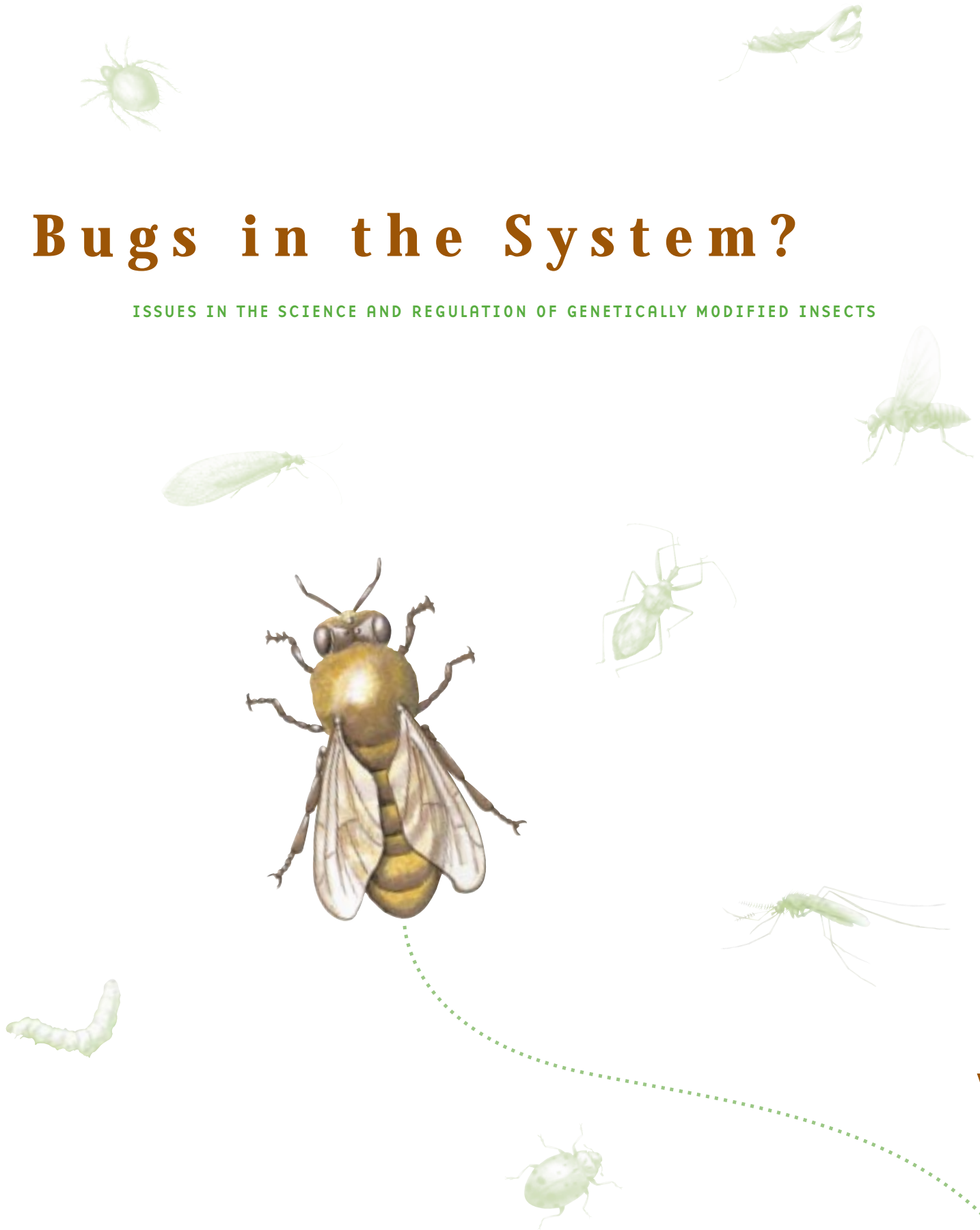


# Bugs in the System?

ISSUES IN THE SCIENCE AND REGULATION OF GENETICALLY MODIFIED INSECTS

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## Introduction

In October 2002, scientists reached a milestone with the simultaneous publication of both the genome of the parasite that causes malaria and of the mosquito species most responsible for its transmission. Many scientists saw this event as a significant step toward producing the malaria-resistant mosquito that had first been envisioned nearly twelve years earlier by the World Health Organization. Since that initial vision, scientists have made much progress—creating tools for stable transformation of mosquitoes and developing a mosquito unable to carry one type of malaria parasite. Scientists hope that they can start preliminary field tests on a malaria-resistant mosquito by the end of the decade and begin to determine whether or not it can actually decrease the spread of malaria.

But the application of genetic engineering to insects is not limited to malaria research. Scientists are currently working to develop a wide array of insects that could affect not only public health, but also crop production, animal health, and the quality of the environment. Some of the applications currently being researched include the use of genetically modified (GM) biological control organisms to control noxious weeds and insect pests, thus reducing the use of pesticides on agricultural, range, and forest lands. Furthermore, programs that use sterile insects to suppress pest insect populations could use GM insects to lower costs and improve effectiveness. Other applications include the use of GM silkworms to produce pharmaceutical or industrial proteins that are otherwise difficult and expensive to create. Honeybees, genetically modified to resist disease, parasites, and pesticides, could ensure our most important agricultural pollinator continues to thrive. The potential benefits of these products are enormous, but currently remain the subject of research rather than commercial realities.

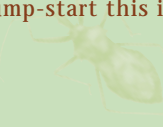
Many have estimated that it may be at least a decade before scientists are ready to conduct large scale releases of GM insects. But advancing research toward that goal has begun to shift the dialogue about GM insects from what is possible to issues of safety and ethics. With every research innovation, new questions arise about the implementation of GM insect programs, the potential effects they could have on regional and global ecosystems, and the capacity of public health systems to manage this innovation. For the potential benefits to be fully realized, these questions must be addressed.

