

Integrating risk management and risk communication into a risk assessment of a Medfly eradication project in California

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Abstract

Health officials are increasingly recognizing that a successful approach to assess and manage health-related issues associated with human exposure to environmental chemicals is to integrate risk assessment, risk management, and risk communication procedures in an overall process to address the specific concerns. The way that risk assessment, risk communication, and risk management were integrated into one project, particularly with the use of an external advisory committee, is described in this article. In 1990, the California Department of Health Services (DHS) evaluated the public health risk of the aerial application of a malathion-bait mixture for eradicating a Mediterranean fruit fly (Medfly) infestation in the greater Los Angeles basin. The department had performed a risk assessment in 1980 on a similar eradication project and had conducted several related epidemiological studies, all of which indicated no adverse health effects from the aerial spraying. However, due to continued concerns about public health and at the request of the executive and legislative branches of state government, DHS prepared a new risk assessment that incorporated review of new scientific studies and the latest risk assessment techniques. As it had done with excellent results in 1980, DHS again convened an external advisory committee. The committee's primary purpose was to provide oversight and quality assurance of the risk assessment, but it also became a forum for risk communication and risk management recommendations.

1. Introduction

In July and August 1989, fertile Mediterranean fruit flies (Medflies) were discovered in Los Angeles, California, and a 14-month-long eradication effort was initiated by the

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California Department of Food and Agriculture (CDFA), which is the California state agency responsible for pest eradication. Aerial spraying of malathion mixed with protein bait was conducted in 21 treatment locations encompassing 536 square miles in Los Angeles, Orange, San Bernadino, and Riverside counties. This area has approximately 1.6 million residents. Up to 11 aerial applications were made in some areas during the 14 months the eradication lasted.

The threat of the Medfly becoming established in California is taken seriously. In Hawaii and in countries where it is endemic, the Medfly has caused major economic damage to many commercial crops. The female Medfly deposits its eggs in ripe or ripening fruit; maggots and bacteria introduced in this process turn the fruit into a rotten mass [1, 2]. Because it would be well adapted to the Mediterranean-type climate found in California, the Medfly is assumed capable of causing similar damage to crops there. CDFA estimates that its permanent establishment in California would result in approximately \$234 million in crop loss, \$48 to \$334 million in additional costs to fumigate produce, and \$100 million in lost export sales [1].

Malathion is a widely used pesticide and has been used since 1956 in eradication against exotic fruit flies [2]. Malathion exerts toxicity by inhibiting cholinesterases that are involved in nerve signal transmission. It is effective against insects at low doses yet poses little health risk to humans at the same doses because of pharmacokinetic differences between insects and mammals [3]. Despite the relative safety for humans, the prospect of widespread application by airplane over a densely populated and urban area causes much controversy. This happened during the 1980–1982 Medfly infestation in San Jose, California [4]. After fruit stripping and ground applications of malathion failed, a technical advisory committee then recommended that the infested area be treated with six aerial applications of malathion applied at a rate of 2.4 fluid ounces per acre mixed with bait. The public strongly opposed the aerial spraying, and had their fears further aggravated by alarming stories in the press of unproved claims about adverse health effects of malathion.

The Department of Health Services (DHS) immediately conducted a risk assessment of the aerial application project and concluded that this program presented no risk of acute toxic effects or of mutagenic or adverse reproductive effects [5]. Although there was no evidence that malathion is carcinogenic, DHS calculated the risk of cancer just to assume the worst case. It found the risk to be negligible.

Nevertheless, public anxiety became so high that literally thousands of calls were received at the information hotline each day from residents concerned about possible health effects and seeking information on protective measures they should take. To lessen the anxiety, the DHS director convened an independent expert health advisory committee [3, 4] that included community clinicians, scientists, and academic physicians including two who had prominently opposed the aerial spraying. They all agreed that the project posed no significant threat to public health. Their pronouncement, along with their recommendations that studies be performed to ascertain whether the project caused any acute or adverse reproductive effects in the exposed population, greatly eased the public's anxieties and positively influenced the media's coverage.

