

G Y P C H E K

Responding to concerns over the use of chemical pesticides, the USDA Forest Service has developed narrow host-range products for the control of forest pests. Among them is Gypchek, a viral pesticide for gypsy moths, but its future availability is not assured. If the private sector will not produce a safe and useful pesticide because the market is unstable, some other approach toward developing such products and making them available is needed. A federal center may be necessary to research biopesticides, transfer technology to the private sector, and develop, register, produce, and market those products that industry will not.

By John D. Podgwaite

Biological Insecticide for the Gypsy Moth

With administrative and financial support from its State and Private Forestry division, the USDA Forest Service has directed much effort toward developing viral pesticides that kill forest insect pests. Most environmentally benign viral pesticides are narrow host-range products (Gröner 1986) that are most useful in situations where environmental concerns are paramount and applications of either broad-spectrum chemicals or other biological pesticides (biopesticides) are undesirable, if not illegal. Killing destructive forest pests is now viewed by many resource managers in the broader context of protecting forest and ecosystem health rather than as a single-minded targeting of a particular species.

Much research has focused on developing the following biopesticides: Neochek-S (Podgwaite et al. 1984) to control sawflies (*Neodiprion sertifer*) on watershed and Christmas tree plantations, TM-Biocontrol-1 (Stelzer and Neisess 1978) to suppress Douglas-fir tussock moths (*Orgyia pseudotsugata*), and Gypchek (Reardon et al. 1996) to control gypsy moths (*Lymantria dispar*). Although these products have been registered with the Environmental Protection Agency (EPA) as general-use pesticides, none are currently in general use. The registration for Neochek-S has been withdrawn, TM-Biocontrol-1 is no longer in production because there are no infestations requiring treatment on public lands, and the annual production of Gypchek was recently reduced from 25,000-acre treatments to 5,000 per year following areawide collapses of gypsy moth populations. Because these products are costly to pro-

duce and are often viewed as less efficacious than chemical pesticides, their use is limited to relatively small and fluctuating markets. That makes them difficult to commercialize without directly subsidizing industry with substantive start-up funding or guaranteed buy-back agreements or both.

Discussions with industry representatives have revealed that large companies are interested in developing large markets that generate \$40 million to \$50 million per year in sales. The market potential for Gypchek, in contrast, is about \$5 million per year. Small companies are usually content to gross \$5 million per year, but they find it difficult to generate start-up costs. To date, every company that has attempted to manufacture a gypsy moth virus product has failed to bring it to market. Yet resource managers continue to value Gypchek and other extremely narrow host-range products and want them made available for their pest management programs. In fact, a recent survey of representatives of both the gypsy moth management community and environmental organizations revealed strong support for Gypchek; two thirds of the managers and three fourths of the environmentalists agreed that in the absence of a commercial product, the Forest Service should continue to make Gypchek available (Podgwaite et al. 1997). However, given flat or declining Forest Service budgets and absent the redirection of funds from other programs, it may be difficult to meet market demand, particularly when gypsy moth populations again reach outbreak levels in the eastern United States. As a result, the Forest Service is reevaluating



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These gypsy moth larvae were killed following aerial application of Gypchek, a biopesticide whose active ingredient is a specific nucleopolyhedrosis virus. The scanning electron micrograph shows the viral occlusion bodies that, when ingested, will kill gypsy moth larvae in 10 to 14 days.



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its role in production of biopesticides and exploring alternatives that would ensure the availability of not only Gypchek but other limited-market biopesticides as well. Some alternatives are suggested in this brief retrospective, which focuses on Gypchek as a model for the expensive, limited-market biopesticide.

The Making of Soft Pesticides

The development of the gypsy moth nucleopolyhedrosis virus (LdNPV) as a biopesticide began in the early 1900s, several years after this insect pest was introduced into the United States. At that time limited field trials using crude viral preparations supported the concept of such a product (Reiff 1911; Glaser and Chapman 1913). During the late 1950s, in response to growing concern over the indiscriminant use of chemical pesticides (principally the areawide use of DDT), the Forest Service began to address the development of environmentally "soft" pesticides, in particular the use of *Bacillus thuringiensis* (Bt) products for gypsy moth control. Environmental safety became a Forest Service research priority before it became a national concern: this effort was initiated well before the publication of *Silent Spring* (Carson 1962) and the establishment of the EPA in the early 1970s.

The development of a microorganism as a biopesticide begins with its discov-

ery, often through a screening of diseased insects. Microorganisms are isolated, identified, presumed safe, and then bioassayed against the target pest to determine efficacy. If the isolate is deemed a worthy candidate, a battery of EPA-mandated safety tests is conducted, a production system is designed and tested, formulations are selected, delivery systems are tested, and field experiments and pilot tests are conducted (Reardon and Podgwaite 1994). Much of this work is concurrent in anticipation of a positive outcome from the safety testing and eventual registration of a product.