Since the mid-1980s, it has been federal policy to regulate biotechnology products no differently than similar products developed in a conventional manner. GM insects pose challenges for regulatory agencies dealing with laws created with other products in mind and for purposes other than regulating biotechnology. To date, only the Animal Plant Health Inspection Services (APHIS) at USDA has issued regulations dealing with GM insects and those regulations are limited to potential plant pests. APHIS has announced intentions to regulate GM insects that transmit animal diseases, but has not yet produced those regulations. It remains to be seen how GM honeybees, some GM biological control organisms, or GM insects that reduce the transmission of human disease will be regulated.



Furthermore, in some cases, scientists are actually modifying insect symbionts—bacteria that live in close association with an insect—rather than modifying the insect itself. This practice is known as paratransgenesis, and while it offers enormous potential for controlling human, animal and even plant diseases, it will certainly pose unique challenges to the regulatory system.

*Bugs in the System? Issues in the Science and Regulation of GM Insects* outlines the development status of GM insects, the enormous potential benefits of these insects as well as the potential public health, environmental, and food safety risk issues associated with them. The report also examines the regulatory system and points out gaps in authority and areas where transparency, clarity, opportunities for public participation, resources and expertise, efficiency and coordination, or adequate risk management tools could be improved. If regulators and scientists want to have a clear set of rules in place by the time unconfined field testing is ready to occur, they will need to start discussions now, because it could take years to work out difficult regulatory issues, establish rules, and address international concerns. Furthermore, regulators will have many scientific questions they will need scientists to answer before they can make informed assessments of the risks posed by GM insects, and answering some of those questions will likely take several years as well. By presenting both scientific and regulatory issues regarding GM insects in this report, the Pew Initiative on Food and Biotechnology hopes to jump-start this important and necessary discussion.