During the eradication campaign, DHS conducted several surveys to assess the acute health effects of the eradication program: three were indirect attempts to assess utilization of health care services; two surveys analyzed self-reported symptoms before and after the initial aerial applications; and two epidemiological studies looked at reproductive effects. None of these studies showed any correlation between exposure and adverse effects from malathion-bait application [6–8].

The 1989–1990 aerial spraying campaign again provoked public opposition. Urban residents felt that they were being asked to accept risks to their health for the benefit of commercial agriculture and that their civil rights were being trespassed on. The specter of helicopters low-flying in formation spraying a poison created fearful images associated with warfare. The declaration of emergency powers seems to conflict with normal democratic processes of local autonomy. Public fears were further intensified by unscientific claims about health effects, dramatic anecdotal reports of illness in the media, and by what appeared to be an unresponsive government. CDFFA attempted to assure residents that the malathion application presented no health hazard, but without a strong risk communication campaign, city and county governing board sessions, and even an unusual meeting of the state Assembly Committee of the Whole, became platforms for confusing messages to be voiced about potential health effects. Although DHS had assessed the risks of malathion and conducted health surveys in 1980–1981, that risk assessment was 10 years old, and seems to be outdated. Given such public fear and opposition, the Governor and the Legislature thus called on DHS to again independently assess the health risks.

2. The Malathion Public Health Effects Advisory Committee (MPHEAC)

The success of using an outside committee of experts in 1981 led DHS to repeat this in the 1989–1990 eradication program. DHS convened the Malathion Public Health Effects Advisory Committee (MPHEAC), which comprised 25 members from southern California chosen for their medical and scientific expertise, their position as local public health officials, or their involvement in environmental organizations. Some members resided in the treatment zone. The committee was asked to advise DHS staff on public health issues and provide objective scientific review of the risk assessment. It was further charged to provide a forum in which scientific and public health concerns could be discussed and to review and comment on CDFFA's risk communication efforts [3].

DHS and the MPHEAC worked under the assumption that there would be public health and economic consequences if the Medfly became established in California. CDFFA maintained that if the Medfly became established in California, more pesticides would be needed to control damage to commercial crops and home gardens. For example, CDFFA estimated that farmers in California would have to apply malathion-bait or other pesticides routinely to their Medfly-susceptible crops, thereby increasing malathion usage by at least 140 000 pounds, active ingredient, yearly [2]. This would possibly result in much higher exposures of pesticide applicators and farm workers, as well as expose other workers to fumigants needed for exporting

produce [9]. Backyard usage of pesticides would also increase by about 2.2 million pounds, and organic farming in California would virtually be destroyed. Overall, there would be increased costs and lower quality fruits and vegetables for California consumers, CDFA stated. Although CDFA's figures were questioned, they were never refuted. Nevertheless, DHS staff and the MPHEAC took the position that public health was its main concern, not protection of agriculture.

3. Risk assessment objectives and conclusions

For the new health risk assessment, more than 30 DHS staff scientists and physicians evaluated nearly 2300 citations dating back to 1966 and specifically reviewed over 500 of them. This review also considered the active metabolite, malaoxon.

DHS also made use of the significant advances in risk assessment methods. For example, DHS assessed exposures to determine external and effective internal doses of malathion that might be received under 25 different exposure scenarios, taking into account different activities and routes of exposure. DHS then calculated exposures, including factors such as consumption of untreated backyard fruits and vegetables and working outdoors all day where there would be physical contact with treated surfaces.

The risk assessment was completed in February 1991, several months after the eradication program ended. It concluded that malathion, as used in the eradication project, would not cause cancer, birth defects, reproductive damage, or eye damage. It found, however, that under certain high exposure circumstances there were less than desirable margins of safety (<100) for skin irritation and lowered levels of cholinesterases, which are necessary for proper nerve signal transmission.

