Washington, DC, April 25, 1995.
99. Fleishman-Hillard, unpublished survey prepared for Novo Nordisk Entotech, Davis, CA, 1994.

100. Flint, M.L., University of California, Davis, CA, "Biological Pest Control: Technology and Research Needs," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1993.
101. Flint, M.L., et al., "Potential Pesticide Losses in California and Identification of Alternative Pest Management Practices in Broccoli," 38(2), Summer 1992.
102. Flint, M.L., and Klonsky, K., "IPM Information Delivery to Pest Control Advisors," *California Agriculture,* March–April 1989.
103. Flint, M.L., et al., *Annual Report, University of California Statewide IPM Project* (Davis, CA: University of California, September 1993).
104. "Food Additives—Unsafe Food Additives; Exception For Conformity With Exemption For Regulation" (348), *Title 21 (Food and Drug: 1 to 180) U.S. Code,* 1972 ed.
105. "Food, Agriculture, Conservation, and Trade Act of 1990" (136a), *Title 21 (Food and Drug: 1 to 180) U.S. Code*.
106. Forster, R., Biologische Bundesanstalt Fur Land-Und Forstwirtschaft, Fachgruppe Biologische Mittelprufung, Braunschweig, Germany, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 2, 1995.
107. Francis, E.Z., Director, Toxics/Pesticides and Water Staff, Office of Research and Science Integration, U.S. Environmental Protection Agency, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, June 9, 1995.
108. Frank, J.H., Professor, Department of Entomology and Nematology, University of Florida, Gainesville, FL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, January 30, 1995.
109. Friederici, P., "The Alien Saltcedar," *American Forests* 47, January/February 1995.
110. Funk, R.C., Vice President of Human and Technical Resources, Davey Tree Expert Company, Kent, OH, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 8, 1994.
111. Gelertner, W.D., "Targeting Insecticide-Resistant Markets: New Developments in Microbial-Based Products," *Managing Resistance to Agrochemicals: From Fundamental Research to Practical Strategies,* M.B. Green, H.M. Lebaron, and W.K. Moberg (eds.) (Washington, DC: American Chemical Society, 1990).
112. Georghiou, G., Department of Entomology, University of California, Riverside, CA, "Insecticide Resistance in the United States," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.
113. Georgis, R., and Manweiler, S.A., "Entomopathogenic Nematodes: A Developing Biological Control Technology," *Agricultural Zoology Review* 6:63–94, 1994.
114. Gibbons, D.M., The EOP Foundation, Inc., Washington, DC, "Report on the Role of the USDA in Biologically Based Pest Control Research," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1995.
115. GIC Agricultural Group, *BioInfo* 2(16), November 21, 1994.
116. Gillespie, J.M., Vice President, Technology Concep, Inc., Bend, OR, personal communications, June 1 and August 8, 1995.
117. Ginsberg, H.S., "Conservation of Invertebrates in U.S. National Parks," *American Entomologist* 40(2):76–78, 1994.
118. Ginsberg, H.S., *Ecology and Environmental Management of Lyme Disease* (New Brunswick, NJ: Rutgers University Press, 1993).
119. Glosser, et al. U.S. Department of Agriculture, Washington, DC, letter to J.R. Cate, N. Leppla, and R. Soper establishing the Interagency Biological Control Coordinating Committee, August 14, 1990.
120. Glynn, C.J., et al., "Integrated Pest Management and Conservation Behaviors,"

Journal of Soil and Water Conservation: 25–29, January–February 1995.

121. Goldberg, J., Congressional Science Fellow, U.S. House of Representatives Committee on Agriculture, personal communication, June 25, 1995.

121A. Goldhammer, A., Director of Technical Affairs, BIO, Washington, DC, personal communication, December 15, 1994.

122. Goodman, B., "Research Community Swats Grasshopper Control Trial," *Science,* 260:887, May 14, 1993.

123. Greathead, D.J., and Greathead, A.H., "Biological Control of Insect Pests By Insect Parasitoids and Predators: The Biocat Database," *Biocontrol News and Information* 13(4):61N–68N, 1992.

124. Green, M., et al., "Public Health Implications of the Microbial Pesticide *Bacillus thuringiensis*: An Epidemiological Study, Oregon, 1985–86," *American Journal of Public Health* 80(7): 848–852, July 1990.

125. Green M.B., LeBaron, H.M., and Moberg, W.K. (eds.), *Managing Resistance to Agrochemicals: From Fundamental Research to Practical Strategies* (Washington, DC: American Chemical Society, 1990).

126. Green Technologies For Pest Control, unpublished proceedings of the Avoidance Technologies: Environmentally Conscious Engineering Conference held by the Private Enterprise-Government Interactions Task Force, Arlington, VA, September 7–9, 1994.

127. Grieshop, J.I., and Pence, R.A., "Research Results: Statewide IPM's First 10 Years," *California Agriculture* 44(5), September–October 1990.

128. Griffiths, H.J., Chairman, Entomological Services, Inc., Corona, CA, remarks at the meeting of the Office of Technology Assessment's Advisory Panel, Washington, DC, July 13, 1995.

129. Grisham, J., "Attack of the Fire Ant," *Bioscience* 44(9):587–590, October 1994.

130. Guest, R.T., et al., "Role of the IR-4 in the Registration of Biological Control Agents," *Regulations and Guidelines: Critical Issues in Biological Control,* R. Charudattan and H.W. Browning (eds.) (Gainesville, FL: Institute of Food and Agricultural Science, University of Florida, 1992).

131. Guither, H.D., et al., *U.S. Farmers' Preferences For Agricultural and Food Policy After 1995* (Urbana, IL: North Central Regional Extension Publication, November 1994).

132. Hall, M.J.R., and Beesley, W.N., "The New World Screwworm Fly in North Africa," *Pesticide Outlook* 1(2):34–37, 1990.

133. Haney, P.B., et al., *Reducing Insecticide Use and Energy Costs in Citrus Pest Management* (Davis, CA: University of California Statewide IPM Project, Publication 15, 1992).

134. Hansen, J.A., Superintendent, Cape May County Mosquito Extermination Commission, Cape May, NJ, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 18, 1995.

135. Hargett, L.T., Director, Product Development, Sandoz Agro, Inc., Des Plaines, IL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 23, 1995.

136. Hargett, L.T., Director, Product Development, Sandoz Agro, Inc., Des Plaines, IL, personal communication, May 3, 1995.

137. Harold, M., Plant Manager, American Home Food Products, CA, personal communication, August 17, 1995.

138. Harman, G.E., and Hayes, C.K. Departments of Horticultural Sciences and Plant Pathology, Cornell University, Ithaca, NY, "Biologically Based Technologies For Pest Control: Pathogens That Are Pests of Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October 1994.

138A. Harmen, G.E., Department of Plant Pathology, Cornell University, Ithaca, NY, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.

