African Genetic Biocontrol Consortium

GenBio News

African Genetic Biocontrol News
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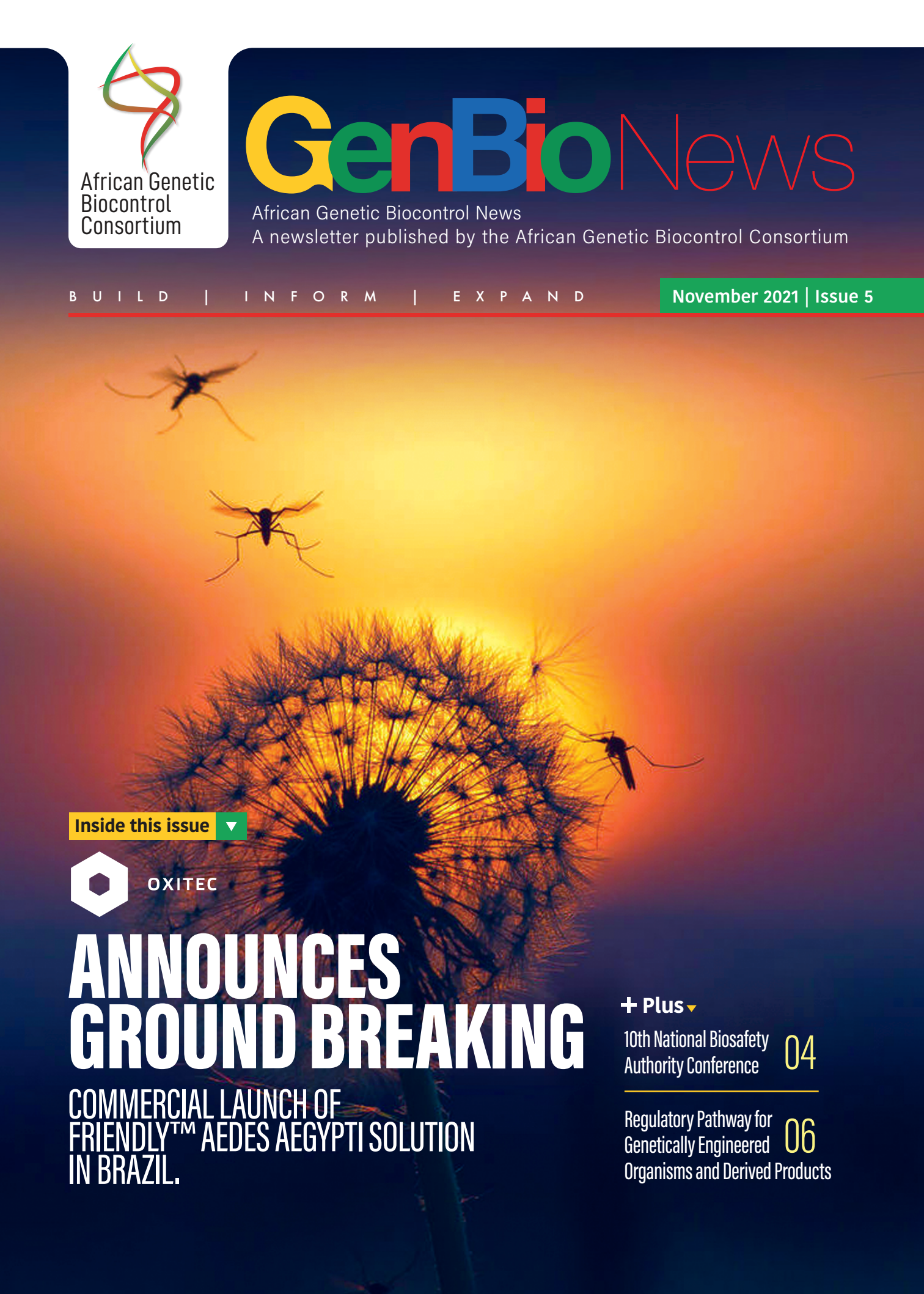

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+ Plus

OXITEC

FRIENDLY™ AEDES AEGYPTI SOLUTION

FEATURE ARTICLE OF THE MONTH:

OXITEC ANNOUNCES GROUND-BREAKING COMMERCIAL LAUNCH OF ITS FRIENDLY™ AEDES AEGYPTI SOLUTION IN BRAZIL.