The active ingredient(s) in Gypchek is a mixture of closely related LdNPV genotypes that were isolated from virus-killed larvae collected in Connecticut in the early 1960s (Lewis 1981). At that time, LdNPV was recognized as the only gypsy moth pathogen effective in regulating natural gypsy moth populations and was a logical choice for development (Campbell and Podgwaite 1972). Though Forest Service scientists were committed to the rapid develop-

ment of substitutes for environmentally harsh pesticides, the commitment was undertaken within the wider scope of integrated pest management programs, the constraints of competitive year-to-year funding, and little in the way of previously developed technology on which to model the effort. At the time, the EPA was using Forest Service testing protocols as the basis for some of its registration standards for biopesticides. Not until 1982 did the EPA publish statutory pesticide assessment guidelines for "biorational pesticides" under the Federal Insecticide, Rodenticide and Fungicide Act (US-EPA 1982). With limited resources, product development was protracted. Nevertheless, with support from colleagues within the Department of Agriculture, academia, and industry, enough resources and data were gathered to support the registration of Gypchek with the EPA in 1978.

Manufacture of Gypchek

Currently Gypchek is manufactured through the collaborative efforts of the Forest Service and the Animal and Plant Health Inspection Service (APHIS). Both agencies have gypsy moth control mandates. The Forest Service supports cooperative gypsy moth suppression programs, and APHIS supports quarantine and eradication programs, for example, the 1994 putative eradication, using

Gypchek, of Asian gypsy moths from 6,000 environmentally sensitive areas in North Carolina. Gypchek is a wettable powder produced from laboratory-reared gypsy moth larvae that have been infected with LdNPV. Larval cadavers are homogenized and processed to remove unwanted particulates, and the viral occlusion bodies (OB) are concentrated in a paste through centrifugation. The paste is frozen, lyophilized, and milled into the technical powder—a relatively simple but labor-intensive manufacturing process (Reardon et al. 1996). Current estimates place the cost of producing Gypchek at \$10 to \$12 per acre treatment (400 billion OBs).

The technical powder is assayed for potency and subjected to microbiological quality assurance testing prior to use (Podgwaite et al. 1983). Immediately before use, the product is tank-mixed either with a carrier (Carrier 038®, Abbott Laboratories) developed specifically for the aerial spraying of Gypchek in gypsy moth suppression and eradication programs, or with a lignosulfonate-molasses formulation that is less costly than Carrier 038 but more difficult to mix and apply.

Gypchek also can be applied to individual trees using ground-based hydraulic equipment and water-based formulations (Webb et al. 1990; Podgwaite et al. 1991). When applied according to label instructions, Gypchek can be expected to reduce healthy gypsy moth populations by 60 to 80 percent;

populations in decline are reduced by more than 90 percent (Podgwaite et al. 1992). In most cases Gypchek applications will prevent severe defoliation and the attendant physiological stress that is placed on trees when they refoliate.

Market Restrictions

Historically, Forest Service research has focused on developing products that support the needs of forest managers. Ideally, if the products are marketable, technology is transferred to private industry for commercial production. Viral pesticides for forestry do not fit that model. In the enthusiasm and heightened environmental awareness surrounding the development of viral pesticides, it was assumed that commercialization of these products would quickly follow. Unfortunately, that has not been the case. Since 1978 about 50,000 acres in the Northeast and mid-Atlantic have been treated with Gypchek, either through methods improvement studies, cooperative suppression programs, or eradication events (fig. 1). But the acres treated represent less than 1 percent of the total acreage treated for gypsy moth control during that period.

The original intent of the Forest Service research was to develop a product that could replace the broad-spectrum products that were being used for gypsy moth control, but it soon became clear that this goal was not realistic. First, gypsy moth NPV does not kill as quickly as other pesticides. This lack of

a “quick knockdown” is unacceptable to many resource managers, who are accustomed to seeing dead larvae one to two days after application of a chemical pesticide, and three to five days after application of *Bacillus thuringiensis* products. Nevertheless, because Gypchek is applied against early instar larvae, the amount of defoliation is comparable to that seen after the application of other pesticides. Second, the virus is environmentally fragile; half of its activity is lost through ultraviolet irradiation within 36 hours of its application to foliage even in the most protective formulation. Third, the high production costs have deterred development by the private sector.

As a result, the Forest Service has continued to manufacture Gypchek and make it available on a limited basis through state cooperative suppression programs. Unfortunately, this policy does not benefit those private landowners who would use the product but cannot participate in cost-share state cooperative programs. They cannot purchase Gypchek from the Forest Service because of regulations governing how cooperative suppression programs are funded. And there are policies that preclude the government from competing with industry for markets. Thus Gypchek cannot be used unless there is strong justification for not using commercially available pesticides—if, say, an endangered species is present, or a fragile habitat would be compromised by broad-spectrum pesticides. Clearly, these policies limit the availability of Gypchek to a narrow range of users. To be responsive to all clients and customers, particularly those in the private sector, some of these regulations need to be reevaluated and perhaps modified.