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## Development, Status, and Potential Benefits of Genetically Modified Insects

Insects have an enormous impact on human and animal health as well as crop production. Each year, people spend billions of dollars on pesticides in an effort to protect their crops, animals, and health from pest insects. Where these efforts fail or where pesticides are not available, crop and animal losses can be severe and loss of human life from disease can be staggering. But insects also play valuable roles in the ecology of our planet. They act as recyclers of waste, function as prey and predators in the food chain, and serve as pollinators of natural flora. Furthermore, honeybees and silkworms produce valuable commodities that humans use every day or provide pollination services vital to agriculture.

Given the economic and human health importance of insects, it is not surprising that scientists are working to genetically modify insects to better serve the needs of humanity. To date, research is underway to develop GM insects that could dramatically improve public health, agriculture and commodity production. Examples include:

> **Mosquitoes incapable of transmitting malaria** – Malaria is spread by infected mosquitoes. Between 300 and 500 million people worldwide contract malaria each year, and between 1 and 3 million of those die from it. Countries where malaria is endemic also suffer enormous economic losses, including a 1.3 percent per year slower economic growth than other countries. To combat this disease, scientists are trying to genetically alter mosquitoes so they can no longer transmit malaria.

> **Kissing bugs unable to transmit Chagas' disease** – Chagas' disease is spread by infected kissing bugs. Between 16 and 18 million people are currently infected with Chagas' disease and nearly 50,000 die from it each year. Scientists hope to stop the spread of this disease by engineering a bacterium in the kissing bug's gut to kill the parasite that causes Chagas' disease as the parasite passes through the kissing bug's digestive system.

> **GM biological control insects** – Biological control, using living organisms to control pests, has been used for years. When biological control is successful, these programs can save millions of dollars in pest control costs and dramatically reduce the amount of pesticides applied. Scientists hope to improve insects used for biological control by increasing their chances to feed on weeds and pest insects through: longer life spans; resistance to disease, parasites and pesticides; increased reproductive capabilities; and tolerance to climatic differences.



> **Genetic control of pink bollworms** – The pink bollworm (PBW) causes hundreds of millions of dollars in damage to cotton each year throughout the southwestern United States. Currently, PBW are kept out of the San Joaquin Valley of California through a genetic control program, in which millions of male PBW moths, sterilized through irradiation, are released to suppress the reproductive success of wild females. Because of this program, the San Joaquin Valley experienced an estimated seven pounds per acre reduction in pesticide use. Scientists want to improve this program by engineering PBW to carry a gene that would prevent its offspring from developing—thereby reducing the need to sterilize through irradiation and decreasing the number of PBW moths needed to suppress the wild population.

> **Better bees** – Honeybees provide between \$1.6 and \$8.3 billion of pollination services and more than \$120 million of honey annually in the U.S. As pollinators, honeybees are essential to the production of crops that require insects to move pollen from one plant to another. Unfortunately, honeybees suffer from several debilitating diseases and parasites that have devastated their populations in the U.S. during the past decade. For this reason, scientists have been working to genetically engineer honeybees to make them resistant to diseases and parasites. Scientists also aim to make them resistant to certain insecticides to which they may be exposed while foraging among farmers' crops.

> **Silkworms as factories** – Researchers are looking into ways that silkworms can be made to produce spider silk that, because of its strength, could be used to make improved bulletproof vests, parachutes, and artificial ligaments. Silkworms can also produce pharmaceutical proteins. Many new medications rely on recombinant protein production, but production facilities are limited even as demand for them grows. With worldwide production of silk at 60,000 tons per year, silkworms could offer the pharmaceutical industry a viable option for bulk recombinant protein production.

With these potential benefits come questions about the impact transgenic insects could have on the environment, public health, agriculture, and food safety. All of these issues will need to be carefully considered before any GM insect is widely released into the environment.



