

NExTRAC Virtual Meeting on Gene Drive
November 10, 2020

Overview of the Recommendations

From the 2016 National Academies'

Gene Drives on the Horizon:

Advancing Science, Navigating Uncertainty, and
Aligning Research with Public Values

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The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Statement of Task for the Committee

- Review the **state of the science** of gene drive research, identifying the key scientific techniques for reducing ecological and other risks, and characterize and assess environmental and other hazards to target and non-target organisms.
- Examine the **oversight mechanisms** for organisms containing gene drives in the **laboratory**, for use in **field releases within the US and in LMIC**.
- Determine the adequacy of existing oversight mechanisms and **risk assessment guidance**.
- Discuss relevant **legal, social or ethical considerations** in selecting sites for field releases and engaging those living in or near potential sites.
- *Provide general principles that will guide **responsible practices** in gene drive research for the laboratory setting through to field releases for use by investigators, their institutions, the research funders, and regulators.*

Overview and Recommendations

- Careful examination of the science, and challenges in assessment and governance in seven case studies
- Two hundred page report, thirty-two recommendations
 - Six overarching recommendations (Chapter 9)
 - Five on phased testing (Chapter 5)
 - Three on risk assessment (Chapter 6)
 - Eight on engagement (Chapter 7)
 - Ten on governance (Chapter 8)

The state of the science in Spring 2016



There is insufficient evidence available at this time to support the release of gene-drive modified organisms into the environment. However, the potential benefits of gene drives for basic and applied research are significant and justify proceeding with laboratory research and highly-controlled field trials.

There are considerable gaps in knowledge, *particularly in regard to ecological and evolutionary considerations for the organism and its ecosystem that in turn affect risk assessments, public engagement, and governance.*

(emphasis added)

Advancing the state of the science



Recommendation 9-1: Funders of gene drive research should coordinate, and if feasible collaborate, to reduce the gaps in knowledge *not only about the molecular biology of gene drives but also in other areas* of fundamental and applied research that will be crucial to the development and application of gene drive technology, *including:*

- population genetics
- evolutionary biology
- ecosystem dynamics
- modeling
- ecological risk assessment
- public engagement

(Emphasis added)

Responsible science for research and potential development of gene drive technologies

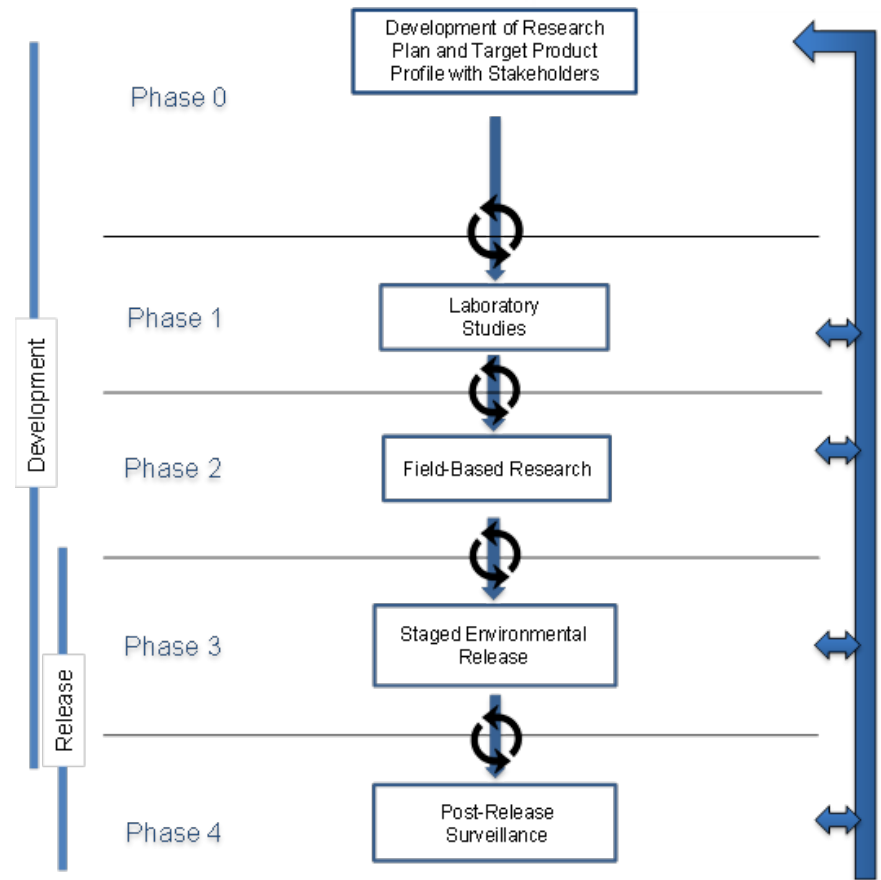


A responsible science approach to research on gene drive calls for not only for best technical practices in the underlying science, but also continuous examination and assessment of its social, environmental, regulatory, and ethical considerations.