DHS stated, as it did in 1980, that the anxiety caused by aerial spraying is itself a public health effect, and efforts should therefore be made to find less invasive alternatives.

A risk assessment report was issued along with a 27-page summary report [3, 9]. The summary gave the main findings of the risk assessment as well as information on the Los Angeles County Health Department studies, research on alternative methods to handle Medfly infestations, and ways the public can help to prevent future infestations. A summary of the main toxicological endpoints, including a comparison of human exposures, is presented in Fig. 1, taken from the summary report.

Although the report was not completed until after the eradication project ended, the risk assessment procedure was in itself a continuing process to identify whether there were any unacceptable risks or hazards. If DHS had identified a potential for any such risks or hazards, it could have asserted a risk management stance and recommended steps to modify the eradication program or stop the aerial spraying.

4. Government and public involvement

DHS's performance of the risk assessment needs to be seen in relation to other entities. The Medfly eradication project included four counties and involved

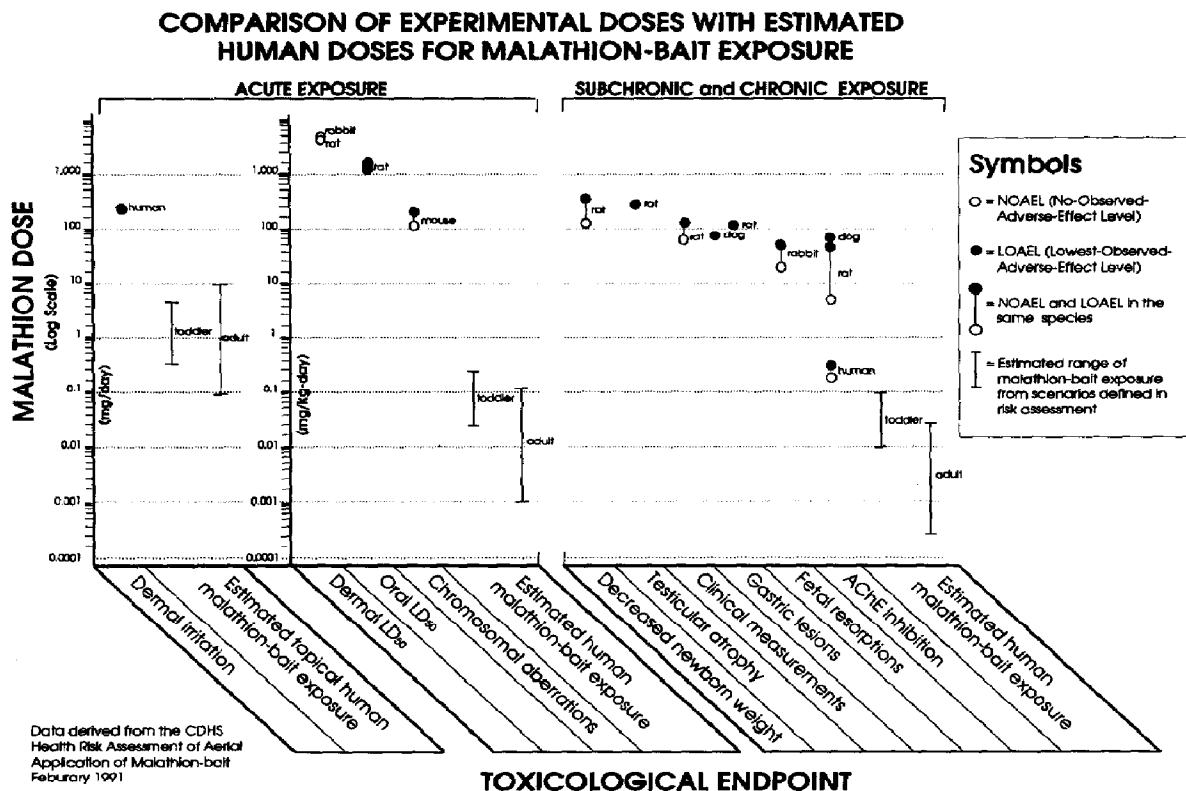


Fig. 1. A comparison of experimental doses for different toxicological endpoints with human doses for malathion-bait exposure was provided in the summary report on the health risks of the aerial spray program.

