

# Genetically engineered mosquitoes in the U.S.

## Introduction

The UK biotechnology company Oxitec has developed a genetically engineered mosquito in an attempt to reduce mosquito populations and in turn limit the spread of disease such as dengue fever. This mosquito, *Aedes aegypti* (OX513A), has been engineered to survive only in the presence of tetracycline — a common antibiotic used in agriculture production and often found in sewage.

The GE mosquitoes are bred in a lab until adulthood, after which the males are released into the wild. In theory, the males will mate and then die off while their tetracycline-dependent gene passes onto their offspring. The offspring die early on in life — in the late larvae or pupae stage — and the mosquito population in a given area will theoretically be suppressed. These GE mosquitoes are not in fact sterile as some news reports claim but are engineered to pass on an “autocidal” gene that kills their offspring.<sup>1</sup>



Oxitec has been moving ahead with field releases of its genetically engineered mosquitoes. The first-ever field releases of GE mosquitoes took place between 2009 and 2010 in the Cayman Islands, a British Overseas Territory, when three million mosquitoes were released.<sup>2</sup> Malaysia was the second country to host Oxitec’s experiments at the end of 2010 and six thousand more GE mosquitoes were released there.<sup>3</sup> Between February and June 2011 more than 33,000 GE mosquitoes were then released in Brazil.<sup>4</sup> According to Oxitec, results from the Cayman trials showed a reduction in *Aedes aegypti* populations of 80 percent.<sup>5</sup>

Despite misleading reports published by the journal *Nature* on its website that “the controlled release of male mosquitoes genetically engineered to be sterile has successfully wiped out dengue fever in a town of around 3,000 people, in Grand Cayman,”<sup>6</sup> (emphasis added) the mosquitoes are in fact not sterile and Oxitec never successfully eradicated dengue fever from any population. Dengue is not endemic in the Cayman Islands (only occasional cases occur in travelers).<sup>7</sup> The company has only shown its technology can reduce mosquito populations in the immediate term in controlled settings. Oxitec has not proven such population reductions lead to disease eradication.

## Genetically engineered mosquitoes: Coming to the U.S.

Recent reports have revealed Oxitec’s plan to release its GE mosquitoes in the Florida Keys. According to Michael Doyle, director of the Florida Keys Mosquito Control District, Oxitec intended to release 5,000 to 10,000 GE mosquitoes over a two week period and release them into an undisclosed 36-square-acre block area as early as January 2012 — likely near the Key West Cemetery. Since then, the trial has been delayed at least until late spring in 2012 due to the regulatory challenges around the release of GE mosquitoes.<sup>8</sup> The trial is expected to last about two months. The mosquitoes will be dusted with a fluorescent powder for identification purposes and then trapped to see



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how far they are flying. If the mosquito population declines, the trial will be considered a success.<sup>9</sup>

While attempts to limit the spread of disease are laudable, there are many regulatory, environmental and ethical challenges facing the release of GE mosquitoes in the U.S. and there are even more unanswered questions.

## Regulatory gaps

Despite the fact that the Florida Keys Mosquito Control District and Oxitec are planning their trial as early as spring 2012 it is unclear which federal agency would regulate the field release of GE mosquitoes.

Originally, Oxitec and the Florida government agencies assumed the U.S. Department of Agriculture would regulate GE mosquitoes as it has other GE insects such as the first-ever release of a GE insect, a fluorescent pink bollworm.<sup>10</sup> But in October 2011 the USDA issued a statement concluding Oxitec's mosquito was outside its jurisdiction since it supposedly didn't pose a threat to animal health.<sup>11</sup>

In the statement, the USDA suggested that Oxitec reach out to other federal agencies — such as the Fish and Wildlife Service, the Centers for Disease Control and the Food & Drug Administration. It is unclear which agency will claim authority, if any, but the FDA could play a major role in any decision since it has authority over genetically engineered animals (such as a GE salmon currently being considered for human consumption), which it regulates through laws written for new animal drugs. In this instance, the engineered genes would be considered the animal drug.