## Environmental Issues

In 2002, the National Research Council (NRC) report concluded that a primary factor in the potential of GM animals to cause ecological harm is the ability of a GM animal to become established in the environment. The NRC Committee named insects as one of the taxonomic groups posing the greatest environmental concerns because insects have all the attributes that would allow them to establish in the environment, including the ability to escape containment, disperse, survive in the wild, and reproduce. If established, GM insects might disrupt ecosystems by displacing other insects, changing predation patterns, consuming native flora, or passing their modified traits to wild relatives, among other possibilities.

The concerns of the NRC illuminate one of the unique aspects of some GM insects. Unlike GM plants, which are intended to grow in a managed environment, many GM insects will have to be established in the native environment in order to work. For example, GM biological control insects will not work unless they remain in the environment long enough to control the target pests. Once released, however, GM insects will be difficult, if not impossible, to recall and could have regional and global ecological impacts that would need to be assessed on a case-by-case basis.

The traits altered through genetic engineering will influence how well a GM insect can survive in the environment. For instance, the traits that would be targeted for genetic engineering in biological control insects include longevity, reproductive abilities, disease or pesticide resistance and temperature tolerance. These are the very traits that would increase the potential for a GM insect to become a pest. For example, if beetles used to control a noxious weed were altered to withstand colder temperatures, the beetles could possibly move into new ecosystems, push out native insects or consume plants other than the targeted noxious weed.

Once released into the environment, GM insects could pass their modified traits to wild relatives or other organisms through gene flow. This could occur through normal reproduction (vertical inheritance) or through means other than sexual transmission (horizontal gene transfer). Vertical gene flow is limited to insects that can mate and produce fertile offspring. Horizontal gene flow is not limited to reproductively compatible species and allows for transfers across taxonomic kingdoms.

The impact of vertical gene flow from a GM insect to its related wild relative would vary greatly on a case-by-case basis. The primary ecological concerns surrounding gene flow are the creation of pest species or the disruption of ecosystems. For example, if a GM insect altered to be disease-resistant passed that trait to a related insect, the receiving insect could have an advantage in survival and adapt to new ecosystems where it could not previously live.



Generally, gene flow between GM organisms and sexually compatible relatives is undesirable and must be controlled. For some GM insects, like the mosquitoes incapable of transmitting malaria, which are intended to replace their wild counterparts, scientists will need to promote gene flow. To do this, scientists may take advantage of horizontal gene flow through “transposons,” pieces of DNA that have the ability to move from location to location within a genome and can carry other DNA with them. By linking the desired transgenes to an active transposon, researchers should, theoretically, be able to “drive” the transgenes into the wild population, essentially spreading the transgenes faster than would normally occur. It will be virtually impossible, however, to recall those drivers or undo any unintended consequences once GM insects are released.

In addition to potentially using transposons as drivers, scientists already use them to genetically modify many insect species. Researchers know that transposons sometimes escape their hosts and move to new ones. If this happened with a GM insect, it could, in theory transfer DNA from a GM insect to a non-GM organism which may or may not be related to the GM insect. In turn, if the transferred DNA functioned in the receiving organism, problems might occur. For example, if a GM insect designed with pesticide resistance genes passed those genes to a pest insect, the pest insect could become more difficult to control. Scientists are still investigating the frequency and mechanisms of horizontal gene transfer, so quantifying the risks associated with this phenomenon is difficult at this time.

Though hypothetical, all of these examples demonstrate the potential environmental risks that GM insects could pose. Careful thought about the best ways to manage these risks will have to occur before any GM insects are released.

## Public Health Issues

Using biotechnology to create insects that no longer transmit diseases like malaria or Chagas’ disease could solve some public health concerns, but it could also create new ones.

Individuals infected with malaria are somewhat immune to the disease for a year or more after infection, but they must be re-infected each year to maintain that immunity. Exposure to mosquitoes that carry malaria is how re-infection occurs and immunity is maintained. If malaria-resistant mosquitoes were released and the incidence of malaria consequently decreased, the level of immunity in the population would also drop because re-infection would be less likely. Consequently, if malaria-resistant mosquitoes ceased to function properly, humans could be susceptible to outbreaks even more severe than if disease transmission had never been interrupted.