numerous local, state, and federal entities (Table 1). While there was strong initial local opposition to the eradication project, only a few cities took formal action to try to block the aerial spraying. The city of Pasadena, for example, enacted an ordinance against helicopters flying low overhead in formation. These efforts were unsuccessful, however, because of the state of emergency declared by the governor under federal authority. CDFA representatives met with city and county governing boards to explain the purposes and methods of the eradication program, but were not always successful in mollifying the opposition.

In the early stages, city and county health departments in the area were highly active in community outreach, particularly the Los Angeles County Department of Health Services (LACDHS). LACDHS mailed technical information to local physicians, hospitals, veterinarians, and day care centers about malathion, and established a health information number for individuals who called the CDFA hotline with health-related questions or complaints. Records of these calls were logged and analyzed. The department also conducted several independent studies, including one on asthma patients and others using urine analyses and skin patch tests on volunteers from among the individuals who reported health problems [9, 10]. The Orange County Health Department also included some questions on health effects in a

Table 1

Agencies involved in the 1989-1990 Medfly eradication program in southern California

Agencies	Program-related responsibilities Activities during program
<i>Federal agencies</i>	
US Environmental Protection Agency	Registers pesticides nationwide Assesses the toxicity of malathion Requires and oversees pesticide tests
US Department of Agriculture	Administers federal pest eradication programs
<i>California state programs</i>	
Department of Food and Agriculture	Pesticide registration and enforcement ^a Conducted the eradication program Provided public information on the program
California Department of Health Services	Public health oversight on pesticides ^b Assessed health risks of the program Prepared to contribute risk management advice Informed public about health risks
Malathion Public Health Effects Advisory Committee	Advisory committee to Department of Health Services ^c Held 14 public meetings on malathion risk Made independent recommendations
<i>Local agencies</i>	
County and city health departments ^d	Public health programs Issued health information locally Conducted health studies
City councils	Local government Held public hearings Some tried to prevent aerial spraying

^a In 1991 pesticide registration was taken over by the California Department of Pesticide Regulation.

^b In 1991 risk assessment activities regarding pesticides were transferred to the Office of Environmental Health Hazard Assessment.

^c Although established by DHS, members were from outside state government.

^d In California counties are the usual jurisdiction for providing public health programs, but a few cities also have their programs.

regularly conducted wellness survey to determine whether there was an increase in certain symptoms in spray areas in that county [9].

Local public health officials employed knowledge of their localities in advising CDFA not to conduct aerial applications in certain areas on nights when special events were planned, such as outdoor graduation ceremonies and ball games.

At the state level, CDFA conducted, in coordination with the US Department of Agriculture (USDA) and county agricultural officials, malathion-bait spraying, sterile Medfly release, and insect monitoring activities that constituted the eradication program. (Due to lack of sufficient sterile flies, CDFA had to repeat aerial applications of malathion-bait as many as 11 times. Rearing facilities for sterile flies have subsequently been increased to more than 500 million flies per week. If sufficient sterile

flies are available, CDFA says only one or two sprayings at most would be needed for similar eradication efforts in the future. Aerial applications will still be sometimes necessary to suppress the initial infestation, CDFA maintains.) Before each aerial spraying, CDFA notified the media and provided notices to every household in the treatment area advising citizens of the date and times of spraying. The notices included precautionary guidelines such as staying indoors during the spraying, covering cars to protect paint, and covering up pet dishes. Information hotline phone numbers were also included.