Oversight by the FDA is important because release of GM mosquitoes is a medical experiment that could have effects on human health. But as a 2004 report by the Pew Initiative on Food and Biotechnology points out, if the FDA does regulate the release of GE mosquitoes it may not “have the expertise to assess the full range of environmental effects that could arise from the release of [GE] insects, including, for example, risks to plants, an expertise housed in other agencies like [USDA’s Animal and

Plant Health Inspection Service] or the Department of the Interior.”<sup>12</sup> Any agency that does have final regulatory authority over the field release of GE mosquitoes should be required to consult other relevant agencies and public stakeholders before making any final decision on whether GE mosquitoes should be released into the environment. The FDA’s track record on consulting other agencies as it considers approval for GE salmon is less than encouraging.<sup>13</sup>

Additionally, the U.S. is not a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity<sup>14</sup> which governs international regulation, including transboundary movement, of genetically engineered organisms. Since the mosquito eggs will be shipped from the United Kingdom to the U.S. it is unknown how the Cartagena Protocol will apply to the field release of GE mosquitoes. Oxitec will be required to provide environmental assessments to the U.S. government *before* the shipment of the mosquito eggs — as mandated by the Protocol. But it is unclear which U.S. authority, if any, will publish, review and consult on this assessment.



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## Environmental risks

The behavior of these mosquitoes and the risks they pose to human health and the environment are hard to predict, leaving the public with more questions than answers.

The most immediate environmental risk a decline in *Aedes aegypti* could have is that such a decline could leave an ecological niche to be filled by other, possibly more harmful pests. For example the Asian Tiger mosquito, *Aedes albopictus*, is considered one of the most invasive species in the world and carries many diseases including dengue fever and the West Nile virus.<sup>15</sup> While the Asian Tiger mosquito has not yet been found in Key West,<sup>16</sup> it could spread to the island if other mosquito populations decline as it has spread across many parts of the U.S. This could mean the spread of more disease and increased use of pesticides. A 2009 study in Gabon found that the Asian Tiger mosquito, in that instance, was more likely to spread dengue fever and the chikungunya virus than *Aedes aegypti*.<sup>17</sup> The impacts from other, potentially more dangerous insects taking over the ecological niche left by *Aedes aegypti* have yet to be properly studied in the Florida Keys.

## Ethical concerns

The release of GE mosquitoes as an attempt to curb the spread of disease should be considered a medical trial and must follow the strict laws and guidelines in place to protect human subjects in medical trials. Central to ethics on human subject trials is the idea of free and informed consent.

According to paragraph 24 of the World Medical Association's Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, the cornerstone of human research ethics:

*In medical research involving competent human subjects, each potential subject must be **adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study.** The potential subject must be informed of the **right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.** Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's **freely-given informed consent, preferably in writing.** If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed<sup>18</sup> (emphasis added).*

Unfortunately, Oxitec has already shown a disregard of the importance of free and informed consent. The first releases of GE mosquitoes took place in the Cayman Islands — first a small-scale trial in 2009 followed by the release of three million GE mosquitoes in 2010. According to Genewatch UK, the Cayman experiments were not revealed to the public until one month after the initial release and “no public consultation was undertaken on potential risks and informed consent was not sought from local people.”<sup>19</sup>

Equally troubling is that the Cayman Islands — a territory of the United Kingdom — does not have any biosafety laws and is not covered by either the Cartagena Protocol on Biosafety or the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, despite the UK being a Party to these treaties.<sup>20</sup> These conventions would have required publication of and consultation on an environmental risk assessment prior to the release of GE mosquitoes. Instead, the only regulatory requirements were a local permit from the



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Cayman Islands Agriculture Department and a notification that GE mosquito eggs were shipped internationally. Neither of these documents appears to have been published.<sup>21</sup>

