Learning from 7 years of experience in environmental release of genetically engineered mosquitoes

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Oxitec has demonstrated over the last 6-7 years that the release of mosquitoes that have been genetically engineered (GE) to be self-limiting can provide substantial reductions in *Aedes aegypti* populations in target areas, with greater than 90% suppression of the *Aedes aegypti* population in the release area being achieved. These trials have been conducted in Cayman, Panama and Brazil and were approved using existing regulatory frameworks; frameworks that were largely designed for GE crops or existing products. Pilot scale projects are now being undertaken in Brazil and Cayman. In Brazil Oxitec received approval to release on an unconstrained basis from National Technical Commission on Biosafety in 2014. Where existing regulatory frameworks for GE plants and other organisms have been in place these have been applicable and adapted to Oxitec self-limiting insects. These regulatory frameworks are well characterised and already embedded at international level (e.g., The Cartagena Protocol on Biosafety).

The risk analysis paradigm of problem formulation, risk assessment and the development of plausible scientific pathways and risk hypotheses leading to potential environmental and human harms being realised, has been used to assess potential risks of GE mosquitoes to human health and the environment. It is anticipated that this robust methodology is equally suitable to gene drive technologies, although this has not yet been tested with submissions to regulatory agencies. However, in a product based regulatory system, such as the US, it has been unclear which agencies have regulatory oversight and jurisdiction over GE mosquitoes. FDA have recently issued a Finding of No Significant Impact for a trial with Oxitec mosquitos under the Federal Food Drug and Cosmetic Act Already the narrow regulatory trigger of producing a product with genetic engineering is leading to differential regulatory scrutiny of products having a similar effect.

This paper will discuss product and process based regulatory systems and their applicability to the evaluation of GE mosquitoes along with lessons learnt on regulatory evaluation over the last 7 years.