On the federal level, the US Environmental Protection Agency (EPA) had already reviewed the toxicity of malathion and is responsible for ensuring that required toxicity tests are carried out for malathion's registration as a pesticide [11]. USDA has carried out Medfly eradication projects in other states and has prepared an environmental impact statement on this subject [12]. In April 1993, CDFA certified the final programmatic environmental impact report on 'The Exotic Fruit Fly Eradication Program Utilizing Male Annihilation and Allied Methods.'

Citizen groups also participated actively. Several citizen groups strongly opposed the aerial spraying. One claimed to have logged more than 30 000 calls from concerned people, including many reports of health complaints; however, they refused to let DHS staff or the MPHEAC verify these records, even if the names of the callers were kept anonymous [13]. On the other hand, groups representing farming interests waged a media campaign in support of the eradication program and emphasized its safety.

5. Integration of risk assessment, risk management, and risk communication in the MPHEAC

The MPHEAC became an arena for integrating risk assessment, risk management, and risk communication recommendations. The committee members provided valuable insights and suggestions on the risk assessment. Representatives from CDFA attended several meetings to discuss management aspects of their eradication program, and a CDFA medical officer was consistently present to maintain liaison.

The MPHEAC meetings provided a platform where the public could observe the risk assessment work, and make their views known. During the 14 meetings that were held, DHS staff publicly briefed the MPHEAC on the many scientific aspects of the health risk assessment, and discussed issues. Citizen activists were present at virtually all these meetings. This open forum was invaluable for establishing the scientific credibility of the process. Opportunities for questions and for submission of scientific evidence were always provided to the audience at the end of the meetings.

While the MPHEAC meetings did allow the public to view and, in a limited manner, participate in evaluating the health effects of the eradication program, this process was not always smooth. For example, an organized group of protesters interrupted the scheduled scientific presentations at one early meeting and demanded that their health complaints be heard and that the spraying be stopped until all health issues had been settled. In another instance, an ophthalmologist from a local

university raised an alarm about potential eye damage. He noted the reports of eye damage in Japan that occurred during the 1970s where pesticides had been applied aerially and that people with certain eye disorders are already being treated with organophosphate pesticides that are much more potent than malathion. In both cases, television news reporters were tipped off that there would be something controversial to cover at the meeting, and they came with cameras and crews. The MPHEAC and DHS staff were not able to respond until after the TV cameras were gone. In the first instance, the MPHEAC members answered that on the basis of the scientific evidence they had reviewed thus far, a recommendation to halt the spraying was not warranted. In the second case, the MPHEAC formed a subcommittee to analyze the eye damage issue and later produced a consensus statement declaring that the findings of eye damage in Japan are not applicable to the kind of pesticide exposure that would occur in the Medfly eradication project [3, 13]. Similar subcommittees were formed for the issues of carcinogenicity and risk communication.

6. Lessons learned and future commitments

Having an expert body oversee the health evaluation no doubt calmed fears and raised the public's confidence. Not all the objectives set for the MPHEAC were accomplished in the time available, however. For example, a full toxicological evaluation of alternatives to malathion was not possible. Some other desirable goals were also not met, such as conducting epidemiological studies during the time that the aerial applications were taking place, including the use of biomonitoring methods to determine exposures. Some of these objectives form the basis of future commitments described below.

In October 1991, a symposium was organized by DHS to bring together state and local agencies and other interested parties who participated in the Medfly eradication episode to assess how the project was conducted, identify future needs, and discuss ways of integrating interdepartmental efforts and public involvement [14]. The recommendations that came out of that meeting and those given by the MPHEAC report provide a basis for the following discussion.