In fact, the lack of public consultation for the Cayman experiments has been strongly criticized by one of Oxitec's powerful collaborators, the Gates Foundation. Anthony James, the lead investigator on the Gates team, said that he would "never" release genetically engineered mosquitoes the way Oxitec did in Grand Cayman.<sup>22</sup>

Despite public concern over the unannounced Cayman field trials, Oxitec again released GE mosquitoes in Malaysia in 2010. According to an open letter sent to the Malaysian government from civil society organizations around the world, the public was only made aware of a field release trial of GE mosquitoes by a press release dated January 25, 2011 — more than one month after the trial began on December 21, 2010. This is despite press reports as late as January 4, 2011 in the Malaysian press claiming the trials had been postponed. "It therefore appears," the letter stated, "that neither the local communities nor the Malaysian public at large knew that these trials had occurred."<sup>23</sup> A larger trial, scheduled for an inhabited area, has not yet taken place.

Such a track record does not bode well for the Florida Keys community that will be the center of the first field release of GE mosquitoes in the United States. Community members must be informed throughout the process through a number of mechanisms — including the establishment of local institutional review boards and ethics committees and hosting of community meetings and public forums — and community members must have a right to leave the field trial area<sup>24</sup> or demand the halt of the experiment entirely if they so decide.

### Are genetically engineered mosquitoes a real solution?

Misleading claims that Oxitec's mosquitoes are sterile<sup>25</sup> make it appear as if the company's technology is a foolproof way to bring an end to mosquito-borne diseases. Unfortunately, its system has many problems that raise serious questions about the viability of GE insects as a way to limit the spread of disease.

As discussed, Oxitec's technology does not make its mosquitoes sterile; rather, they are engineered to be dependent on tetracycline and die in its absence. In fact, 3 to 4 percent of Oxitec's mosquitoes survived into adulthood in the lab in the absence of tetracycline despite supposedly carrying the lethal gene.<sup>26,27</sup> If in the presence of the common antibiotic tetracycline, an Oxitec document showed, survival rates could be as high as 15 percent.<sup>28</sup>

Since tetracycline is commonly found in sewage, and *Aedes aegypti* have been found to breed in sewage treatment plants, septic tanks, and cesspits in the Florida Keys,<sup>29</sup> the possibility and risk that Oxitec's mosquitoes could survive in the environment must be studied before any release takes place. As Dr. John Mumford at Imperial College London, a leader and proponent in the field of genetically engineered insects, has said, "it would also be prudent in a risk analysis to seek evidence of the levels of tetracycline in the environment that would be likely to be encountered by released mosquitoes and their offspring... If there are points of high tetracycline concentration then the risk analysis would need to consider a risk management measure that would deal effectively with it."<sup>30</sup>



Mosquito larva.



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Additionally, Oxitec claims it only plans to release male GE mosquitoes into the environment since it's the female mosquito that bites humans and therefore spreads diseases such as dengue fever. But its process of sorting males and females is also not guaranteed. The sorting is conducted by hand and could result in up to 0.5 percent of the released insects being female.<sup>31</sup> This would raise new human health concerns as people could be bit by GE mosquitoes. It could also hamper efforts to limit the spread of dengue fever.

Mosquitoes reproduce continually and Oxitec readily admits it will need to continually release GE mosquitoes in a given area in order to keep populations low.<sup>32</sup> In fact, Oxitec does not expect its technology to lead to population collapses; rather, it states it is only able to decrease existing mosquito populations by approximately 80 percent.<sup>33</sup> This claim is based on unpublished results from the Cayman Islands. In reality it remains unknown whether population suppression using this approach would be effective in the long term or over larger areas. Continual releases would need to occur every month or every few weeks, with upwards of a million mosquitoes per release. This is why Oxitec has suggested that 100 million to a billion GE mosquitoes should be stockpiled for each project.<sup>34</sup>

This is problematic for a number of reasons. First, any environmental assessment of a full-scale field release of GE mosquitoes cannot simply look at the risks from one release; rather, the impacts of releasing millions of mosquitoes on a continual basis must be fully assessed.