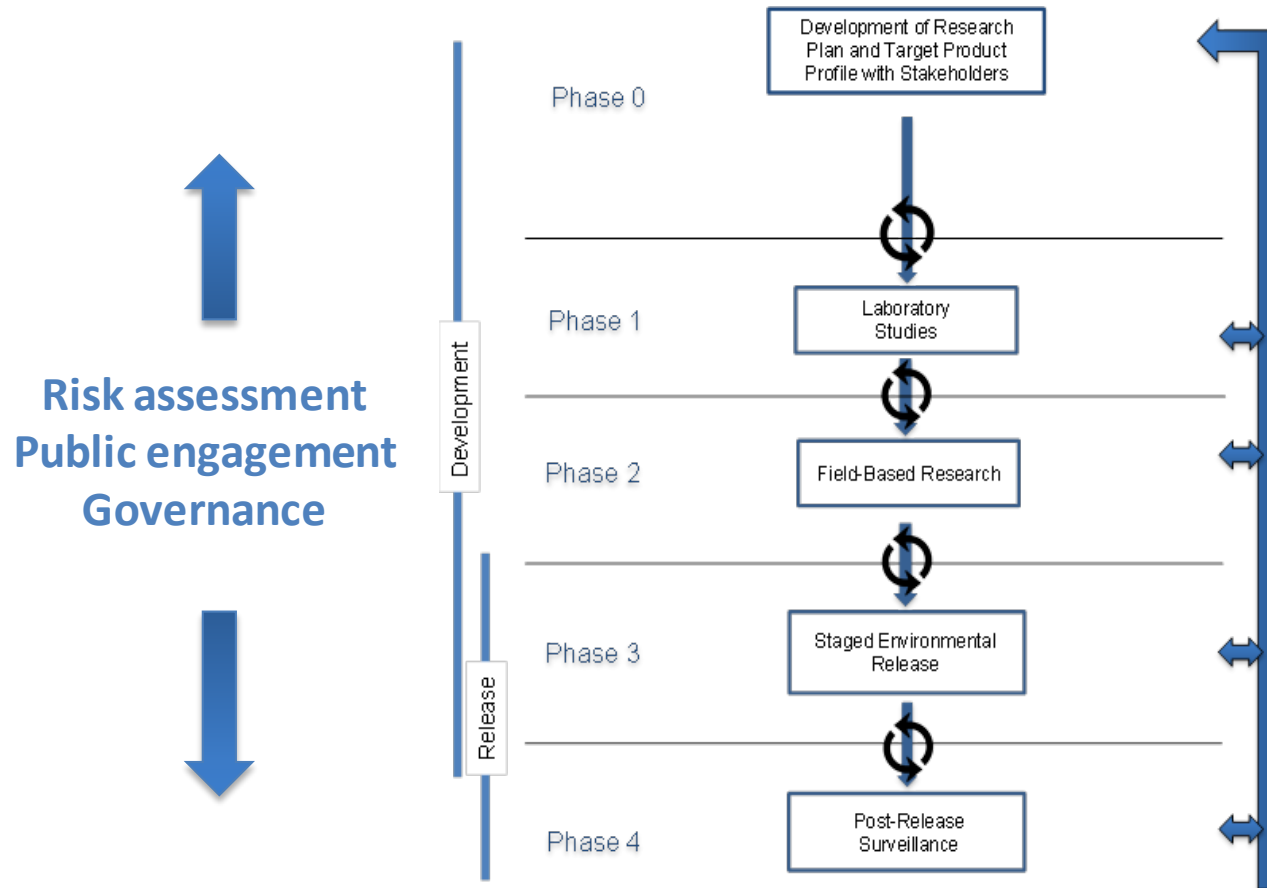
Phased testing: Responsible science in practice



Recommendation 5-1 : Scientists conducting research on gene drives should follow a phased testing pathway, a step-by-step framework that begins with developing a research plan and continues through, if applicable, monitoring gene-drive modified organisms in the environment. Each phase...should include pre-defined “go/no-go” decisions...