139. Hasan, S., and Delfosse, E., "Host-Specificity of *Uromyces heliotropii*, a Fungal Agent For the Biological Control of Common *Heliotrope* (*Heliotropium europaeum*) in Australia," *Annals of Applied Biology* 121:697–705, 1992.
140. Hasan, S., and Delfosse, E., "Susceptibility of Australian Native, *Helioptropii crispatum*, to the Rust Fungus *Uromyces heliotropii*, Introduced to Control Common Heliotrope, *Heliotropium europaeum*," *New Phytologist*, In press.
141. Hawkins, L., Senior Environmental Research Scientist, Department of Pesticide Regulation, Environmental Monitoring and Pest Management, California Environmental Protection Agency, Elksgrove, CA, personal communication, June 23, 1995.
142. Hawksworth, D.L., and Ritchie, J.M., *Biodiversity and Biosystematic Priorities: Microorganisms and Invertebrates* (Wallingford, Oxon, UK:CAB International, 1993).
143. Hennessey, R., Entomologist, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, August 4, 1995.
144. Henstridge, A.P., Deputy Director, Legislative and Public Affairs, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC, personal communication, May 10, 1995 and August 3, 1995.
145. Hileman, B., "Environmental Estrogens Linked to Reproductive Abnormalities, Cancer," *Chemical and Engineering News* 75(5):19–23, July 31, 1994.
146. Holmes, R., "The Perils of Planting Pesticides," *New Scientist* 34, August 28, 1993.
147. Hommel, C., Consumer Safety Officer, Food and Drug Administration, U.S. Department of Health and Human Services, Rockville, MD, personal communication, January 9, 1995.
148. Hommel, C., Consumer Safety Officer, Food and Drug Administration, U.S. Department of Health and Human Services, Rockville, MD, letter to the Honorable Peter Hoekstra, U.S. House of Representatives, Muskegon, MI, January 5, 1995.
149. Houghton, J.M., Houghton and Associates, St. Louis, MO, "Biologically Based Technologies For Pest Control: Workshop on the Role of the Private Sector," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, September 20–21, 1994.
150. Houghton, J., Houghton and Associates, St. Louis, MO, "The View of Biological Pest Control From the Pesticide Industry," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1993.
151. Howarth, F.G., Entomologist, Bishop Museum, Honolulu, HI, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 22, 1994.
152. Hoy, M.A., "Genetic Engineering of Predators and Parasitoids For Pesticide Resistance," *Proceedings of the SCI Symposium Resistance '91: Achievements and Developments in Combating Pesticide Resistance*, I. Denholm and D.W. Devonshire (eds.) (NY: Elsevier Applied Science, July 15–17, 1991).
153. Huffaker, C.B., and Messenger, P.S. (eds.), *Theory and Practice of Biological Control* (New York, NY: Academic Press, 1976).
154. Huffman, W.E., and Evenson, R.E., *Science For Agriculture: A Long-Term Perspective* (Ames, IA: Iowa State University Press, 1993).
155. Hunter, C.D., *Suppliers of Beneficial Organisms in North America* (Sacramento, CA: California Environmental Protection Agency, 1994).
156. Hutton, P., Biologist, Biopesticides and Pollution Prevention Division, U.S. Environmental Protection Agency, Washington, DC, personal communication, July 27, 1995 and August 14, 1995.

157. International Organization For Biological and Integrated Control of Noxious Animals and Plants, *Symposium on Quality Control in Natural Enemy Production*, Ascot Berks, UK (MontFavet, France: Office of the General Secretariat, 1992).

158. Isaacson, D., Program Director, Noxious Weed Control Section, Oregon Department of Agriculture, Salem, OR, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 17, 1994.

159. Isaacson, D., Program Director, Noxious Weed Control Section, Oregon Department of Agriculture, Salem, OR, personal communication, July 18, 1995.

160. Jacobsen, B., USDA IPM Coordinator, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 17, 1995.

161. Janisiewiczs, J., Group Coordinator, North Atlantic Area Appalachian Fruit Research Station, Agricultural Research Service, U.S. Department of Agriculture, Kernsville, WV, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, January 9, 1995.

162. Jetter, K., and Klonsky, K., Department of Economics, University of California, Davis, CA, "Economic Assessment of the Ash Whitefly (*Siphoninus phillyreae)* Biological Control Program," unpublished contractor report prepared for the California Department of Food and Agriculture, Sacramento, CA, June 30, 1994.

163. Johnson, M.W., and Tabashnik, B.E., "Laboratory Selection For Pesticide Resistance in Natural Enemies," *Applications of Genetics to Arthropods of Biological Control Significance,* K. Narang (ed.) (Boca Raton, FL: CRC Press, 1993).

164. Johnson, S.L., Acting Director, Registration Division, U.S. Environmental Protection Agency, Washington, DC, letter to State Pesticide Agencies, Federal Agencies and EPA Pesticide Regional Directors, December 23, 1993.

165. Jones, A.H., National Alliance of Independent Crop Consultants, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 26, 1995.

166. Jones, T.L., Special Assistant to the Director, Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA, personal communication, June 23, 1995.

167. Jones, T.L., Special Assistant, Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 19, 1995.

168. Kareiva, P., Professor, Department of Zoology, University of Washington, Seattle, WA, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 1995.

169. Kareiva, P., Professor, Department of Zoology, University of Washington, Seattle, WA, personal communication, July 13, 1995.

170. Kareiva, P., Professor, Department of Zoology, University of Washington, Seattle, WA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 20, 1994.

171. Kauffman, W.C., and Nechols, J.R. (eds.) *Selection Criteria and Ecological Consequences of Importing Natural Enemies—Proceedings*, 1992.

172. Kim, J., Ginzburg, L.R., and Dykhuizen, D.E., "Quantifying the Risks of Invasion By Genetically Engineered Organisms," *Assessing Ecological Risks of Biotechnology,* L.R. Ginzburg (Boston, MA: Butterworth-Heinemann, 1991).

173. King, E.G., "Augmentation of Parasites and Predators For Suppression of Arthropod Pests," *Pest Management: Biologically Based Technologies,* R.D. Lumsden and

J.L. Vaughn (eds.) (Washington, DC:American Chemical Society, 1993).

174. Kingsley, P.C., et al., "Alfalfa Weevil (Coleoptera: Curculionidae) Biological Control: Spreading the Benefits," *Environmental Entomology* 22:1234–1250, December 1993.

175. Kirsh, P. and Lingren, B., "Commercial Advancement in Pheromone Related Monitoring Control Technology," *Proceedings of the Working Group, Use of Pheromones and Other Semiochemicals in Integrated Control, Chatham, UK*, International Organization for Biological and Integrated Control of Noxious Animals and Plants (Montfavet, France: General Secretariat IOBC/SROP, 1993).

176. Klassen, W., Center Director and Professor, Institute of Food and Agricultural Sciences, Tropical Research and Education Center, University of Florida, Homestead, FL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 17, 1995.

177. Klingman, D., and Coulson, J., "Guidelines For Introducing Foreign Organisms to the United States For the Biological Control of Weeds," *Bulletin of the Entomological Society of America*, Fall 1983.