Oxitec, the leading developer of biological solutions to control pests, announced today the landmark commercial launch of its Friendly™ Aedes aegypti solution designed specifically for use by homeowners, businesses, and communities to control the dengue-spreading Aedes aegypti mosquito.

This launch represents the first time globally that the benefits of using biologically engineered mosquito control technology that can be purchased directly by consumers.

Having received full biosafety commercial approval in 2020 from the Brazilian government's biosafety authority, CTNBio, the company is making its just-add-water solution available for delivery directly to customers' doorsteps starting in the State of São Paulo. Available for purchase online, the product comprises durable outer boxes and Friendly™ male mosquito egg refill packs.

Once delivered, customers need only to add water to the Friendly™ box, place it in a garden, patio, or around a home or business, and the boxes will produce Oxitec's non-biting male mosquitoes over time, which disperse to find and mate with invasive, biting **Aedes aegypti** females. Their female offspring cannot survive, which means fewer biting female mosquitoes in the following generations. While the Friendly™ **Aedes aegypti** males pursue and mate with female **Aedes aegypti**, customers need only reactivate the easy-to-use box once per month. This technology controls the pest without harming beneficial species like bees and butterflies and does not persist in the environment.

Committed to making its ground-breaking sustainable solutions accessible to everyone, Oxitec has developed a direct-to-customer model, making the company the first vertically integrated biotechnology company delivering pest control solutions directly to end-users. This allows Oxitec to build strong, lasting relationships with customers, manage rapid fulfilment and product support, and continually innovate on product features that matter most to customers.

After launching in São Paulo, Oxitec will scale production and expand availability to other states nationally.

Source: Oxitec (2021). **Oxitec Announces Ground-breaking Commercial Launch of Its Friendly™ Aedes aegypti Solution in Brazil.** Retrieved from: https://www.oxitec.com/en/news/oxitec-announces-ground-breaking-commercial-launch-of-its-friendly-aedes-aegypti-solution-in-brazil

10TH NATIONAL BIOSAFETY AUTHORITY CONFERENCE

THE AFRICAN GENETIC BIOCONTROL CONSORTIUM PARTICIPATES IN THE 10TH NATIONAL BIOSAFETY AUTHORITY CONFERENCE

The National Biosafety Authority (NBA), in conjunction with its partners, hosted the 10th Biosafety Conference, running under the theme:

"A Decade of Biosafety Regulatory Excellence: Experiences and Lessons". The Conference celebrated a decade of excellence in Kenya's biosafety regulation, shared experiences and collected lessons to inform the further enhancement of efficiency in the National Biosafety Regulatory Framework.

The African Genetic Biocontrol Consortium made a presentation on Day 1 of the conference focusing on the topic **"Introduction to gene drives and its applications in management of malaria in Africa."**

Gene drive is a genetic phenomenon that induces biased inheritance of a specific trait from parent to offspring at an increased chance to upwards of 99% contrary to the 50% Mendelian inheritance. As a result, the selected trait can become common within a particular species over the course of several generations. There are many possible applications of gene drive across public health, agriculture, and conservation. Gene drives rely on the gene editing tool CRISPR/Cas9 system to alter a specific gene and insert a desired gene. For example, disease vectors such as mosquitoes can be altered and prevent them from acquiring and spreading diseases.