Second, this system locks communities and nations into a permanent scheme of repeated ongoing payments to Oxitec once releases begin since Oxitec's mosquitoes are patented. The company stands to make significant profits if countries and communities must make continuous payments to it. These payments would presumably continue endlessly unless the community wanted the release of GE mosquitoes to stop in which case disease prevalence could rise when conventional mosquito populations rebound. The company has yet to provide data on what would happen to mosquito populations or prevalence of disease if releases were halted.

Concern also exists around the possibility of the dengue virus to evolve and become more virulent in response to the introduction of GE mosquitoes.<sup>35</sup> The fact is that the virulence and spread of disease combined with mosquito population levels and behavior involve incredibly complex systems and difficult to predict in advance. Significantly more research is needed on these and other potentially unintended consequences of the introduction GE mosquitoes.

Researchers do not know much about the correlation between population levels of *Aedes aegypti* and dengue fever infection in humans. According to a 2002 article in *Science*, the density of *Aedes aegypti* populations is at best weakly correlated with human infection rates. This is due to the fact that mosquitoes "persist and effectively transmit dengue virus even at very low population densities because they preferentially and frequently bite humans."<sup>36</sup> Additionally, any introduction of GE mosquitoes that does not eradicate a population could lead to increased survivability of the dengue virus and increased risk of human infection.<sup>37</sup>

In a 2003 review of research conducted in the 1970s by Dr. Phil Lounibos and colleagues, then at the International Centre of Insect Physiology and Ecology, in which sterile *Aedes aegypti* were released in Kenya, it was found that sterility levels needed to be very high in order to reduce the number of adult *aegypti* mosquitoes. In this study, introducing sterility levels of 60-70 percent of the mosquito population was not enough to actually reduce adult *Aedes aegypti* numbers. The dynamics between the wild and introduced strains, as well as the fitness of the introduced mosquitoes must be rigorously tested. For these reasons, the study concludes, "changes in human behavior might accomplish



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reductions in vector-human contact more simply than genetic-control interventions.”<sup>38</sup> In other words changes in human practices, such as installing screens over windows or using bug spray may be a simpler and more direct route to reducing people’s contact with *Aedes aegypti* and therefore dengue fever.

## Alternatives

Genetically engineered mosquitoes are not the only tool available to try and limit the spread of dengue fever and other diseases. Community-based programs that educate communities about dengue prevention and low-cost ways to prevent mosquitoes from breeding are one way disease rates can be brought down. Community-based dengue prevention programs have been found to be successful across the world. For example, a 2005 study in Vietnam found that targeted biological control and community involvement was successful in eliminating *Aedes aegypti* in 32 of the 37 communities studied and as a result, no dengue cases have been reported since 2002.<sup>39</sup> As the World Health Organization has stated, “community is the key to dengue prevention.”<sup>40</sup> What worked in Vietnam might not work in the Florida Keys and while community-based programs are not the only answer they do show that sometimes solutions can be low-cost, low-risk social innovations rather than expensive, patented technologies.

Bed nets may be a relatively cheap and effective way to prevent the spread of dengue fever. Preliminary results from a trial in Haiti found that insecticide-treated bed nets led to an immediate drop in dengue-carrying mosquito populations, despite the fact that these mosquitoes bite during the day.<sup>41</sup> Treating other household materials with insecticides, such as window curtains and water jar-covers, was successful in significantly reducing *Aedes aegypti* numbers in a study conducted in Venezuela.<sup>42</sup>

Recent research has even found that infecting mosquitoes with an engineered strain of the common bacteria, *Wolbachia pipientis*, completely prevents the dengue virus from growing in mosquitoes. Field trials in a remote part of Australia found that after releasing 300,000 infected adult mosquitoes, nearly all the wild mosquitoes tested were infected with the bacteria ten weeks later.<sup>43</sup>