The Forest Service could withdraw from producing limited-market biopesticides altogether, an option that might be viewed as fiscally prudent by some but politically and ecologically unwise by others. The widespread concern for protecting ecosystems, endangered species, and threatened habitats remains strong and has earned broad public support. However, the agency has been hesitant both to guarantee markets to industry in the form of buy-back agreements and to provide

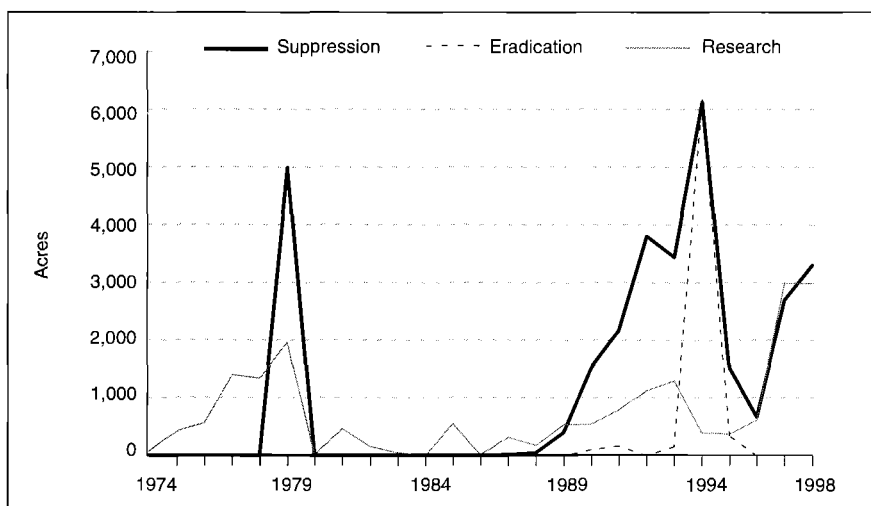


Figure 1. Acres treated with Gypchek. In addition to the treatments shown above, researchers conducted one-acre experiments in 1963 and 1972.

substantive start-up incentives to small companies interested in developing biopesticides. Given the high failure rate of those companies that have tried to develop a gypsy moth NPV product, that hesitancy is understandable. But without subsidies there will be little hope for the commercialization of limited-market products.

There is precedent for a user-pay approach to the federal development and marketing of a product. The APHIS boll weevil program is one: cotton growers pay 70 percent of the costs associated with eradication. Also, during the height of the gypsy moth outbreaks in the early 1980s, when Gypchek was in very short supply, the National Park Service and the Department of Defense offered to support production of Gypchek so that it would be available for use on their lands. But because at that time there was commercial interest in the development of a product, the offer was not seriously considered. Further, there are federally supported yet privatized organizations that sell products and services back to the taxpayers that support them (such as the Postal Service and Amtrak). To date, there have been few serious attempts to explore this approach, even on a small scale, to the federal development and marketing of biopesticides.

A Federal Option

It is time to consider that there are some environmentally valuable biopesticide products that industry will not produce no matter what the subsidiary arrangement because the markets are unstable. There is a need for a more formalized, less fractured approach toward developing these products and making them available to customers. Though some would argue that the government has no business being *in* business, strong consideration should be given to establishing and funding a biopesticide research and development center within the Forest Service or another USDA agency. Its mandate would be to research biopesticides and not only transfer technology to the private sector but also to develop, register, produce, and market those products that industry will not.

At present there are four separately funded organizations within USDA that

conduct or fund research on biopesticides: Forest Service Research, Forest Service State and Private Forestry, the Agricultural Research Service, and APHIS. Although these organizations cooperate regularly with each other on issues dealing with biopesticides, they are loosely linked and, though some would disagree, often competitive in work involving the development of biopesticide products. At the very least, the feasibility of bringing this function together administratively under a common mission should be studied.

The establishment of such a center would be particularly timely given the heightened awareness of the threat of invasion of US forests by exotic pests (US-OTA 1993; Wallner 1996). The recent expansion of world travel and the increased trade in logs and wood by-products have increased this risk. Some of these pests—the hemlock woolly adelgid (*Adelges tsugae*) and the pine shoot beetle (*Tomicus piniperda*)—are already established. Others, such as the siberian silk moth (*Dendrolimus superans sibericus*) and the nun moth (*Lymantria monacha*), if established, would pose a major threat to the health of the coniferous forests in the eastern United States. It is prudent to be prepared to combat the anticipated impacts of exotic invaders in environmentally sensitive areas with ecologically safe tactics like narrow host-range biopesticides. Because these pesticides likely would be targeted to small markets and be of little value as commercial products, they could be marketed on a user-pay basis and the proceeds returned to the biopesticide center to help support its activities.

Currently the Forest Service is making a major effort to be more responsive to *all* its clients and customers. A biopesticide research and development center would be another step in that direction.

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