6.1. Risk communication

It has been clear that a pest eradication program that involves large-scale aerial spraying of a pesticide in residential areas is bound to arouse public anger even if it poses minimal risk. Urban residents feel that they are being asked to accept risks to their health for the benefit of commercial agriculture. The declaration of emergency powers seems to trespass on normal democratic processes of local autonomy. In this atmosphere, public fears will be intensified when unscientific claims are made about the health effects of the pesticide, when dramatic anecdotal reports of illness appear in the media, and when government seems unresponsive. There needs to be a dependable and trusted authority that the public and media can turn to for information and for interpretations on controversial health issues. CDFA, which was the lead agency

for risk communication, could be seen to be allied too closely to agricultural interests.

DHS attempted to gain public confidence by promising to conduct the best possible risk assessment with review by outside experts in a process open to public scrutiny. However, risk communication involves much more than this. MPHEAC's risk communication subcommittee stated that for future episodes, outreach needs to begin immediately with local organizations, and much more public education material needs to be provided in the early stages. Moreover, the subcommittee emphasized, and the dialogue at the symposium underscored, risk communication must include a two-way communication with the public, including public access into decision making. It is not just provision of more or better materials to convince the public that government is taking the correct action.

The MPHEAC worked well for discussing the scientific and technical information relating to health effects, but it did not provide an arena for public discussion about resolving the broader policy issues. Therefore, it was recommended that in the future another type of committee or forum be established to handle the risk communication and public participation issues. Such a committee should include representatives of all affected publics.

Other recommendations concerning risk communication included translating educational materials into languages other than English, i.e., Spanish, Korean, etc., before another eradication is started, convening multilingual meetings where the public can ask questions and receive answers from experts in the field, appointing an ombudsperson or someone designated by the community to investigate environmental health complaints, maintaining dialogue with all affected communities, and recognizing that risk communication efforts need to be ongoing and must be adequately funded and field tested.

CDFA has begun implementing some of these recommendations. In several cases since 1991 when CDFA has conducted ground spraying against small Medfly infestations, CDFA has provided information to the city councils and offered to attend their meetings to answer questions. Thus far, however, the city councils have not requested presentations because aerial spraying was not involved. Few property owners have resisted having ground crews spray malathion on their trees and bushes. In one instance, CDFA set up a community meeting after members of a group opposed to pesticide spraying distributed fact sheets that were inconsistent with the analyses and recommendations of the DHS risk assessment. More than 20 public officials, including state medical officers, attended the meeting, but only four members of the public came. Thus the effectiveness of the new risk communication efforts is difficult to measure when aerial spraying is not taking place.

CDFA has created a full-time staff position and has begun several new programs for educating the public about the problem of introducing Medflies and other exotic insect pests through illegally imported produce. Southern California has a large immigrant population that has strong cultural ties to their homelands. Recent intensified inspections conducted at California airports and shipping ports have confirmed suspicions that residents returning from trips abroad, or their foreign visitors, were bringing in untreated fruits. CDFA is emphasizing public prevention in its press

conferences and has also begun assessing each airline and ship arriving from foreign countries to pay for educational materials for travelers. This has paid for brochures to be given to airline and ship passengers, an animated film for showing on airlines, and training for ship and airline personnel. Also, 'amnesty bins' have been provided at terminals for depositing illegal fruits. CDFA is also giving out educational materials at ethnic festivals in southern California.

A recent development has been an agreement among four state departments as to responsibilities in the event of another aerial pesticide program. In July 1991, a reorganization in state government created the California Environmental Protection Agency (Cal/EPA). This agency includes two new departments that will carry on most of the pesticide functions of their parent departments: (1) the Office of Environmental Health Hazard Assessment (OEHHA), originally in DHS, with public health oversight responsibilities for pesticides; and (2) the California Department of Pesticide Regulation (DPR), originally in CDFA, which has assumed primary responsibility for registering pesticides and enforcement of pesticide laws. DHS will have the lead in speaking for the public health aspects of aerial malathion applications, with OEHHA providing expert risk assessment assistance. A plan has also been developed for organizing press conferences, meeting with local officials, and so on in the event another aerial spraying takes place.