In malaria control, gene drives can take two forms namely population suppression or population alteration. The principle of population suppression is to knock out the female fertility genes to prevent them from laying eggs or distort sex chromosome inheritance. Population alteration entails a reduction of the vector's ability to transmit disease by preventing the malaria parasite from binding to the receptors within the vector. Currently, different laboratories are conducting gene drive research with potential field applications in Africa to support malaria control and elimination. Stakeholder engagement is crucial during decision making taking into account also the risks and benefits of gene drives. Capacity strengthening of institutions and knowledge sharing will lead to informed decisions on gene drive as well as other emerging biotechnologies.

> "...DISEASE VECTORS SUCH AS MOSQUITOES CAN BE ALTERED AND PREVENT THEM FROM ACQUIRING AND SPREADING DISEASES.

The African Genetic Biocontrol Consortium provides a platform for informational opportunities and in-depth discussion on the needs and requirements for testing genetic biocontrol technologies by experts from African countries that would potentially experience its risks and benefits.

National Biosafety Authority

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10TH NATIONAL BIOSAFETY AUTHORITY CONFERENCE

A Decade of Biosafety Regulatory Excellence: Experiences and Lessons

Celebrating a decade of excellence in Kenya's biosafety regulation, sharing experiences and collecting lessons to inform the further enhancement of efficiency in the National Biosafety Regulatory Framework.

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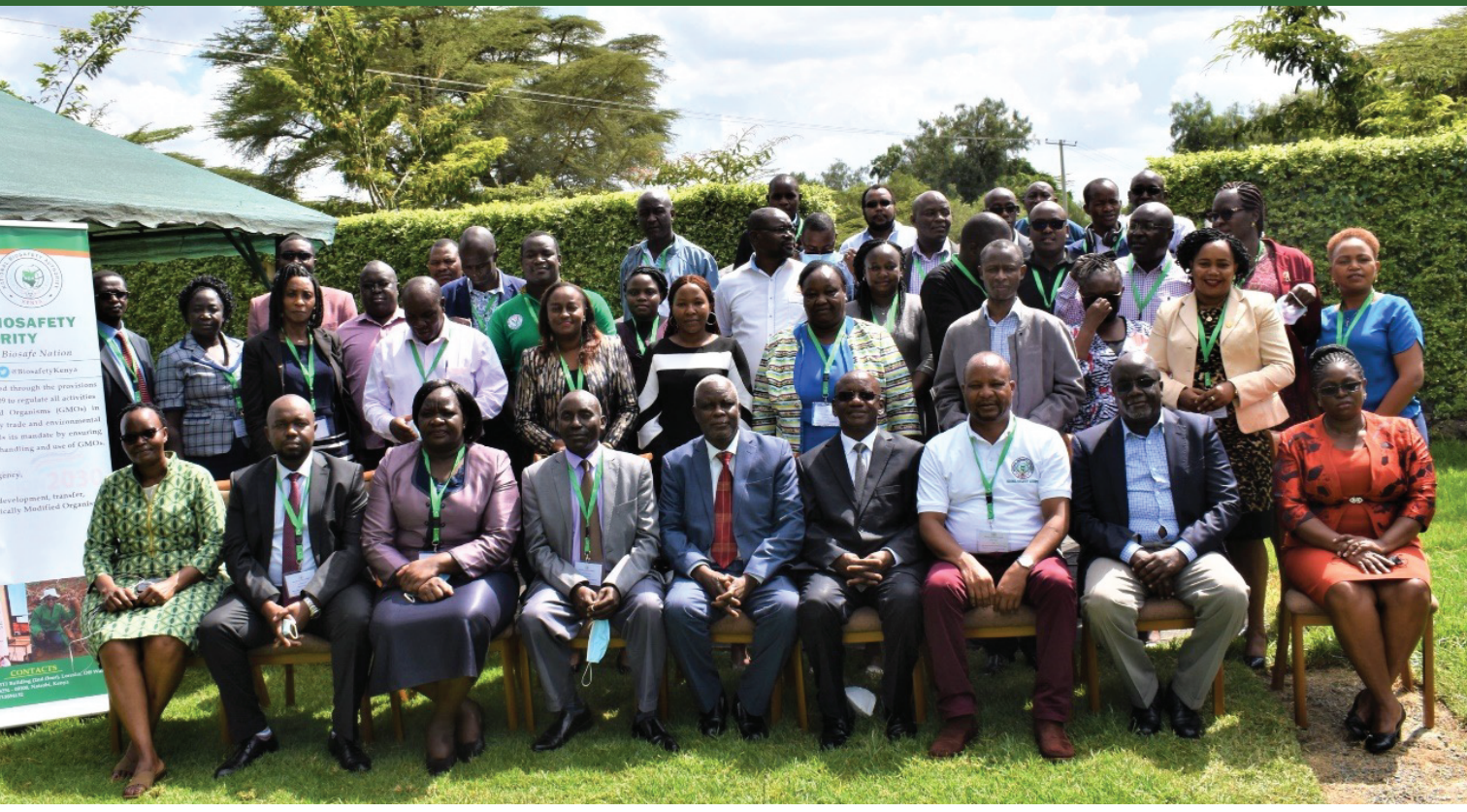


