Transgene insects: Scientists call for more open data

February 1 2012

The yellow fever mosquito (*Aedes aegypti*) can transmit various diseases, such as yellow fever and dengue fever. Scientists hope that genetically modified mosquitoes will result in decimating the wild population and thus lower the risk of infections for human beings. The possible risks of such an elimination strategy, however, are not sufficiently known. Credit: Science Photo Library / Agentur Focus

While genetically modified plants have already been introduced into the wild on a large scale in some parts of the world, the release of genetically modified animals is still at a relatively early stage. A team of scientists from the Max Planck Institute for Evolutionary Biology in Plön, Germany has now published a study examining the free release of genetically modified insects in Malaysia, USA, and Cayman Islands. Their findings suggest deficits in the scientific quality of regulatory documents and a general absence of accurate experimental descriptions available to the public before releases start. The researchers call for clear and accurate descriptions of releases to be very widely circulated before

insects are released in a trial - particularly if mosquito species that bite humans are involved. They also provide an innovative checklist to assist journalists and the public in assessing the scientific credibility of regulatory release authorizations.

Genetically modified insects are being developed with a view to suppress insect populations of the same species which spread human diseases, such as malaria and Dengue Fever, or that are agricultural pests destroying crops. The first generation of "designer insects" have been engineered to be fluorescently marked, to be sterile to varying degrees, or both. These insects are released experimentally to develop species-specific and chemical-free ways to reduce the size of insect pest populations. A team of researchers from the Max Planck Institute for Evolutionary Biology have now investigated the regulatory history of genetically modified insects, with a particular focus on the pre-release information available to the public in the first three countries permitting free releases: the Cayman Islands (mosquitoes, 2009-?), Malaysia (mosquitoes, 2010-2011), and the USA (moths, 2001-2011). The study centres on the US regulatory experience, which is currently being promoted as a global regulatory model for genetically modified insects.

Global deficits in transparency and public oversight

The world's first environmental impact statement on genetically altered insects was produced by US authorities in 2008 and has since then been used as a basis for approval of subsequent experiments around the world. The scientists raise some doubts about the scientific value of this environmental impact statement: for example the majority of novel transgenic approaches it endorses are based on just two laboratory studies out of approximately 170 scientific studies cited. These two studies focus only one of the four species covered by the document. Apparently, such deficits do not only apply to the US. "We noted that public access to scientific information is highly restricted throughout the

world, particularly information made available before releases start", says Guy Reeves from the Max Planck Institute for Evolutionary Biology.

The Cayman Islands was in 2009 the site of the first free release of genetically modified mosquitoes. There were, however, some doubts about the relative strength of the legal safeguards that existed. The Cayman Islands had no enacted legislation specifically mentioning the release or transportation of living genetically modified organisms. In 2009 only 21 of the world's 191 countries also had not updated their existing environmental protection or animal control laws to specifically regulate living genetically modified organisms. While the Cayman Islands is a British overseas territory and consequently not a sovereign state, it is noteworthy that none of these 21 countries is thought to have approved any release of a living genetically modified organism.

The first and most obvious question of people living in the release sites of the genetically modified mosquitoes (OX513a) in the Cayman Islands, Malaysia, and Brazil is whether humans can be bitten by genetically modified mosquitoes. In public information available in the Cayman Islands and Malaysian trials, this obvious question is either conspicuously ignored or it is implied that the there is no biting risk, 'as only male mosquitoes are released and they cannot bite'. However, it is clearly detailed by the Max Planck scientists, that it is probable that transgenic daughters of the released males will bite humans. This is because the released males are more accurately described as partially sterile males, rather than the commonly used term sterile males – or most recently 'sterile' males.

A potential concern about the effects of humans being bitten by these genetically modified females is discussed. The context of this discussion is not to suggest that this technology is inherently dangerous. It is to highlight the fact that public confidence in regulators will be eroded, if

written discussion of obvious and scientifically plausible concerns is conspicuously absent from all written documents. As far as the authors are aware there are no publically available documents that scientifically consider possible human health impacts of being bitten by transgenic females (beyond unsubstantiated statements in the general media).

Community engagement and consent requires transparency

The general lack of accurate information available before starting releases is problematic. This is because community engagement fundamentally requires that release descriptions be widely circulated before releases start. The need for high-quality community engagement, particularly in early releases, has repeatedly been argued as essential by expert scientists. "It is rather uncontroversial to state that in the absence of meaningful and accurate descriptions being made widely available, community engagement cannot credibly be said to have occurred", says Reeves.

If those that conducted the trials cannot produce pre-release written descriptions, then they need to explicitly state why meaningful community engagement and consent might not be necessary for experimental releases into towns and cities. Individuals providing justifications based on the pressing humanitarian need to rush development of this technology, must also explain why the same argument cannot be applied to clinical trials of vaccines.

Giving genetically modified insects a fair trial

Large numbers of genetically modified mosquitoes are currently being released in Brazil. Further releases are reportedly under evaluation in various countries, including France, Guatemala, India, Mexico, Panama,

Philippines, Singapore, Thailand, Vietnam and the UK. Proposed experimental releases are for both human health purposes and to control agricultural pests.

Given the enormous human burden of diseases like dengue fever and crop loss from insect attack, it is important that new control techniques are developed. Field trials are an essential step in the evaluation process. "However, we need an informed public to ensure that experimental testing of this potentially valuable technology can be given a fair chance and that testing does not needlessly provoke public mistrust", says Reeves. Avoiding the kind of questionable practices which characterized the commercial development of genetically modified plant is likely to be important.

More information: R. Guy Reeves, Jai A. Denton, Fiammetta Santucci, Jarosław Bryk, Floyd A. Reed Scientific Standards and the Regulation of Genetically Modified Insects. PLoS Neglected Tropical Diseases 6(1). Issue 31/1/2012. www.plosntds.org/article/info: … journal.pntd.0001502

Provided by Max-Planck-Gesellschaft