178. Knipling, E.F., Former Director of Insect Pest Management Program, Agricultural Research Service, U.S. Department of Agriculture, Arlington, VA, personal communication, June 5, 1995.

179. Knott, D., Head, Permit Unit, Biological Assessment and Taxonomic Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, May 4, 1995 and August 2, 1995.

180. Knutson, A., Associate Professor and Extension Entomologist, Texas Agricultural Extension Service, Texas A&M University, Dallas, TX, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 2, 1995.

181. Koltes, K., National Biological Service, U.S. Department of the Interior, personal communication, June 1995.

182. Kough, J., Biologist, Biopesticides and Pollution Prevention Division, U.S. Environmental Protection Agency, Washington, DC, personal communication, August 8, 1995.

183. Kough, J.L., et al., *Rationale For Mammalian Toxicity/Pathogenicity Data Requirements For Microbial Pesticides*, 1994.

184. Krafsur, E.S., Department of Entomology, Iowa State University, Ames, IA, personal communication, July 1995.

185. Krysan, J.L., National Program Leader For Pest Management Systems, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.

186. Krysan, J.L., Former National Program Leader For Pest Management, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 27, 1995.

187. Krysan, J.L., National Program Leader For Pest Management, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, personal communication, March 3, 1994.

188. Krysan, J.L., Former National Program Leader, National Program Staff, Agricultural Research Service, U.S. Department of Agriculture, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 31, 1995.

189. Kuch, P.J., Chief, Agriculture Policy Branch, Office of Policy, Planning and Evaluation, U.S. Environmental Protection Agency, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, February 14, 1995.

190. Kulcher, F., "Changing Pesticide Policies," *Choices* 15–19, Second Quarter 1994.

191. Kuris, A., Department of Biological Sciences and Marine Science Institute, University of California, Santa Barbara, CA, "Biologically Based Technologies For Pest Control: A Review of Biologically Based Technologies For Pest Control in Aquatic Habitats," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, October 1994.

192. Kuris, A., Professor, Department of Biological Sciences and Marine Science Institute, University of California, Santa Barbara, CA, personal communication, August 29, 1995.

193. Lafferty, K.D., and Kuris, A.M., "Potential For Biological Control of Alien Marine Species," *National Oceanic and Atmospheric Administration Report on Nonindigenous Estuarine and Marine Organisms*, D. Cottingham (ed.) (Washington, DC: Department of Commerce, 1993).

194. Laird, M., et al., *Safety of Microbial Insecticides* (Boca Raton, FL: CRC Press, Inc., 1990).

195. Lake, R., Director, Policy and Public Planning, Center For Food Safety and Applied Nutrition, Food and Drug Administration, U.S. Department of Health and Human Services, Washington, DC, personal communication, February 16, 1995.

196. Lambert, W. Extension Entomologist, University of Georgia, personal communication, August 1995.

197. Lanterman, W.S., Lee, B.G., G., and Zuniga, M.A.C. Executive Committee, North American Plant Protection Organization, Orlando, FL, unaddressed letter, October 15, 1994.

198. Lebaron, H.M., and McFarland, J., "Herbicide Resistance in Weeds and Crops: An Overview and Prognosis," *Managing Resistance to Agrochemicals: From Fundamental Research to Practical Strategies*, M.B. Green, H.M. Lebaron, and W.K. Moberg (eds.) (Washington, DC: American Chemical Society, 1990).

199. Lee, G., "EPA Announces Plans to Review, Phase Out Use of Cancer-Causing Pesticides," *The Washington Post*, A20, October 13, 1994.

200. Leppla, N., Associate Director, National Biological Control Institute, Animal and Plant Health Inspection, U.S. Department of Agriculture, Riverdale, MD, letters to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 24 and August 3, 1995.

201. Leppla, N., National Biological Control Institute, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communications, May 24, 1995 and August 1995.

202. Levine, R., "Recognized and Possible Effects of Pesticides in Humans," *Handbook of Pesticide Toxicology Volume I*, W.J. Hayes Jr. and E.R. Laws Jr. (eds.) (San Diego, CA: Academic Press, Inc., 1991).

203. Levy, J., Operational Officer, Operational Support, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communication, April 5, 1995.

203A. Lockwood, J.A., Associate Professor, Department of Plant, Soil and Insect Science, University of Wyoming, Laramie, WY, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, December 19, 1994.

204. Lockwood, J.A., "Environmental Issues Involved in Biological Control of Rangeland Grasshoppers (Orthoptera: Acrididae) with Exotic Agents," *Environmental Entomology*, 22(3):503–518, June 1993.

205. Lugo, G., et al., "A New Risk of Occupational Disease: Allergic Asthma and Rhinoconjuntivitis in Persons Working With Beneficial Arthropods—Preliminary Data," *International Archives of Occupational and Environmental Health* 65(5):291–294, 1994.

206. Lynch, S., and Jordan Lin, C.T., "Food Safety: Meal Planners Express Their Concerns," *Food Review* 1714-18, May–August 1994.
207. Mahr, D., University of Wisconsin, Madison, WI, "Implementing Biological Control of Arthropods in the North Central States: An Extension Perspective," unpublished report prepared for the NCA-15, 1990.
207A. Mahr, D., University of Wisconsin, Madison, WI, "Biological Control in the United States: A Survey of the Perceptions, Resources and Needs of Extension Entomologists," unpublished report prepared for the National Agricultural Pesticide Impact Assessment Program, Cooperative State Research, Education, and Extension Service, 1995.
208. Mann, C.C., "Fire Ants Parlay Their Queens Into a Threat to Biodiversity," *Science,* 263:1560–1561, March 18, 1994.
209. Manweiler, S., Nematode Product Registration, Biosys, Palo Alto, CA, personal communication, July 25, 1995.
210. Marrone, P.G., Davis, CA, "Biointensive Integrated Pest Management For U.S. Agriculture," unpublished white paper prepared for the National Institute of Science and Technology, Advanced Technology Program, 1994.
211. Marrone, P.G., Former President, Novo Nordisk Entotech, Davis CA, personal communications, July and August 3, 1995.
212. Marshall, E., "A Is For Apple, Alar, and Alarmist?," *Science* 254(28):20–24, October 4, 1991.
213. Matthews, C., Assistant Director, Environmental and Pest Management Division, Florida Fruit and Vegetable Association, personal communication, August 16, 1995.
214. Matten, S., Chair, Pesticide Resistance Management Workshop, U.S. Environmental Protection Agency, Environmental Fate and Effects Division, personal communication, August 14, 1995.
215. May, R.M., "Resisting Resistance," *Nature* 361:593–594, February 18, 1993.
216. McCammon S.L., Science Advisor to the Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.
217. McClintock, J.T., Team Leader/Microbiologist, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC, personal communication, April 21, 1995.
218. McClintock, J.T., Kough, J.L., and Sjoblad, R.D., "Regulatory Oversight of Biochemical Pesticides By the U.S. Environmental Protection Agency: Health Effects Considerations," *Regulatory Toxicology and Pharmacology* 19:115–124, 1994.
219. McEvoy, P.B., Department of Entomology, Oregon State University, Corvallis, OR, "Testing Biocontrol Agents and Microbial Pesticides For Host Specificity," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1995;
220. McEvoy, P.B., Associate Professor, Department of Entomology, Oregon State University, Corvallis, OR, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 18, 1995.
221. McGaughey, W.H., and Whalon, M.E., "Managing Insect Resistance to *Bacillus thuringiensis* Toxins," *Science* 258(87):1451–1455, November 1992.
222. Melland, R., Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, DC, letter to AMT members describing the "APHIS Biological Control Philosophy," August 7, 1992.
223. Mendelsohn, M., U.S. Environmental Protection Agency, Washington, DC, personal communication, May 25, 1995.
224. Mendelsohn, M., et al., "Commercialization, Facilitation and Implementation of Biological Control Agents: A Government