6.2. Risk assessment

While the toxicological database for malathion has some studies in all categories required by regulatory agencies, some required studies still had not been completed or were judged inadequate. The risk assessment identified the health effects that need further investigation. For example, there are subtle neurotoxic effects that are not mediated by cholinesterase inhibition and that may cause behavioral changes before cholinesterase levels are depressed. The carcinogenicity evidence for malaoxon was equivocal. Immunological effects also need more study. Follow-up studies are underway to resolve some scientific issues regarding malathion toxicity, including cancer bioassays, ocular toxicity studies, neurotoxicity studies including behavioral effects, and an inhalation study. The symposium recommended that the risk assessment be ongoing and be updated as the new scientific information is received. The process should allow public access to all the information and allow for public debate.

The state has begun interdepartmental efforts to prioritize the study recommendations in the DHS risk assessment and the MPHEAC reports. Staff have also formed several subcommittees to work on several scientific and public health issues related to malathion. These issues include setting up 'hotlines' and conducting surveillance during the next major eradication project; following up on pharmacokinetics, biological monitoring, chemistry, and environmental fate; and exploring the potential for a National Academy of Sciences Committee policy review on urban pest eradication. DHS has also begun a study with malathion-exposed farm workers on the feasibility of using biomonitoring markers as a measure of exposure. OEHHA will review the scientific literature and pesticide registration database annually to determine the need for updating the 1991 health risk assessment document.

6.3. Risk management

The risk assessment considered public exposures and estimated doses of malathion to provide a thorough evaluation of the risks of the aerial application. If the risk assessment had revealed there were unacceptable public health risks, DHS would have recommended steps to modify the program or cease the aerial application. This did not occur; however, DHS and the MPHEAC have made recommendations for the ongoing risk assessment, as just described.

One of the conclusions of the risk assessment was that CDFFA should try to develop alternatives to aerial pesticide spraying because of the anxiety and public resistance to aerial spraying. CDFFA has made efforts in this direction [2, 9]. Over the past two years, with episodes in Santa Clara and Los Angeles counties, CDFFA has demonstrated the effectiveness of a coordinated campaign of ground spraying, fruit stripping, and sterile fly releases in combating exotic fruit fly outbreaks. It has increased its sterile Medfly hatching facilities sixfold since 1989. CDFFA has also awarded more than \$700 000 in research grants for alternative Medfly control methods, including better traps and attractants, and parasites and predators. Faster detection of Medflies through increased trapping will enable localized eradication and avoid the need for aerial spraying. The research program has already developed a new trap with a sex attractant for male Medflies that is seven times more effective than previous traps. Although extremely effective in identifying the extent of an infestation, this trap is not yet considered sufficient for eradication.

7. Conclusion

DHS was directed to assess the health risks of aerial spraying of malathion in a highly urban area. In responding to this mandate, DHS formed an external committee of experts to provide oversight and advice on the risk assessment process. This action both ensured a more comprehensive risk assessment and helped restore public confidence in the project by introducing public oversight and providing a forum for the discussion of scientific issues. In this way, risk communication was integrated directly into the risk assessment process, but it was also apparent that the MPHEAC with its mandate to address scientific issues could not also be a forum for the public to discuss the broader policy issues behind the eradication program. The MPHEAC and its subcommittee also made many important recommendations regarding risk communication for future incidents requiring aerial pesticide application. The chief recommendation is that risk communication must involve the community in a two-way communication and not just give out more or better materials that try to convince the public of the correctness of governmental actions.

Risk management was also integrated into the risk assessment because findings of adverse health effects would have resulted in recommendations for mitigating the risks. DHS found that the public anxiety produced by aerial spraying is a public health concern in its own right and therefore recommended that alternatives to this treatment method be researched and implemented.

The integration of these activities allowed better management of a major public health controversy by both addressing the concerns of the public and supporting the needs of the agencies responsible for carrying out actions and decision making.

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