AFRICAN GENETIC BIOCONTROL CONSORTIUM
THIRD WEBINAR

MOVING RESEARCH FROM THE LABORATORY FOR FIELD TRIALS:

Regulatory Pathway for Genetically Engineered Organisms and Derived Products

On 25th November 2021, the African Genetic Biocontrol Consortium successfully hosted its second webinar titled "Moving Research from the Laboratory for Field Trials: Regulatory Pathway". The panelists during this webinar included:

- Fredros Okumu - Director of Science, Ifakara Health Institute.
- Nathan Rose - Head of Regulatory Affairs, Oxitec.
- Emma Orefuwa - PAMCA, African Gene Drive for Vector Control Network.
- Jonathan Kayondo - Principal Investigator, Target Malaria.
- Lilian Chimphepo - Principal Environmental Officer, Environmental Affairs Department.

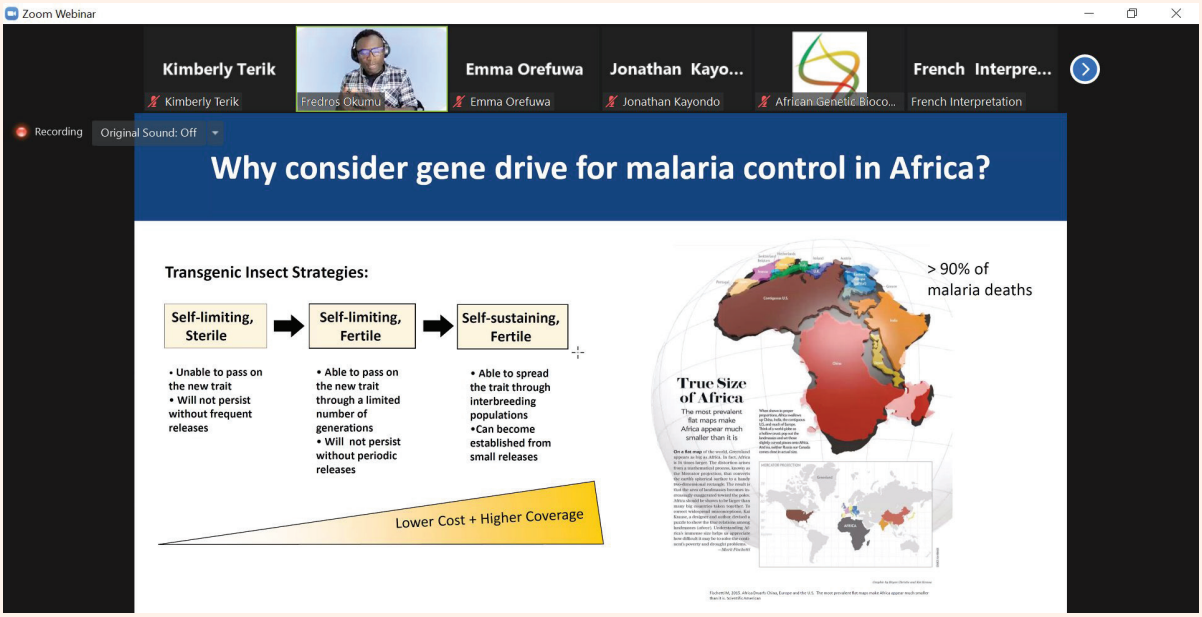
The objectives of the webinar were:

