

Gene Drives: Pursuing Opportunities, Minimizing Risk

A report from the Johns Hopkins Center for Health Security

Gene Drives: Pursuing Opportunities, Minimizing Risk finds that the first gene drive release, perhaps in just a few years, will be an outgrowth of current research to control malaria spread. This report focuses on the anticipated challenges that will emerge after the malaria use case has provided a clear proof of principle of the gene drive technology and its benefits.

The report is available at:
centerforhealthsecurity.org/gene-drives



Gene drives, a genetic technology that can occur naturally or be lab-made, are designed to spread targeted genetic changes from generation to generation of a single wild species at an accelerated rate. Once released, the gene drive can change entire populations with little or no further input or resources. This capability is different from any genetically modified organism (GMO) previously released into the environment that is expected to live alongside its unmodified wild cousins or die out rather quickly.

Without national policies and regulations, gene drives pose a unique set of risks.

Gene drives carry risks distinct from other GMOs because they act differently in the wild. Some of these risks have extremely low probability but high-impact consequences, such as ecological or agricultural disruption. These risks can involve complex, cascading, and long-range consequences in the evolution and ecology of the wild host species carrying the gene drive. A deployed gene drive may have side effects, could unintentionally cross between closely related species, or may not work as it was intended. Since gene drive technologies have yet to be successfully demonstrated in the field, the impact of hypothetical threats is hard to gauge.

Key policy recommendations to prepare for gene drives:

1. **Create a national tiered registry system** for gene drive research and development, with increasing requirements for information disclosure as deployment becomes imminent.
2. **Evaluate each proposed gene drive system on a case-by-case basis.** Regulatory bodies should oversee gene drives. Organizations including the FDA, USDA, and EPA should create regulations and risk assessment plans for each gene drive entering the deployment stage.
3. **Avoid full moratoriums on gene drive research**, but still mandate appropriate biosafety, risk assessment processes, and regulatory controls.
4. **Create special international agreements** to address the use of gene drives in species of agricultural importance or in human-influenced species such as deer or ocean-caught fish.
5. **Prevent the release of any gene drive without a tested reversal drive.**
6. **Mandate the incorporation of multiple containment strategies during the research and development stage** to mitigate the risk of spread in the event of an accidental release or laboratory escape.
7. **Require coordination and communication between researchers, local, and international stakeholders** as prerequisite to gene drives deployment.

For more information contact:

Lane Warmbrod,
klwarmbrod@jhu.edu

Margaret Miller,
margaret.miller@jhu.edu