Integrating science and values in phased testing



This stepwise, iterative approach to scientific evaluation should also identify and integrate social, environmental, regulatory, and ethical considerations.

Results at each stage guide future research and evidence-based decision making and governance.

Reframing risk and risk assessment



Recommendation 6-1: Researchers, regulators, and other decision-makers should use *ecological risk assessment* to estimate the probability of immediate and long-term environmental and public health effects of gene-drive modified organisms and to *inform decisions about* gene drive research, *policy*, and application.

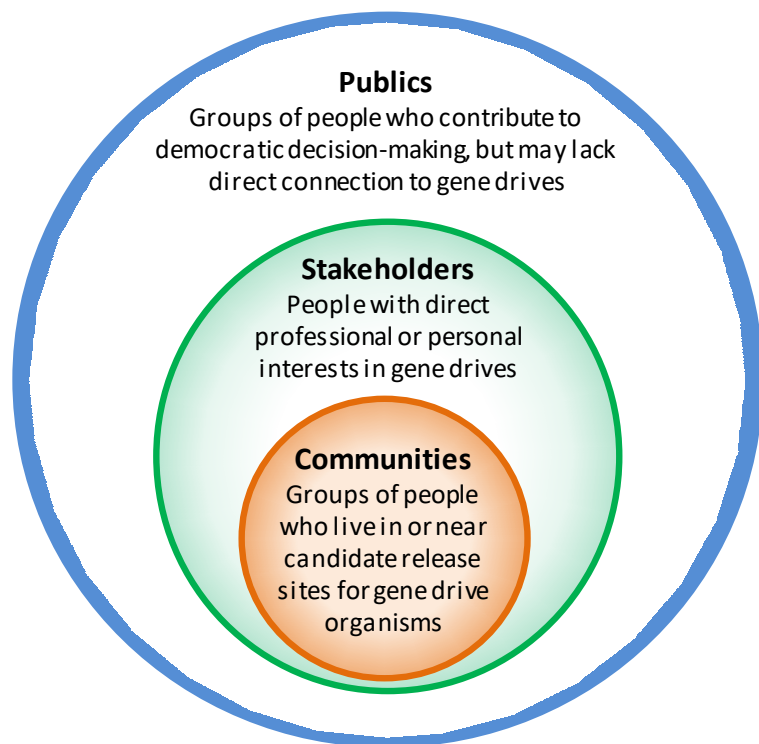
Ecological risk assessment provides multifactorial evaluation of potential benefit and harm, quantifies the probability of specific outcomes, traces cause-and-effect pathways; identifies sources of uncertainty, and incorporates public concerns.

(Emphasis added)

Public engagement is essential to research, risk assessment, and governance



Public engagement cannot be an afterthought.



Recommendation 9-5: Governing authorities, including research institutions, funders, and regulators, should develop and maintain clear policies and mechanisms for how public engagement will factor into research, ecological risk assessments, and public policy decisions about gene drives. Defined mechanisms and avenues for such engagement should be built into the risk assessment and decision-making processes from the beginning.

Recommendations on governance



Recommendation 8-4: The U.S. government should clarify the assignment of regulatory responsibilities for field releases of gene-drive modified organisms, including the roles of relevant agencies not currently included in the Coordinated Framework for the Regulation of Biotechnology.

Recommendation 8-8: If field testing or environmental releases are expected to be conducted in other countries, U.S. funders and researchers should give careful consideration to the regulatory systems in those countries, their adequacy to control the development and release of gene-drive modified organisms, and the relevant community and other voices that will need to be considered in related governance.

Recommendations for governance – cont.



Recommendation 8-10. Research institutions, regulators, and funders should revisit international regulatory frameworks, national laws, non-government policy, and professional codes of conduct on research to determine whether and how they may be applied to specific contexts of gene drive research, particularly with regard to site selection issues, capacity building for responsible and inclusive governance systems, scientific and post release surveillance, and stakeholder engagement.

A one-size fits all approach to governance is not likely to be appropriate.

Recommendations for governance – cont.



Recommendation 9-6: In selecting sites for field testing and environmental releases, researchers and funders should be guided by their professional judgment, the feasibility of risk assessment and community engagement, and the community's values and understanding of the balance of benefits and harms.

In site selection, preference should be given to locations in countries with the existing scientific capacity and governance frameworks to conduct and oversee the safe investigation of gene drives and development of gene-drive modified organisms.

Visit nas-sites.org/gene-drives for:

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- PDF of the report for free download
- *Report in Brief* - a 4-page lay summary
- Briefing slides and archived webcast of public release