- To provide an overview of how the process of moving Research from the laboratory for field trials: regulatory pathway for genetically engineered organisms and their derived products.
- To discuss the considerations for site selection for biocontrol agents.
- To discuss how the process of moving research from the laboratory for field trials of insects would be different from that of GM crops.
- To discuss how countries with regulatory frameworks for GM crops are likely to consider field trials for genetically engineered insects.

The opening remarks were given by Emma Orefuwa who welcomed the attendees to the webinar by the African Genetic Biocontrol Consortium. She then welcomed the speakers and gave an overview of the program. She finalized by giving the housekeeping rules and then proceeded to introduce the first speaker.

The first speaker was Fredros Okumu who made a presentation on **"Gene Drive Mosquitoes: Considerations for moving from Laboratory to Field Studies."** Fredros started off by posing a mind-provoking question, 'What would be needed to ensure safe and efficient field-testing and implementation of low threshold gene drive mosquitoes in sub-Saharan Africa?" There is need to consider gene drive for malaria control in Africa. The available transgenic insect strategies include self-limiting sterile (unable to pass on the new trait but will not persist, self-limiting fertile (able to pass on the new trait through a limited number of generations but will not persist), and self-sustaining fertile (able to spread the new trait through inbreeding populations and become established from small releases). He went to mention that gene drive is a convergence of two new technologies. First, it is genetic modification, a controversial technology, whereby countries are still uncertain how to regulate GM crops. In regard to GM insects, they have only begun to be tested and commercialized (Brazil). Second, a drive is persistence in the environment, which is an unusual feature for GMOs.

The WHO has phased pathway for GM mosquitoes. Phase 1 involves laboratory studies and laboratory population cages; Phase 2 involves physically confined field trials and ecologically confined field



trials; Phase 3 involves staged open field releases; whereas Phase 4 involves post-implementation surveillance. For self-sustaining gene drive mosquitoes, a testing continuum is preferred rather than discreet testing phases due to the presumed ability of gene drive products to persist in the environment. The discreet testing phases include laboratory studies, small scale isolated releases, small scale open releases, large scale open releases, and post-implementation surveillance. Arthropod containment guidelines released recently indicated that initial discovery and development work should be done under careful containment in the laboratory. An enhanced Arthropod Containment Level 2 (ACL-2) is recommended. Considerations for field site selection has a number of requirements including biological environment (target mosquito present with disease transmission conditions), existing legal and regulatory structure, community engagement, no social or political barriers, and a geographical isolation for first release.

An initial field work is required to understand the field site through entomological, epidemiological, and ecological data. The standards for moving to field testing include meeting pre-established safety criteria, show efficacy (malaria reduction), and must meet ongoing obligations. The general monitoring and evaluation consideration require all parties to reach agreement on the goals and methods of monitoring. The different types of monitoring include entomological efficacy, epidemiological efficacy, and environmental safety. Further, the general authorization consideration are individual informed consent, community engagement, and broader engagement of other stakeholders. In conclusion, low threshold gene drive products for control of malaria transmission can be tested in a safe and ethical manner but will require significant advance planning and coordination among researchers, funders, regulators, government officials, and policy makers.