While there is currently no vaccine or cure for dengue fever, a dengue vaccine may become a reality in the next few years. According to the Health Ministry in Malaysia, a dengue vaccine is currently in its last trial phase and is expected to be released by 2014 or 2015.<sup>44</sup> Sanofi Pasteur, the vaccines division of pharmaceutical giant Sanofi-aventis Group, has partnered with the International Vaccine Institute and the World Health Organization, among others, to develop its own dengue vaccine. The company is also in the final stage of testing its vaccine and is conducting clinical studies around the world.<sup>45</sup> Clinical trials for vaccines, unlike the potential field release of GE mosquitoes in the U.S., must undergo years of testing to ensure the vaccine works and is safe.

While such experiments may carry their own unique risks (human health risks due to exposure to insecticides, mosquitoes growing a resistance to those insecticides,<sup>46</sup> and unknown risks from the *Wolbachia* bacteria) they illustrate that there exists innovative ways to tackle dengue fever that do not involve expensive and risky genetic engineering technologies. In the end there will likely be no single “silver bullet” in fighting dengue fever since insect populations and the spread of disease are part of a much more complex ecosystem that will require numerous approaches in which communities are not just consulted but are integral actors.



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## Conclusion

Despite Oxitec's claims, questions still remain as to whether GE mosquitoes are safe for the environment, safe for people or are even effective in fighting the spread of dengue fever. While the goal of limiting the spread of disease is laudable, too many questions remain to allow the release of genetically engineered mosquitoes in the U.S.

The federal government and the state of Florida must be open and transparent throughout any deliberations on whether or not to allow Oxitec to release GE mosquitoes in Key West or anywhere in Florida. Our government must require the company to obtain the free and informed consent of the Florida community before any trial is allowed to move forward and mechanisms should be made available to halt the experiment if the community demands. Oxitec must not be allowed to repeat its mistakes in the Cayman Islands and Malaysia where it released mosquitoes without public knowledge or consent.

Comprehensive and independent analyses of the risks GE mosquitoes may pose to the environment and human health must be conducted and released to the public with ample time for review before any trial begins. These assessments must look at:

- The ecological risks of released GE mosquitoes including the risk of disrupting food chains or providing a new ecological niche more dangerous insects to take the place of *Aedes aegypti*;
- The risks of releasing biting females, including possible increased risk of allergic reactions if people are bitten;
- The risks associated with mosquitoes surviving into adulthood if tetracycline is present in the surrounding environment;
- The risk from the unintentional release of GE mosquitoes into the environment due to a natural disaster, wear-and-tear or human error;
- Potential adverse impacts the release of GE mosquitoes may have on the ability of dengue fever to evolve and become more virulent or the likelihood of the released mosquitoes leading to increases in disease transmission;
- The full range of impacts from releasing millions of mosquitoes on a regular basis;
- The consequences of ending a GE mosquito program would have for mosquito populations and disease, as well as the economic impacts on countries and communities that are indefinitely dependent on Oxitec for GE mosquito eggs to fight dengue fever; and
- Alternatives to using GE mosquitoes as a way to limit the spread of dengue fever such as bed nets, community-based prevention programs and other biological tools that do not depend on expensive and risky genetic engineering technologies.

Additionally, Oxitec must be legally liable in case something goes wrong with the field release of its GE mosquitoes. If its actions harm the environmental or public health, Oxitec must be legally responsible for the damages and must compensate the communities. It must also be required to repair the damage it caused to the greatest extent possible.

Until such studies have been independently completed and made available to the public, it is premature to allow the release of GE mosquitoes in the U.S. or elsewhere. The burden of proof rests with Oxitec to show the public its mosquitoes are safe. Until that burden of proof is met GE mosquitoes must remain inside the lab.



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