To address this potential hazard, scientists would have to ensure that the mosquitoes remain disease-resistant once they are released into the environment. But biological systems are ever changing and adaptable, and it is difficult to predict the stability of transgenes or their usefulness in a dynamic population over many generations. Scientists will have to address many issues like this before it can be determined that public health is, in fact, improved by the release of GM insects.



## Food Safety

Some of the most persuasive arguments in support of GM organisms relate to the potential benefits they offer to improve the safety of the food supply. Because insect pests can reduce yields or damage crops, resulting in the annual loss of billions of dollars of crops in the U.S., producers often turn to chemical pesticides. The EPA estimated that approximately 82 million pounds of insecticides and 470 million pounds of herbicides were used in agriculture in 1997, and it is very likely some entered the food supply as residue. Additionally, farm workers are often exposed to pesticides during food production. One way to reduce pesticide use is to utilize living organisms to control pest insects and weeds through biological control programs. Insects that could be genetically modified to be more efficient biological control organisms offer improved tools to reduce pesticide use and, consequently, help ensure a safer food supply.

While the use of some GM insects in agriculture could reduce reliance on pesticides, other transgenic research will necessitate an examination of food safety risks. For example, most of the traits being considered for alteration or addition in the honeybee are not directly related to honey production. Instead they focus on making the bee resistant to pesticides, parasites, and diseases. While there is no reason to think these kinds of changes will alter the honey produced, the public will want to be assured there are no unintentional effects to honey due to the genetic modification process.

## Social Issues

Despite the obvious humanitarian benefits GM insects could provide, the public may have concerns about the application of genetic engineering to insects. A poll conducted by the Pew Initiative on Food and Biotechnology in August 2003 suggested that the American public is less comfortable with the notion of genetically engineering insects than crops. As GM insects move from the lab to the field, some effort will have to be made to address public concerns. The unique use of GM insects may garner unusual questions from the public.

While GM insect research may be applied in the U.S. for agricultural pest control, much of the research being conducted on insects that transmit disease is ultimately intended for many tropical and sub-tropical countries. The use of GM insects for disease control will offer many challenges for the individual nations involved. The government and public of those countries will need to decide whether the technology is appropriate for their specific circumstances. Because some GM insects will be intended for permanent establishment and dispersal into the environment, however, the choice of any one nation could well affect all of its neighbors, if not the world.

If the public is to support the introduction and release of GM insects, it will need assurances that the issues these insects raise regarding the environment, public health, agriculture, society and food safety, have been carefully considered. In the United States, the public has a history of looking to its regulators and the regulatory review process for such evaluation. It is therefore important to clarify which bodies can manage a review of GM insects, the laws that would guide such review, and to identify any gaps in the regulatory system that may need to be addressed before a wide release of GM insects takes place.





## Regulation of GM Insects

Since 1986, biotechnology products have been regulated according to the Coordinated Framework for Regulation of Biotechnology, a federal policy that directs three principal agencies—the Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency—to coordinate the evaluation of biotech products using existing laws. This framework remains federal policy, despite the fact that the laws the agencies must use: were enacted prior to the development of many biotechnology products, reflect widely different regulatory approaches and procedures, and have required the agencies to engage in creative and expansive interpretation to cover some biotechnology products. GM insects do not fall neatly into a pre-existing product category and will challenge regulators to determine which agency should lead the regulatory review and what laws should be relied on to ensure the many questions raised by GM insects are adequately addressed.

One way to evaluate the regulatory system is to examine how it measures against four elements often thought to be part of an adequate regulatory review:

- > Whether or not an agency has the legal authority to evaluate a GM insect;
- > If a particular law gives that agency all of the tools needed to manage perceived risks;
- > If the process for reviewing a GM insect is transparent, clear and allows for public participation; and
- > Whether or not an agency has all the resources and expertise needed to conduct an adequate review.