The next speaker was Nathan Rose who made a presentation on **"Regulatory Pathways for Genetically Engineered Self-Limiting Insects."** He begun by stating that pest threat to global food sustainability and public health is expanding rapidly, everywhere. Climate change, collapsing ecosystems and a growing and hungry human population require a radical and urgent shift in how we manage insects and other pests. Oxitec is forging a category of safe, sustainable and highly-effective chemical-free pest control solutions. Using proven technologies, Oxitec's Friendly™ solutions leave no environmental impact while effectively targeting insects and other pests that threaten public health, agriculture, livestock and the environment. The technology delivers multiple benefits namely male-only releases; safe, non-toxic, non-allergenic; targeted pest suppression; insecticide resistance management; traceable in the field; and

self-limiting in the environment. In programs funded by the Bill and Melinda Gates Foundation, Oxitec is developing Friendly™ **Anopheles albimanus** and **Anopheles stephensi**, two important malaria vectors. If (**An. stephensi**) disperses beyond its current distribution in eastern Ethiopia... the region could face malaria outbreaks of unprecedented size. **An. stephensi** is uniquely adapted to thrive and transmit malaria in urban areas. It is set to increase the threat of malaria transmission in large urban areas, where other malaria vectors cannot thrive. The fall armyworm (FAW), **Spodoptera frugiperda**, has developed resistance to biotech corn, and is now a major challenge for growers in Latin America and globally, causing an estimated >US$2 billion in losses and management costs1every year in Brazil alone. The potential benefits of Oxitec Fall Armyworm include reduction of pest populations to very low levels, development of fall armyworm resistance to biotech corn, and safe and non-toxic targeted pest control. Oxitec's proven vector control results are combined with exceptionally high public support in a range of markets. Brazilian Biosafety Regulators (CTNBio) assessed all aspects of biosafety, and granted full commercial biosafety approval after evaluating characteristics of the GMO, human health risk assessment, and environmental risk assessment.

The mosquito **Ae. aegypti** OX5034 does not present additional risks to the environment, humans and animals when compared to the same non-genetically modified species. In addition, it demonstrates important potential to serve as an additional tool for the control of the mosquito that causes arboviruses such as Dengue, Zika, Chikungunya and Yellow Fever, with demonstrated larvicidal efficacy of 100% against **Aedes aegypti** females and suppression capacity of up to 96% of the population of the wild species, in keeping with the biosafety aspects mandatory for their use. The released mosquitoes of **Aedes aegypti** OX5034 will be males that will not be able to bite humans or other animals, and will not transmit disease.

The requirements for site selection for field trials include:

- Field trial locations are dependent on insect biology – for example, many mosquitoes are anthropophilic.
- Appropriate human, animal and environmental risk assessment will facilitate identification of any risks associated with particular field sites, to enable appropriate mitigation.
- Field sites should take into account insect production, deployment and monitoring requirements.
- Effective community engagement is important when releasing GM insects.
- Complete site isolation (e.g. islands) is not needed for field trials of self-limiting GM insects.

> **For self-sustaining gene drive mosquitoes, a testing continuum is preferred rather than discreet testing phases due to the presumed ability of gene drive products to persist in the environment.**

Regulating Self-Limiting and Gene Drive Insects: Key Similarities and Differences

- Varied barriers to public acceptance of GMOs.
- Phenotypic characterization -gene expression, protein levels, fitness, fertility/fecundity, behavior of mosquito, allergenicity/toxicity, etc.
- Requirements for toxicity testing in animals – rodents and other non-target animals.
- Requirements for environmental risk assessments including direct effects on predators, endangered species, and indirect effects caused by suppression/ elimination.
- Requirements for assessment of vector competence/vectorial capacity.
- Production and deployment challenges.

- Persistence of gene drive insects will require long-term monitoring for resistance to drive mechanisms.
- Longer-term environmental impact assessments needed for population-elimination gene drives.
- Mitigation strategies in case of adverse effects.
- Reversibility of self-limiting insect releases, whether GM or SIT, appears to result in stronger public acceptance.
- Potential for spread of gene drives across national boundaries.

An engaging and organic discussion followed that incorporated all the panelists. The link to this discussion can be accessed below under the title ""Moving Research from the Laboratory for Field Trials: Regulatory Pathway".

Link: https://www.genbioconsortium.africa/events/#

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