

Regulation of transboundary movement of Living Modified Organisms (LMOs) in the environment

Target Malaria is working towards the development and potential release of gene drive mosquitoes in Africa. One of the potential benefits of gene drive technology could be the ability of gene drive mosquitoes to spread over large areas to support area-wide vector control beyond national borders.

The capacity to spread depends on the genetic design, not all gene drive strains are meant to spread over large areas. While the potential for spread presents many inherent benefits for vector control, there are aspects surrounding regulatory oversight of transboundary movement of Living Modified Organisms (LMOs) to consider. These considerations must be explored with various national government regulatory authorities and stakeholders to provide regulatory predictability.

What is “transboundary movement”?

Regulation of the transboundary movement (movement across political borders) of materials and articles is not a new phenomenon specifically related to genetically modified organisms (referred to as Living Modified Organisms-LMOs-under international agreements).

All flying insects have the potential to cross borders between two or more countries/areas through natural or even human mediated movements. Long-distance insect migration of winged insects is also known for locusts, dragonflies, flies, and butterflies, for example. Some flying insects may also occasionally move long distances on air currents. Long term establishment in an area following movement by air currents is thought to be very rare. In the



same manner, as insects travel, the diseases they are vectors of can also move across borders.

There are international health regulations that require insecticidal treatment of aircraft; for example, when leaving vector-borne disease endemic countries to help manage this transboundary risk of movement of potentially infected insects. Similarly, if an insect is a pest species of economic importance, their entry to other countries is often highly regulated through the examination and/or treatment of cargos or commodities in the place of origin or destination. Spread via wind and spontaneous flight cannot be prevented in such a way.

Regional Harmonization of LMO transboundary movement in Africa

The African Union (AU) and its development agency (AUDA-NEPAD) are leading the development and implementation of regional policy initiatives and guidelines on genetically modified mosquitoes (genetically modified mosquitoes), and more specifically gene drives for malaria control to support and inform AU member countries.

The African Union High Level Panel on Emerging Technologies (APET) issued, in May 2020, a report on “Gene Drives for Malaria Control and Elimination in Africa”, which in the context of government actions on transboundary movement of genetically modified mosquitoes outlined the following recommendations:

- “Recommended AU Agenda and Regional Economic Communities (REC) facilitate development, coordination and harmonization of regulations and guidelines for regulating the development, approval and use of the final product.
- Encouraged interaction between different agencies mandated to regulate emerging technologies including genetically modified organisms and related technologies.
- Recommended member states and the AU, NEPAD Agency and RECs adopt a regional approach to the harmonization of policies and implementation of the gene drive technology across African countries”.

Other notable recommendations of the 2020 report included elements of co-development, risk assessment and early engagement with stakeholders. The APET was further directed in 2022 to provide support in the establishment of an African Integrated Vector Management Platform, and to commence research and publishing of a supplementary report on the Panel’s earlier report.

The establishment of a West African Integrated Vector Management Program (WAIVM) and subsequent publication of a comprehensive set of technical guidelines, as well as various capacity building initiatives have set the groundwork for continental scale-up of an IVM platform.

The 2nd edition APET report on “Gene Drives for Malaria Control and Elimination in Africa” was released in 2025. Key recommendations include case-by-case project evaluations; sequential milestone driven strategies; and systematic stakeholder engagement. Regarding the regulation of transboundary movement, the 2025 report makes recommendations around risk assessment and regulatory harmonisation. The report specifically makes the following two recommendations:

Recommendation 4.2

Considering the specific potential of the gene drive elements for integrated vector management to spread in the environment and persist in the target species, we call for the harmonization of relevant regulations at all levels, and researchers and developers to establish functional regulatory and institutional frameworks to register their projects, share information, to ensure transparency and self-regulation.

Recommendation 4.3

To ensure effective implementation of the integrated vector management to harness emerging vector control technologies, policy makers should avoid developing overly restrictive regulations that could cause Africa to lose the expected potential health benefits, but rather ensure that there is a reasonable balance between environmental considerations and the public health benefits when developing regulatory policies.

AUDA-NEPAD and regional actors have been working to facilitate regional decision-making and interagency coordination between countries, Regional Economic Communities (RECs), and at the pan-African level for genetically modified mosquitoes regulation. Under the Cartagena Protocol on Biosafety, in the International Treaty on the Use of Living Modified Organisms, provisions exist to allow multilateral decision making regarding the cross-border movement of gene drive mosquitoes. Considering the urgency needed to address the malaria burden in Africa, AU agencies and both regional and national actors can look to building on these existing provisions to facilitate both early-stage research trials and future operational implementation of a vector control tool for malaria.