Perspective," *Biological Control of Post Harvest Diseases: Theory and Practice,* C.L. Wilson and M.E. Wisnieaski (eds.) (Boca Raton, FL: CRC Press, Inc., 1994).

225. Mendoza, M., Staff Officer, Animal Damage Control, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, personal communication, April 19, 1995.
226. Mergentime, K., and Emerich, M., "Organic Sales Jump Over $2 Billion Mark in 1994," *Natural Foods Merchandiser* 16(6):74–76, June 1995.
227. Metcalf, R.L., and Metcalf, R.A., *Destructive and Useful Insects: Their Habits and Control 5th Ed.* (New York, NY: Mcgraw-Hill Inc., 1993).
228. Metterhouse, W.W., Cream Ridge, NJ, "The States' Roles in Biologically Based Based Technologies For Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.
229. Metterhouse, W.W., Executive Director, Interstate Pest Control Compact, National Association State Departments of Agriculture, Cream Ridge, NJ, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 31, 1995.
230. Meyerdirk, D.E., Biological Control Operations, Plant Protection and Quarantine, Animal Health and Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.
231. Michigan State University, Agricultural Experiment Station, *Michigan Fruit Industry Survey,* Research Report 524, (East Lansing, MI, April 1992).
232. "Milky Spore Disease May Not Be Effective Biological Control For Grubs," *Turf Grass Trends* 13, May 1994.
233. Miller, D.W., Vice President For Research and Development, EcoScience Corporation, Northborough, MA, letters to the Office of Technology Assessment, U.S. Congress, Washington, DC, March 2, 1995 and August 1995.
234. Miller, H.I., "A Need to Reinvent Biotechnology Regulation At the EPA," *Science* 266(192):1815–1818, December 16, 1994.
235. Miller, M., and Aplet, G., "Biological Control: A Little Knowledge Is a Dangerous Thing," *Rutgers Law Review* 45(285):314, 1993.
236. Mills, N., Assistant Professor, Center For Biological Control, University of California, Berkeley, CA, personal communication, August 22, 1995.
237. Moffat, A.S., "New Chemicals Seek to Outwit Insect Pests," *Science* 261(121):550–551, July 30, 1993.
238. Morgan, C.L., "Integrated Pest Management Cuts Use of Chemicals," *Farmline,* 13–16, April 1992.
239. Mycogen Corporation, "MVP (R) Bioinsecticide: The Persistent Solution to Resistant Budworm and Bollworm in Cotton," information sheet, 1993.
240. National Foundation For Integrated Pest Management Education, *Regional Producer Workshops: Constraints to the Adoption of Integrated Pest Management* (Austin, TX, August 1993).
241. National Research Council, *Pesticides in the Diets of Infants and Children* (Washington, DC: National Academy Press, 1993).
242. National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (Washington, DC: National Academy Press, 1987a).
243. National Research Council, *Report of the Research Briefing on Biological Control on Managed Ecosystems* (Washington, DC: National Academy Press, 1987b).
244. Narang, S.K., National Program Leader, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, fax to Office of Technology Assessment, U.S. Congress, Washington, DC, August 17, 1995.

245. Nechols, J.R., Kansas State University, personal communications, December 21, 1993 and August 21, 1995.
246. Nechols, J.R., Department of Entomology, Kansas State University, Manhattan, KS, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 19, 1995.
247. Nechols, J.R., and Obrycki, J.J. Kansas State University and Iowa State University, "OTA Preliminary Assessment of Biological Control: Current Research," unpublished report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994;
248. Neely, D., and Smith, G., "IPM Strategies Used By Arborists," *Journal of Arboriculture* 17(1):8–12, 1991.
249. Nelson, E.B., "Biological Control of Turfgrass Disease," Information Bulletin 220 of the Cornell Cooperative Extension, Geneva, NY, 1993.
250. Nishimi, R., Senior Associate, Office of Technology Assessment, U.S. Congress, Washington, DC, personal communication, June 20, 1995.
251. "Nonmailable Plant Pests and Injurious Animals" (3015), *Title 39 (Postal Service) U.S. Code*, 1980 ed.
252. Novak, T., "Swarms of Impostor Lady Beetles Bug Oregon," *Statesman Journal*, November 4, 1993.
253. Nowak, P.J., Department of Rural Sociology, University of Wisconsin, Madison, WI, "Educating Users About Biologically Based Methods of Pest Control," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, April 1995.
254. Oack, C. et al., "Dismantling Government Policy in Science and Technology," *Journal of Irreproducible Government Agencies* R(1P):1972–1995, July 20, 1995.
255. O'Conner III, C.A., "Registration of Pheromones in Practice," *Behavior-Modifying Chemicals For Insect Management: Applications of Pheromones and Other Attractants*, R.L. Ridgway, R.M. Silverstein and M.N. Inscoe (eds.) (New York, NY: Marcel Dekker, 1990).
256. Obrycki, J.J., Associate Professor, Department of Entomology, Iowa State University, Ames, IA, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, March 24, 1994.
257. Oltman, D., "Ground Rules," *California Farmer* 6–7, 28, 1995.
258. Oltman, D., "A Lesson Plan," *California Farmer* 10–11, 31–32, January 1995.
259. Oregon State University, Integrated Plant Protection Center, *Areawide Management of the Codling Moth: Implementation of a Comprehensive IPM Program For Pome Fruit Crops in the Western United States* (Corvallis, OR: July 1994).
260. Organic Farming Research Foundation, *1993 National Organic Farmers' Survey*, Fall 1994.
261. Organic Farming Research Foundation, "Bulletin 1," Winter 1995.
262. Padgett, M., Agricultural Economist, Economic Research Service, U.S. Department of Agriculture, Washington, DC, personal communication, June 26, 1995.
263. Parella, M.P., Heinz, K.M., and Nunney, L., "Biological Control Through Augmentative Releases of Natural Enemies: A Strategy Whose Time Has Come," *American Entomologist* (38):172–179, Fall 1992.
264. Parkwood Research Associates, *Shopping For Organic: Food Shoppers' Views on Organically Grown Produce* (Rodale Press, Inc., March 1994).
265. Pass, R.C., Chairman, Department of Entomology, University of Kentucky, Lexington, KY, personal communication, July 27, 1995.
266. Pearson, W., County Extension Agent, Columbus, MT, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 27, 1994.
267. Pedigo, L., *Entomology and Pest Management* (New York, NY: Macmillian Publishing Company, 1989).