Following is an overview of the legal authority that the federal agencies could arguably use to oversee GM insects and a discussion of the adequacy of the regulatory tools available to the agencies. There is also some discussion of issues unique to GM insects, including coordination of international laws and organizations, which regulators may also have to address.

### *Legal Authority*

All transgenic and paratransgenic insects could come under the authority of one or more agencies, but the scope and standards of legal review that could be used vary widely. In fact, any one of the following five statutory authorities could apply to transgenic insects: the Plant Protection Act (PPA) and the Animal Health Protection Act (AHPA), administered by the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS); the Federal Food, Drug and Cosmetic Act (FFDCA), administered by the Food and Drug Administration; and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA), administered by the Environmental Protection Agency.

#### *USDA*

Under the Plant Protection Act (PPA), APHIS has broad authority to regulate plant pests to protect crops and other plants. APHIS has issued regulations that set out notification and permitting requirements for field trials and environmental releases for GM organisms that are or could be plant pests. It is under this authority that APHIS has issued permits for field trials of GM insects, although jurisdictional questions still remain regarding how APHIS treats GM insects versus other biological control organisms.

The AHPA provides APHIS authority to act against the spread of livestock diseases and pests, including insect-borne diseases. Because insect pests that transmit livestock disease are subject to regulation by APHIS, the agency could use the authority under AHPA to develop a regulatory permit program for GM vectors of livestock disease. APHIS has indicated that it is developing such regulation, but has not yet published proposed rules.

While these authorities give USDA authority over a broad range of GM and paratransgenic insects that could affect plant and animal health, they do have limitations in the kinds of risks that can be considered. APHIS does not have the authority to act on the basis of concerns not relevant to its specific legal responsibilities for preventing and controlling the spread of plant pests, and preventing or containing diseases and pests that might harm livestock. Broader risk concerns, such as risks to wildlife or human health, would be outside the scope of these authorities.

#### *FDA*

The Federal Food, Drug and Cosmetic Act (FFDCA) gives FDA several possible jurisdictional claims for authority over GM insects and related microorganisms. Under FFDCA, new animal drugs must be approved as safe and effective before they can be marketed. FDA has informally asserted that the genetic construct used to genetically modify animals, as well as the “expression products” in the animal, are within the definition of “drug.” Because insects are animals, FDA could presumably assert its jurisdiction over GM insects. If FDA were to apply its interpretation of the new animal drug approval provisions of the FFDCA to insects, FDA’s jurisdiction would arguably apply to all GM insects, regardless of their intended use. FDA’s interpretation of the new animal drug provisions of FFDCA as applying to the genetic modification of animals expands the boundaries of the definition of animal drugs.

While FDA has authority under FFDCA to consider the safety and effectiveness of animal drugs, including their indirect health impact on humans, it is unclear whether FDA can consider potential environmental risks. FDA has asserted that, in examining the safety of a new animal drug under the FFDCA, the agency is permitted to consider environmental impact that could indirectly result in harm to humans or animals. It is uncertain, however, if FDA could look at purely ecological risks that could stem from gene flow from GM animals.

Other provisions of the FFDCA may give FDA additional authority for reviewing some types of GM insects. For example, the FDA might consider insects, designed so they can no longer carry diseases, as human drugs or drug delivery devices. FDA would also have the authority to review the safety and efficacy of any human pharmaceuticals produced by a transgenic insect. Finally, FDA could assert authority over a GM insect modified to produce a protein that would cause an immune system response in humans who are bitten.

