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## HOW IS GENE DRIVE RESEARCH REGULATED?

Research on gene drive is regulated at the national level. Research institutions in each country, such as universities, comply with national laws and regulatory frameworks that define what research can take place and under what conditions.

So far, as gene drive research is still in early stages, most of the research takes place in established laboratories which have existing permits. When new institutions start work on gene drive, if they do not yet have the permits in place for carrying out work on genetically modified organisms, they need to apply for permission with their national regulatory authorities. This may involve upgrading research facilities to meet new containment requirements, training staff on new protocols for managing modified organisms and undergoing national inspections before the permit can be granted.

Permits are granted with specific conditions which with the research team must comply and are to be renewed on a regular basis. Inspections or audits to assess compliance may be conducted periodically while the work is ongoing, depending on the requirements of the national authority.

Several national authorities have recently started processes to examine their national regulatory frameworks and assess whether they are suitable for managing gene drive research and, potentially, for evaluating a gene drive-based technology if one is developed and an application for an outdoor field evaluation is submitted. Given the current state of research, no gene drive-based technology will be ready for assessment for some years, so these processes are happening in a timely fashion and can help provide guidance to researchers.



## List of recent initiatives to review or discuss gene drive regulation

- Australian Academy of Science: "Synthetic Gene Drives in Australia: Implications of Emerging Technologies" (May 2017)
- European Academies Science Advisory Council: "Genome editing: scientific opportunities, public interests and policy options in the European Union" (March 2017)
- American Academy of Sciences, Engineering and Medicine: "Gene Drives on the Horizon" (June 2016)
- German Central Committee on Biological Safety "Position statement of the on the classification of genetic engineering operations for the production and use of higher organisms using recombinant gene drive systems" (February 2016)
- Dutch National Institution for Health and Environment (RIVM) "Gene drives: Policy Report" (2016)
- United States Environmental Protection Agency "2017 Update to the Coordinated Framework for the Regulation of Biotechnology" (2017)



## WHO PROVIDES OVERSIGHT TO THE RESEARCH ON GENE DRIVE?

The overall framework for oversight is provided at the national level and then administered at the level of the university or research facility. The university or research facility to which the research team is affiliated often provides the immediate first layer of oversight and they manage how research is carried out by their teams, from a safety and an ethics perspective, in compliance with national regulations.

If teams need to carry out work in the field, for example for stakeholder engagement, they have to submit a research protocol to the University's ethics committee, which will review and approve it before the activities can take place. In addition to the approval of the University's ethics committee, in case of activities such as the collection of insects and animals, the government wildlife agencies and/or the public land managers may also need to grant a specific authorization or permit.

For specific research activities, research teams may need to request specific permissions from national authorities. This would apply to importing modified organisms from abroad or setting up a new research facility with different capabilities from existing ones.

Research teams may also have to comply with additional requirements that are specific in their grant or funding agreements, for example regarding how findings are to be published and whether any commercial benefits can be derived from the research.



## ARE CURRENT FRAMEWORKS SUFFICIENT?

Innovation and regulation have to work closely together to ensure the development of new technologies can be appropriately managed. Gene drive is no different from other innovative research fields and it is important for national authorities to review their frameworks to decide whether any modification or additions are needed. Much of gene drive research may be suitably managed under existing frameworks for genetically modified organisms, but it is possible that particular features will require additional considerations when a potential technology is ready for testing, in particular for small-scale outdoor field evaluations.

Researchers need guidance from regulators on their expectations and the rules to follow so they can design their research process to match these requirements and be prepared to provide adequate information to regulators.