268. Penn, S., President, Beneficial Insectary, Oak Run, CA, personal communications, June 23, 1993.
269. Penn, S., President, Beneficial Insectary, Oak Run, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, June 19, 1995.
270. Penn, S., and Henke, R., Beneficial Insectary, Oak Run, CA and Agricultural Advisors, Inc., CA, personal communication, August 7, 1993 and June 21, 1995.
271. Pennsylvania Department of Agriculture, *Development of Integrated Pest Management Certification Guidelines For Agricultural Crops: Results of Initial Focus Group Session*, February 1994.
272. Pennsylvania State University, College of Agricultural Sciences, *Pennsylvania Tree Fruit Production Guide, 1994–1995* (State College, PA: 1995).
273. "'Person' Defined" (151 et seq.), *Title 7 (Agriculture 281 to 1099) U.S. Code,* 1980 ed.
274. Peterson, C.G., Special Projects Staff, Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 4, 1995.
275. "Plant and Non-Domestic Animal Quarantine" *Title 4, Subtitle 6, Chapter 71 (Non-Domestic Animal and Microorganism Import Rules) Hawaii Administrative Rules.*
276. Poinar, Jr., G.O., "Taxonomy and Biology of Steinernematidae and Heterorhabditidae," *Entomopathogenic Nematodes in Biological Control,* R. Gaugler and H.K. Kaya (eds.) (Boca Raton, FL: CRC Press, Inc., 1990).
277. "Policy and Purpose" (2101), *Title 16 (Conservation: 1151 to 3100) U.S. Code,* 1985 ed.
278. Prokrym, D., Project Leader, Russian Wheat Aphid Biological Control Project, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Niles, MI, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 11, 1995.
279. Prokrym, D., Project Leader, Russian Wheat Aphid Biological Control Project, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Niles, MI, personal communication, August 10, 1995.
280. Quimby, P.C., Research Leader, Rangeland Weeds Laboratory, Agricultural Research Service, U.S. Department of Agriculture, Bozeman, MT, personal communication, July 27, 1995.
281. Quimby, P.C., Research Leader, Rangeland Weeds Laboratory, Agricultural Research Service, U.S. Department of Agriculture, Bozeman, MT, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, January 26, 1995.
282. Rajotte, E., Entomologist, Pennsylvania State University Extension Service, State College, PA, personal communication, August 15, 1995.
283. Randall, J.M., Invasive Weed Specialist, The Nature Conservancy, Davis, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 24, 1995.
284. Randall, J., and Pitcairn, M. Exotic Species Program, The Nature Conservancy, Galt, CA, and the Biological Control Program, California Department of Food and Agriculture, Sacramento, CA, "Biologically Based Technologies For Pest Control in Natural Areas and Other Wildlands," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.
285. Ravensberg, W.J., "Biological Control of Pests: Current Trends and Future Prospects," *BCPB Pest and Diseases, Proceedings* 2:591–600, 1994.
286. Reichelderfer, K., "Economic Feasibility of Biological Control of Crop Pests," *Biological Control in Crop Production,* G.C.

Papazizas (ed.) (Totowa, NJ: Allanheld, Osmun, 1981).

287. Ridgway, R.L., and Inscoe, M.N., U.S. Department of Agriculture, Agricultural Research Service, "Biologically Based Pest Control: Markets, Industries, and Product," unpublished special report, December 2, 1993.
288. Riechmann, D., "Ladybugs Bedevil Md. Residents," *The Washington Post*, Md. 3, March 30, 1995.
289. Riley, R., Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, personal communication, August 23, 1995.
290. Roberts, T.C., Range Conservationist, Bureau of Land Management, U.S. Depart of the Interior, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 23, 1995.
291. Rockey, S.J., Division Director, National Research Initiative Competitive Grants Program, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, personal communication, July 6, 1994, June 19, 1995, and August 1995.
292. Rockey, S.J., Division Director, National Research Initiative, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 10, 1995.
293. Rockey, S.J., Division Director, National Research Initiative Competitive Grants Program, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, Washington, DC, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, March 29, 1995.
294. Rodgers, P.B., "Potential of Biopesticides in Agriculture," *Pesticide Science*, 39(2):117–129, 1993.
295. Rogers, M., "What's New: Biological Controls," *Grounds Maintenance*, 90–94, March 1994.
296. Rosen, J.D., "Much Ado About Alar," *Issues in Science and Technology*, 685, Fall 1990.
297. Rosenblum, G., *On the Way to Market: Roadblocks to Reducing Pesticide Use on Produce* (Washington, DC: Public Voice For Food and Health Policy, March 1991).
298. Rosenfeld, A., *Cutting to the Core: Cosmetic Quality and Pesticide Use on Apples—A Survey of U.S. Apple Growers* (Washington, DC: Public Voice For Food and Health Policy, September 1991).
299. Royer, M., Chief Operations Officer, Biological Assessment and Taxonomic Support, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, personal communications, April 4, 1995; April 12, 1995; April 20, 1995 and May 11, 1995.
300. Ruff, M.D., Technology Transfer Coordinator, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 26, 1994.
301. "Sales of Biopesticides Expected to Rise at the Expense of Chemically-Based Pesticides," *Pesticide Outlook*, 4–5, February 1994.
302. Sandoz Agro, *Key Findings: The 1994 Sandoz National Environmental Poll* (Des Plaines, IL: 1994).
303. Schneider, E., National Biological Service, U.S. Department of the Interior, Washington, DC, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 4, 1995.
304. Schneider, W., Microbiologist, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, "158 Data Requirements For Biological Pesticides," SAP Presentation, November 11, 1994.