#### *EPA*

EPA has two potential legal authorities that could be applied to regulate GM insects: the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Though FIFRA gives EPA authority to regulate pesticides, EPA has previously disclaimed authority over most biological-control organisms used to control pests except for certain microorganisms used as “bio-pesticides.” Following this precedent, EPA might not assert authority over transgenic

insects under FIFRA, but might instead choose to assert authority over paratransgenic insects under TSCA as “new” chemical substances. EPA has historically regulated microorganisms modified through rDNA techniques. An FDA decision to regulate GM insects as human or animal drugs, however, would preclude EPA from using either FIFRA or TSCA to regulate GM insects, because substances that are regulated as human or animal drugs are specifically excluded from regulation under FIFRA or TSCA. While EPA has claimed that TSCA gives it authority to regulate higher level organisms, such as GM animals or insects, it is not certain that EPA legally has this authority under TSCA. Furthermore, because TSCA is limited to substances “with a commercial purpose,” EPA may not be able to regulate those GM insects developed for non-commercial purposes. To date, most GM insects are being developed by the public sector for non-commercial purposes.

### *Adequacy of Risk Management Tools*

#### *USDA*

APHIS has a broad range of tools with which to regulate GM insects that fall within its jurisdiction. APHIS can impose conditions on field trials or general release through its permit process under the PPA. APHIS has the authority to withdraw a permit application if there is non-compliance with the permit conditions. APHIS also has broad statutory authorities to prevent the dissemination of a GM insect that is a plant pest, including the authority to hold, seize, quarantine, treat, destroy or otherwise dispose of new plant pests, including declaring an extraordinary emergency.

APHIS has broad statutory authorities to address livestock pest and disease risks. Because APHIS has not established a permit program to date for GM insects that are vectors of livestock diseases, there is currently no way to address specific risks from these insects.

#### *FDA*

The drug approval provisions of the FDCA are broad, flexible and afford the FDA a great deal of authority before and after product approval. FDA can impose labeling and use restrictions as part of its approval and requires developers to report adverse events.

Though FDA is not required to approve new whole food varieties before they can be marketed, FDA has the authority to enjoin the sale and distribution of foods that cause harm. How FDA would apply its food safety authorities to honey or other food products from GM insects, however, is unclear.

#### *EPA*

Under TSCA, EPA reviews “new” microorganisms and imposes measures necessary to prevent unreasonable risk to human health and the environment. EPA may regulate when there is insufficient information to determine whether the microorganism may present such a risk. EPA is required to evaluate both the costs and benefits of the new microorganism as well as the economic effects of regulation.

Under FIFRA, EPA reviews pesticides for potential impacts on human health and the environment to ensure that they do not impose unreasonable risks. EPA requires registration of pesticides and can impose restrictions or conditions on the use of such products. EPA may also suspend or cancel registrations and can force a recall of a pesticide. Other than for dietary exposures, EPA is required to balance the costs and benefits of a pesticide in its assessment of the product.



## *Transparency, Clarity, and Public Participation*

### *USDA*

The APHIS process for regulating GM plant pests is generally accessible to the public. While the amount of confidential business information (CBI) in applications for GM plants has been criticized in a recent National Academy of Sciences review, so far, the developers of GM insects have not extensively deleted information from their applications as CBI. APHIS has solicited public input as part of the NEPA process, both for environmental assessments, as well as through the decision to pursue an environmental impact statement for the field release of GM pink bollworms.

### *FDA*

The FDA new animal drug approval process is a closed process that allows little transparency, clarity, and public participation in FDA's decision-making process. Because the process is entirely confidential and designed to protect trade secrets and confidential business information, there is no opportunity for public participation. The public is not even aware that an application for a new animal drug has been made until FDA announces its approval and releases a summary of the data the agency has examined. Because the new animal drug process effectively limits transparency and public participation, it could undermine public confidence in the decision-making process.

### *EPA*

Under both TSCA and FFDCA, the public would have access to information about GM insects in the regulatory pipeline and would be afforded an opportunity to provide input into the agency's decision making process.

