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%

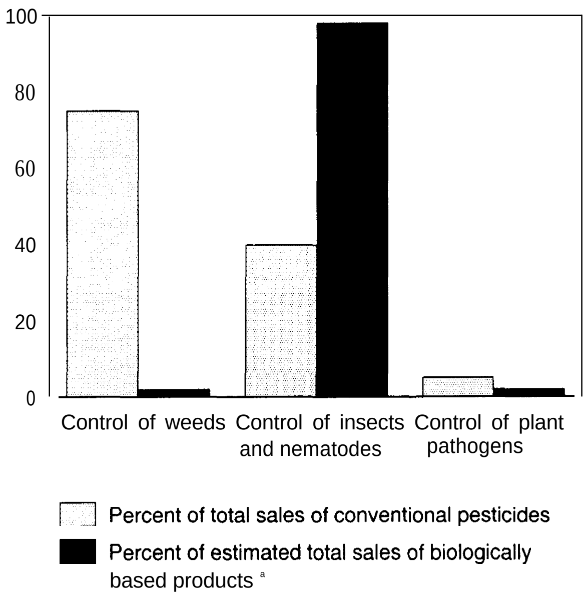
[a] Pheromones may include some products for pest monitoring as well as control. Sources do not report the data in a way that would allow this level of discrimination.

[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.

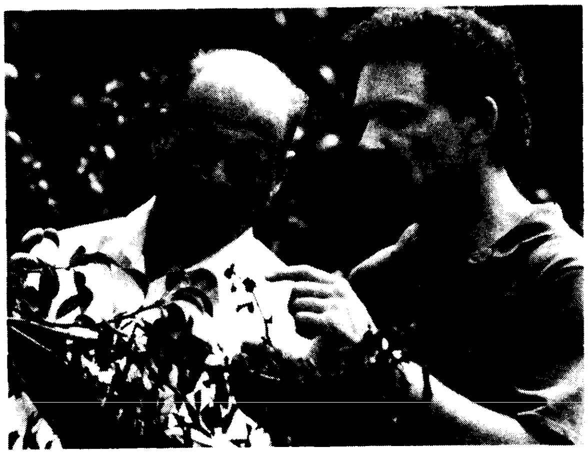
Under the Status Quo

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 P/ant 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.*