305. Schneider, W., Microbiologist, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Arlington, VA, personal communications, May 30, 1995; July 27, 1995 and August 1, 1995.
306. Schrimpf, P., "The Next Seed Revolution," *Lawn and Landscape Maintenance* 30–34, June 1995.
307. Schroth, M., Chairman, Department of Plant Pathology, University of California, Berkeley, CA, personal communication, August 9, 1993.
308. Schroth, M.N., Professor Emeritus, Department of Plant Pathology, University of California, Berkeley, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, December 11, 1994.
309. Setting, M., Association of American Pest Control Officials, personal communication, August 15, 1995.
310. Shani, A., "Role of Pheromones in Integrated Pest Management," *Proceedings of the Working Group Use of Pheromones and Other Semiochemicals in Integrated Control,* (International Organization for Biological and Integrated Control of Noxious Animals and Plants, 1993).
311. Siegel, J.P., and Shadduck, J.A., "Safety of Microbial Insecticides to Vertebrates—Humans," *Safety of Microbial Insecticides,* M. Laird, L.A. Lacey and W. Davidson (eds.) (Boca Raton, FL: CRC Press, Inc., 1990).
312. Simberloff, D., Professor, Department of Biological Sciences, Florida State University, Tallahassee, FL, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 16, 1995.
313. Simberloff, D., and Stiling, P. Department of Biological Sciences, Florida State University, Tallahassee, FL and University of Southern Florida, Tampa, FL, "Biological Pest Control: Potential Hazards," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994.
314. Sjoblad, R.D., McClintock, J.T., and Engler, R., "Toxicological Considerations For Protein Components of Biological Pesticide Products," *Regulatory Toxicology and Pharmacology,* 15:3–9, 1991.
315. Sjogren, R., Meridian Precision Release Technologies, Minneapolis, MN, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.
316. Smith, K.R., "Making Alternative Agricultural Research Policy," *American Journal of Alternative Agriculture* 10(1):10–18, 1995.
317. Smith, K.R., Henry A. Wallace Institute for Alternative Agriculture, Hyattsville, MD, "Biological Pest Control: An Assessment of Current Markets and Market Potential," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1994.
318. Smith, K.R., Director, Policy Studies Program, Henry A. Wallace Institute For Alternative Agriculture, Hyattsville, MD, personal communication, June 19, 1995.
319. Sorensen, A.A., "The Role of IPM in Reducing Environmental Problems," *Proceedings of the Second National IPM Workshop/Symposium* 1994).
320. St. John, J.B., Acting Associate Deputy Administrator, National Program Staff, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 10, 1995.
321. Stanley, D., "Whitefly Causes Bleak Times for Growers," *Agricultural Research* 16:2, January, 1991.
322. Steiner, M.Y., and Elliott, E.P., *Biological Pest Management For Interior Plantscapes* (Vegreville, Canada: Alberta Environmental Centre, March 1897).
323. Stevens, W.K., "Pesticides May Leave Legacy of Hormonal Chaos," *The New York Times*, C1, August 23, 1994.
324. Stewart, J.L., Director, Forest Insect and Disease Research, Forest Service, U.S.

Department of Agriculture, Washington, DC, personal communication, April 6, 1995 and June 22, 1995.

325. "Summary of State Training Programs For Pesticide Users," *North Carolina Insight* September 1994.

326. Tabashnik, B.E., "Evolution of Resistance to *Bacillus thuringiensis*," *Annual Review of Entomology*, 39:47–79, 1994.

327. Takahashi, G., Maritime Supervisor, Plant Quarantine, Department of Agriculture, Hawaii, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 26, 1995.

327A.TeBeest, D.O., Professor, Department of Plant Pathology, University of Arkansas, Fayetteville, AK, personal communication, July 13, 1995.

328. TeBeest, D.O., Professor, Department of Plant Pathology, University of Arkansas, Fayetteville, AK, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, May 18, 1995.

329. Tichenor, R., Maryland Department of Agriculture, Annapolis, MD, personal communication, June 20, 1995.

330. Toscano, N., Department of Entomology, University of California, Riverside, CA, personal communication, August, 1995.

331. Trinka, David, Horticulture Manager, MBG Marketing, MI (formerly Michigan Blueberry Growers' Association), personal communication, August 17, 1995

332. Turner, C., Agricultural Research Service, U.S. Department of Agriculture, Albany, CA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.

333. Tyree, S., Biotechnology Industry Organization, personal communication, 1995.

334. U.S. Congress, Congressional Research Service, *Federal Land and Resource Management: A Primer*, 93-787 ENR (Washington, DC: 1993).

335. U.S. Congress, Congressional Research Service, *CRS Issue Brief: Pesticide Policy Issues in the 103rd Congress*, prepared by J. Womach, IB93082 (Washington, DC: February 1, 1994).

336. U.S. Congress, General Accounting Office, *Pesticides: Pesticide Reregistration May Not Be Completed Until 2006*, RCED-93-94 (Washington, DC: May 1993).

337. U.S. Congress, Office of Technology Assessment, *A New Technological Era For American Agriculture*, OTA-F-474 (Washington, DC: U.S. Government Printing Office, August 1992).

338. U.S. Congress, Office of Technology Assessment, *Harmful Non-Indigenous Species in the United States*, OTA-F-565 (Washington, DC: U.S. Government Printing Office, September 1993).

338A.U.S. Congress, Office of Technology Assessment, unpublished proceedings of the advisory panel meeting, July 13, 1995.

339. U.S. Department of Agriculture, *Biological Agents for Pest Control: Status and Prospects* (Washington, DC:U.S. Government Printing Office, February 1978).

340. U.S. Department of Agriculture, *Agricultural Resources and Environmental Indicators Update: Crop Consultants* (Washington, DC, 1995).

341. U.S. Department of Agriculture, *1994 Special Projects, Integrated Pest Management Program, Extension Service* (Washington, DC: 1994).

342. U.S. Department of Agriculture, "Strategic Directions of the Cooperative Extension System," as of May 5, 1995. URL=http://www.esusda.gov/mission/commit/ces.htm.

343. U.S. Department of Agriculture, "Pest Risk Assessment of Biological Control Organisms," unpublished report prepared by P. Lima, no date.

344. U.S. Department of Agriculture, Agricultural Research Service, *Stored-Product Insects Workshop: Final Report,* May 4–6, (Washington, DC:1992).
345. U.S. Department of Agriculture, Agricultural Research Service, *Principles of Insect Parasitism Analyzed From New Perspectives,* E.F. Knipling (author), AHN 693 (Washington, DC: 1992).
346. U.S. Department of Agriculture, Agricultural Research Service, *Biological Control of Postharvest Diseases of Fruits and Vegetables, Workshop Proceedings,* C.L. Wilson and E. Chalutz (eds.), ARS-92 (June 1991).
347. U.S. Department of Agriculture, Agricultural Research Service, *ARS National Biological Control Program, Proceedings of Workshop on Research Priorities,* 1988-203-044 (Washington, DC: U.S. Government Printing Office, August 1988).
348. U.S. Department of Agriculture, Agricultural Research Service, "Biological Weed Control, Rangeland Weeds, and Their Biological Control Agents," unpublished report provided by McNeel, H., Weed Management Specialist, Bureau of Land Management, U.S. Department of the Interior, Billings, MT, July 13, 1993.
349. U.S. Department of Agriculture, Agricultural Research Service, briefing for the Office of Technology Assessment, U.S. Congress, Washington, DC, June 23, 1995.
350. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Explanatory Notes: Fiscal Year 1996* (Washington DC, 1995).
351. U.S. Department of Agriculture, Animal Plant Health Inspection Service, "Biological Control of the Russian Wheat Aphid, 1993," APHIS Pub. No. 1507 (Washington D.C.: December 1993).
352. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Introduction of Nonindigenous Organisms," proposed rule and notice of public hearings 7 CFR Part 335, *Federal Register* 60(17):5288–5307, January 26, 1995.
353. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Introduction of Nonindigenous Organisms," proposed rule; withdrawal, 7 CFR Part 335, *Federal Register* 60(116):31647, June 16, 1995.
354. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Safeguard Guidelines For Containment of Plant Pests Under Permit,* June 1983.
355. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Charter for the Technical Advisory Group on the Introduction of Biological Control Agents of Weeds," unpublished draft guidelines, 1990.
356. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Biological Control of Leafy Spurge," PAN 1435, August 1992.
357. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Biological Control of Spotted and Diffuse Knapweeds," PAN 1529, December 1994.
358. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Plant Protection Act,* proposed bill, August 1995.
359. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *Release of Nonindigenous Organisms: Information Requested From Applicants in Support of Permit Applications*, September 9, 1994.
360. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Biological Assessment and Taxonomic Support, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.
361. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, National Biological Control Institute, Animal and Plant Health Inspection Service, Riverdale, MD, unaddressed letter, July 11, 1995.

362. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, National Biological Control Institute, Riverdale, MD, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 13, 1994.

363. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, National Biological Control Institute, "Draft Program Logic Model," Riverdale, MD, October 13, 1994.

364. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Riverdale, MD, unpublished proceedings of a briefing for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.

365. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Control Operations, Riverdale, MD, unpublished briefing report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.

366. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Assessment and Taxonomic Support, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, August 3, 1995.

367. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biological Control Operations, unpublished 1994 data provided by D.E. Meyerdirk, Senior Staff Officer, April 1995.

368. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, National Biological Control Laboratory, Russian Wheat Aphid Biological Control Project—FY 1993 Project Report, prepared by D.R. Prokrym, et al., (Niles, MI: 1993)

369. U.S. Department of Agriculture, Cooperative State Research, Education, and Extension Service, "Request for Proposals, National Integrated Pest Management Implementation Program, Fiscal Year 1995," special projects guidelines, 1995.

370. U.S. Department of Agriculture, Cooperative State Research, Education, and Extension Service, "Summary Report: Cooperative Extension System Educational Programs on Pesticides," unpublished report prepared by J.W. Impson, March 1995.

371. U.S. Department of Agriculture, Cooperative State Research Service, National Research Initiative Competitive Grants Program, *The National Research Initiative on Agriculture, Food and Environment: Annual Report Fiscal Year 1993*, (Washington, DC: 1994).

372. U.S. Department of Agriculture, Cooperative State Research, Education, and Extension Service, *Strategic Directions of the Cooperative Extension System*, (Washington, DC: 1995).

373. U.S. Department of Agriculture, Cooperative State Research Service, Experiment Station Committee on Organization and Policy, Pest Management Strategies Subcommittee, "Integrated Pest Management For the 21st Century: A Blue Print For Sustainable Pest Management," (Washington, DC, 1991).

374. U.S. Department of Agriculture, Cooperative State Research Service National Research Initiative Competitive Grants Program, *National Research Initiative Competitive Grants Program: Program Description*, (Washington, DC: 1994).

375. U.S. Department of Agriculture, Economic Research Service, *Agricultural Resources and Environmental Indicators*, (Washington, DC: December 1994).

376. U.S. Department of Agriculture, Economic Research Service, *Agricultural Resources and Environmental Indicators Updates: Crop Consultants*, No. 3 (Washington, DC:1995).

377. U.S. Department of Agriculture, Economic Research Service, *Adoption of Integrated Pest Management in U.S. Agriculture,* prepared by A. Vandeman, et al., Bulletin No. 707 (Washington, DC: 1994).

378. U.S. Department of Agriculture, Economic Research Service, *Agricultural Pesticide Use Trends and Policy Issues,* prepared by C.D. Osteen and P.I. Szmerda, AER-622 (Washington, DC: September 1989).

379. U.S. Department of Agriculture, Economic Research Service, *Agricultural Resources and Environmental Indicators,* AH-705 (Washington, DC: December 1994).

380. U.S. Department of Agriculture, Economic Research Service, *Federal Grade Standards For Fresh Produce: Linkages to Pesticide Use,* prepared by N. Powers and R.G. Heifner, Agriculture Information Bulletin 275 (Washington, DC: August 1993).

381. U.S. Department of Agriculture, Economic Research Service, *Economic Returns to Boll Weevil Eradication,* prepared by G.A. Carlson, G. Sappie and M. Hammig, AER Pub. No. 621 (Washington DC: September, 1989).

382. U.S. Department of Agriculture, Forest Service, *Gypsy Moth News* (35): September 1994.

383. U.S. Department of Agriculture, Forest Service, unpublished data on the Forest Service's use of chemical pesticides for 1994, Washington, DC, 1995.

384. U.S. Department of Agriculture, Forest Service, unpublished briefing report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, May 9, 1995.

385. U.S. Department of Agriculture, Forest Service and Animal and Plant Health Inspection Service, *Gypsy Moth Management in the United States: A Cooperative Approach,* (Washington, DC: April 1995).

386. U.S. Department of Agriculture, National Agricultural Pesticide Impact Assessment Program, *The Biologic and Economic Assessment of Chlorpyrifos and Diazinon in Ornamentals and Sod Production* (Washington, DC: 1994).

387. U.S. Department of Agriculture, Office of Communications, "USDA's Integrated Pest Management," Release No, 0942.94, December 14, 1994.

388. U.S. Department of the Interior, "Strategy For the Containment of Proliferation of Non-Indigenous Plant Species on Public Lands," unpublished white paper, Washington, DC, 1993.

389. U.S. Environmental Protection Agency, "Biochemical Pesticides Data Requirements," *Code of Federal Regulations,* Title 40, Sec. 158.690, 1994.

390. U.S. Environmental Protection Agency, "Microbial Pesticides; Experimental Use Permits and Notifications," final rule, *Federal Register,* 59(169):45612, September 1, 1994.

391. U.S. Environmental Protection Agency, "Plant-Pesticide *Bacillus thuringiensis* Cry III(A) Delta Endotoxin and the Genetic Material Necessary for its Production in Potato," conditional registration, May 1995.

392. U.S. Environmental Protection Agency, "*Bacillus thuringiensis* CryIA(b) Delta Endotoxin and the Genetic Material Necessary for its Production (Plasmid Vector pCIB4431) in Corn, Significant New Use," August 10, 1995.

393. U.S. Environmental Protection Agency, *Pesticide Testing Guidelines Subdivision M: Biorational Pesticides,* EPA 540/9-92-028 (Washington, DC: November 1982).

394. U.S. Environmental Protection Agency, *Pesticide Testing Guidelines Subdivision M of the: Microbial and Biochemical Pest Control Agents,* H-7501C (Washington, DC: July 1989).

395. U.S. Environmental Protection Agency, *Urban Integrated Pest Management,* EPA 735-B-92-001 (Washington, DC: July 1992).

396. U.S. Environmental Protection Agency, briefing package prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, April 1995.