## *Resources and Expertise*

### *USDA*

APHIS has extensive expertise to assess risks from insect plant pests and insect-borne livestock diseases. While APHIS has the appropriate expertise to assess threats to crops, some have expressed concern that its ability to review permit applications and to inspect field trials to ensure compliance with permit requirements is constrained by limited resources. A recent review of APHIS's ability to respond to threats from traditional plant pests that are frequently unintentionally imported into this country concluded that APHIS's resources are already stretched thin to monitor and act against such threats.

### *FDA*

FDA clearly has the expertise to address human health and food safety issues. It may not, however, have the expertise to assess the full range of environmental effects that could arise from the release of GM insects, including, for example, risks to plants—an expertise housed in other agencies like APHIS or the Department of the Interior. Moreover, while FDA has a regulatory program in place for plant-based biotechnology that could form the basis for a GM insect regulatory program, FDA may need additional staff and resources, including field personnel, to develop an effective regulatory program for GM insects.



## *EPA*

EPA has expertise relative to environmental and human health risks, but it may not have expertise relative to animal health risks presented by GM insects. Since EPA does not have a regulatory program in place for GM insects, there would need to be an infusion of funding and staff in order to establish a credible regulatory program.

## *Unique Regulatory Issues*

Whichever agency and statutory authority are ultimately used to review GM insects, several unique factors will have to be addressed and it is not clear how the Coordinated Framework will accommodate such concerns.

Much of the work in the area of GM insects is being done for public health or public agricultural purposes by federal researchers or university scientists who have little familiarity with formal government regulatory processes. These researchers will need advice on how to guide GM insects between the stages of laboratory research, field trials, and release. Unfortunately, the laws the agencies use to regulate biotechnology are primarily concerned with approval of commercial products, and their application to non-commercial products may not work as well.

The mobility and size of GM insects are such that these particular products of biotechnology would be difficult to recall once they are released. Furthermore, the success of many GM insect programs requires that the desired trait be “driven” into the wild insect population. Therefore, the decision to release GM insects may need to be weighed more heavily than decisions to release other biotechnology products that were not intended to be established in the environment.

Because the greatest potential benefits of GM insects in disease prevention will be found in nations that have the highest incidence of such diseases, the procedures for approval and testing GM organisms in other nations will eventually come into play with GM insects. While the International Plant Protection Convention and the Cartagena Protocol on Biosafety could be used to address GM insects, it is also likely that new international regulations could be developed. It will be difficult for the U.S. to help guide the development of such international policies if domestic regulatory policy has not first been clarified.



## Summary

In summary, the application of biotechnology to insects and their symbiont microorganisms could provide numerous benefits. GM insects could enable mankind to better control insect-borne diseases in humans and livestock, create more efficient biological and genetic control insects, reduce pesticide use for disease and pest control, create pharmaceutical proteins from insects, and protect honeybees from diseases and pests. But the creation of these new organisms raises numerous questions about the safety of the environment, public health, agriculture, and food supply. To facilitate the movement of GM insects from the laboratory to the field, U.S. regulators need to clarify how they plan to address these questions and advise scientists on large scale releases.

With respect to the U.S. regulatory system, the policy issue presented by GM insects is not so much the lack of legal authority as it is whether existing legal authorities will be used in a coordinated way to ensure an adequate regulatory review of risks. Without such clarification, it is difficult for the public to trust the safety of GM insects, and scientists have little to guide their activities. Lastly, U.S. regulatory policies will be an important building block in the development of international policies regarding GM insects; but it will be difficult for the U.S. to help guide such development without a clear regulatory approach.

The lack of a clear federal regulatory framework does not suggest an imminent risk. At the moment, most work remains at the laboratory research stage, and in the event that a field test were required, some federal agency likely has the authority to review it. Moreover, at present, only a few hundred researchers worldwide work on transgenic insects. Their work, however, will eventually reach the field trial stage, and shortly thereafter, experimental releases will have to be considered. Therefore, the federal government needs to move deliberately, and quickly, to clarify how it intends to address the regulatory issues posed by GM insects.



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