GENETICALLY MODIFIED ORGANISMS (GMOs)

Dengue fever is a painful, debilitating mosquito-borne disease caused by any one of four closely related dengue viruses related to the viruses that cause West Nile infection and yellow fever. Dengue fever is transmitted by the bite of an Aedes mosquito infected with a dengue virus. The mosquito becomes infected when it bites a person with dengue virus in their blood. It can’t be spread directly from one person to another person. An estimated 390 million dengue infections occur worldwide each year, with about 96 million resulting in illness. Most cases occur in tropical areas of the world, with the greatest risk occurring in:

- The Indian Continent (Afghanistan, Pakistan, India, Nepal, Bangladesh, Sri Lanka, Myanmar, Indonesia etc.)
- Southern China
- Taiwan
- The Pacific Islands
- The Caribbean (except Cuba and the Cayman Islands)
- Mexico
- Africa
- Central and South America (except Chile, Paraguay, and Argentina)

Most cases in the United States occur in people who contracted the infection while traveling abroad. But the risk is increasing for people living along the Texas-Mexico border and in other parts of the southern United States. Local transmission of dengue fever was reported in the Florida Keys in 2009 and 2010, with 22 people diagnosed in 2009 and a further 66 people in 2010, with other cases in Miami-Dade and Broward counties. A CDC report issued in 2010 estimated that nearly 1,000 people in the Florida Keys had been exposed to the virus (approximately 5% of the population). 2009 saw the first occurrence of locally-acquired dengue in the Keys since the 1930s.

There is no vaccine to prevent dengue fever. The best way to prevent the disease is to prevent bites by infected mosquitoes, involving protecting yourself and making efforts to keep the mosquito population down. To reduce the mosquito population, get rid of places where mosquitoes can breed and regularly change the water in outdoor bird baths and pets’ water dishes. Another opportunity in reducing dengue fever is to use the GMO technology to control the vector mosquito population responsible for the infection.

Sterile Insect Technique (SIT) methodology has successfully controlled several insect species in different countries over the last 50 years using radiation based sterilization. An adaptation of SIT is a mosquito
control program involving repeated controlled release of genetically engineered (GE) male *Aedes aegyptii* mosquitoes (line OX513A), expressing a conditional lethality trait and a fluorescent marker. This line has been characterized for over 10 years. Male OX513A mosquitoes mate with the wild females of their own species only, leading to a reduction in the population of the local population of *Aedes aegyptii*. Male mosquitoes do not bite humans or animals and therefore are unable to transmit or vector viruses or other saliva constituents. OX513A mosquitoes can be used in two ways: to reduce the *Aedes aegyptii* population in an area, and/or to prevent its recurrence once control in the area has been achieved.

Oxitec Ltd, a British biotechnology company that develops genetically modified insects to assist in insect control, including the line OX513A. Oxitec proposed an investigational field trial to evaluate the mating ability of released OX513A mosquitoes with local wild-type *Aedes aegyptii* females, to assess the survival of the resultant progeny in order to estimate mortality related to inheritance of the OX513 recombinant DNA (rDNA) construct, and to determine the efficacy of sustained releases of OX513A mosquitoes for the suppression of a local population of *Aedes aegyptii* in the defined release area in the Florida Keys, specifically an area known as Key Haven, in Monroe County, which is within the jurisdiction of the Florida Keys Mosquito Control District for mosquito control. Physical measures would include premises that conform with the Arthropod Containment Guidelines to prevent escape; use of screens, filters, traps, and multiple levels of containment; devices for transport that have multiple layers of containment; as well as use of trained personnel to ensure containment is appropriately implemented. Geographic containment would be provided by the siting of the egg production unit in the UK, which is beyond the isothermal range of the mosquito (i.e., it is too cold for *Aedes aegyptii* to survive outside the climate controlled environment of the laboratory). Geophysical containment would be provided by the island location of the proposed release site, which is predominantly surrounded by ocean, and the mosquito in any life stage cannot survive due to the high salinity of the waters. Biological containment would be afforded by the introduction of the conditional lethality trait into the OX513A *Aedes aegyptii* line, where on mating with the local females of the same species, >95% of the progeny will not survive to functional adulthood in the absence of tetracycline leading to the overall reduction in the population of *Aedes aegyptii* at a given site. The Arthropod Containment Guidelines have been developed by the American Committee on Medical Entomology and American Society for Tropical Medicine and Hygiene to provide risk-based guidelines for arthropod containment and to safeguard individuals coming into contact with arthropods.

Based on the analysis of data available in the literature, FDA concluded that the investigational use of OX513A *Aedes aegyptii* mosquitoes in Key Haven, Florida would not result in significant impacts on the environment. The dispersal of OX513A mosquitoes appears to be adversely affected as measured by MDT, but not by maximum distance traveled, indicating, that in general, the population of OX513A is not expected
to exhibit dispersion greater than wild-type Aedes aegyptii. The location of the proposed trial site and mosquito control measures implemented by FKMCD would considerably limit the dispersal of OX513A mosquitoes as well. FDA therefore concludes that it is highly unlikely that OX513A mosquitoes and their progeny would be able to establish at the proposed field trial site, or spread beyond its boundaries, should the trial proceed. The consequences of release, establishment, and dispersal of OX513A in the environment have been extensively studied: data and information from these studies indicate that the proposed investigational use of OX513A Aedes aegyptii mosquitoes is not expected to cause any significant adverse impacts on the environment or human and non-target animal health beyond those caused by wild-type mosquitoes.

REFERENCES AND NOTES


3 They have been adopted by most institutions working with arthropods as the operating standard for containment, and can be found online at http://www.astmh.org/subgroups/acme#arthropod.


5 In addition to the primary sources cited above, additional references include: New York Times, Washington Post, Mercury News, Bayarea.com, Deccan Chronicle, the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, The Guardian, Pravda, Spiegel, Connexion, etc.

Disclaimer: All information is intended for your general knowledge only and is not a substitute for medical advice or treatment for specific medical conditions or any specific health issues or starting a new fitness regimen.

"Where the mind is without fear and the head is held high, Where knowledge is free Where the world has not been broken up into fragments, By narrow domestic walls." Rabindranath Tagore (1861-1941), Gitanjali, 1912.

One World One Family
AUM! SWASTI!

Om! Asatoma Sadgamaya, Tamasoma Jyotirgama, Mrityorma Amritamgamaya, Om Shanthih, Shanthih, Shanthih! (Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

SWASTI! AUM!