397. U.S. Environmental Protection Agency, *Pesticides Industry Sales and Usage: 1992 and 1993 Market Estimates*, prepared by A.L. Aspelin 733-K-94-001 (Washington, DC: June 1994).

398. U.S. Environmental Protection Agency, *Biotechnology Research Program Overview*, EPA 600/K-93/007 January 1994).

399. U.S. Environmental Protection Agency, *Pesticides Industry Sales and Usage: 1992 and 1993 Market Estimates*, prepared by A.L. Aspelin 733-K-94-001 (Washington, DC: June 1994).

400. U.S. Environmental Protection Agency, Office of Communications and Public Affairs, *EPA Journal: Pesticides and Food Safety* 16(3):May/June 1990.

401. U.S. Environmental Protection Agency, Office of Pesticide Programs, *Annual Report For 1994*, 735-R-95-001 (Washington, DC: January 1995).

402. U.S. Environmental Protection Agency, Office of Pesticide Programs, remarks at a briefing for the Office of Technology Assessment, U.S. Congress, Washington, DC, Alexandria, VA, April, 27, 1995.

403. U.S. Environmental Protection Agency, Office of Pesticide Programs, remarks at a briefing for the Office of Technology Assessment, U.S. Congress, Washington, DC, Alexandria, VA, 1994.

404. U.S. Environmental Protection Agency, Office of Pesticide Programs, *Fee Authorities*, May 1995).

405. U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, *Analysis of FY 1993 Emergency Exemption Program*, (Washington, DC: December 22, 1992).

406. U.S. Environmental Protection Agency and U.S. Department of Agricultural, Extension Service, *Applying Pesticides Correctly: Private Applicator Supplement*, E-2472 (East Lansing, MI: Michigan State University Extension, December 1993).

407. U.S. Environmental Protection Agency and U.S. Department of Agriculture, Extension Service, *Applying Pesticides Correctly: A Guide For Private and Commercial Applicators*, (Washington, DC: 1991).

408. United Nations, Environment Programme, *Convention on Biological Diversity June 5, 1992* (As of July 20, 1995: URL=gopher://Gopher.UNDP.Org:70/00/Unconfs/Unced/English/Biodiv.Txt, no date.

409. United Nations Food Agriculture Organization, *Draft Code of Conduct For the Import and Release of Biological Control Agents* (Rome, Italy: November 1994).

410. University of California, Division of Agriculture and Natural Resources, *Beyond Pesticides: Biological Approaches to Pest Management in California* (Oakland, CA: ANR Publications, 1992).

410A. Van Driesche, R., Department of Entomology, University of Massachusetts, Amherst, MA, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.

411. Van Driesche, R., Bellows, T.S., Mikenburg, O., Adang, M., Federici, B., McCoy, C., Maddox, J., Kaya, H., Lewis, J., Cardé, R., and Krafsur, E.S., Department of Entomology, University of Massachusetts, Amherst, MA (Van Driesche only), "Report on Biological Control of Invertebrate Pests of Forestry and Agriculture," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, December 1994.

412. Virginia Cooperative Extension Service, et al., *The National Evaluation of Extension's Integrated Pest Management Programs,* VCES Publication 491-010 (February 1987).

413. Voss, G., and Miflin, B., "Biocontrol in Plant Protection: CIBA's Approach," *Pesticide Outlook* 29–34, April 1994.

414. Waage, J.K., Director, International Institute of Biological Control, Ascot Berks, UK, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, 1994.
415. Waage, J.K., Director, International Institute For Biological Control, Ascot Berks, UK, personal communication, July 13, 1995.
416. Waage, J.K., Director, International Institute of Biological Control, Ascot Berks, UK, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 13, 1995.
417. Waage, J.K., Director, International Institute of Biological Control, Ascot Berks, UK, letter to the Office of Technology Assessment, U.S. Congress, Washington, DC, July 14, 1995.
417A. Walters, T.L., President, American Competitiveness Enterprise, Altadena, CA, personal communication, May 2, 1995.
418. Wapshere, A.J., Delfosse, E.S., and Cullen, J.M., "Recent Developments in Biological Control of Weeds," *Crop Protection* 8227–250, 1989.
419. Warner, D., "The Food Industry Takes the Offensive," *Nation's Business* 79(7):42–45, July 1991.
420. Watson, A.K., Department of Plant Science, McGill University, Quebec, Canada, "Biologically Based Technologies For Pest Control: Agricultural Weeds," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1994.
421. Weaver, R.D., Evans, D.J., and Luloff, A.E., "Pesticide Use in Tomato Production: Consumer Concerns and Willingness-to-Pay," *Agribusiness* 8(2):131–142, 1992.
422. Whalon, M.E., and McGaughey, W.H., "Insect Resistance to *Bacillus thuringiensis*," *Advanced Engineered Pesticides*, L. Kim (New York, NY: Marcel Dekker, Inc., 1993).
423. Whitacre, D.M., Vice President, Development, Sandoz Agro, Inc., Des Plaines, IL, personal communication, March 1994.
424. Whitmore, R.W., et al., "National Home and Garden Pesticide Use Survey," *Pesticides in Urban Environments,* K.D. Racke and A.R. Leslie (eds.) (Washington, DC: American Chemical Society, 1993).
425. Whitson, T.D., et al., *Weeds of the West* (Jackson, WY: Pioneer of Jackson Hole, 1992).
426. Wilson, C., Fruit Pathology Unit, Appalachian Fruit Research Station, Agricultural Research Service, U.S. Department of Agriculture, Kearneysville, WV, personal communication, August 8, 1995.
427. Winfree, R.A., National Biological Service, U.S. Department of the Interior, unpublished NBS briefing sheet prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1995.
428. Witt, I., Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Riverdale, MD, fax to the Office of Technology Assessment, U.S. Congress, Washington, DC, March 30, 1995.
429. Wood, H.A., and Hughes, P.R., "Biopesticides," *Science* 261(119):227, July 16, 1993.
430. Wood, M., "Weed-Eating Insects Take the Starthistle Challenge," *Agricultural Research*, 11, July 1993.
431. Wright, R., U.S. Environmental Protection Agency, Washington, DC, personal communication, August 15, 1995.
432. Young, F.E., "Weighing Food Safety Risks," *FDA Consumer* 23(7):8–14, September 1989.
433. Zalom, F.G., and Fry, W.E. (eds.) *Food, Crop Pests, and the Environment* (St. Paul, MN: APS Press, 1992).
434. Zilberman, D., Sunding, D., Dobler, M., Campbell, M. and Manale, A., "Who Makes Pesticide Use Decisions: Implications For Policy Makers," *Pesticide Use and Product Quality*, W. Armbruster (ed.) (Glenbrook, CA: Farm Foundation, 1994).

435. Zilberman, D., and Yarkin, C., Department of Agricultural and Resource Economics, University of California, Berkeley, CA, "The Economics of Development and Adoption of Pest Control Products With Emphasis on Biologically Based Controls," unpublished contractor report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, December 1994.