

Policy and Regulatory Issues for Gene Drives in Insects

WORKSHOP REPORT

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Scientists around the world, including leading researchers at the University of California, are working to apply gene editing technologies to quickly “drive” desired traits throughout populations of insects. The hope is that the method could be used to engineer populations of insects in the wild, with the goal of reducing insect-borne diseases such as malaria or dengue fever, or controlling agricultural pests, such as those that transmit citrus greening disease. Many benefits could be realized if these research efforts are successful, but several challenges must first be overcome.

In January, 2016, JCVI’s Policy Center and UC San Diego convened a workshop to examine the regulatory and policy challenges associated with the development and use of “gene drive” engineered insects. The workshop brought together leading gene drive researchers with federal regulators, ecologists, ethicists, and environmental policy analysts. The task given to participants was to identify a path, if possible, to safely move gene drive insects from the laboratory to field trials, and if appropriate, to eventual deployment.

Participants identified and discussed the key challenges that scientists and decision makers will face as researchers develop gene drive insects intended for environmental release, and identified a series of “action items” to help address these challenges and hurdles. The resulting report outlines specific suggestions for researchers and research funders, United States regulators and policymakers, and international organizations. If implemented, these actions could help advance this promising new approach for combatting insect-borne human disease and insect agricultural pests, while ensuring that environmental safety and societal issues are addressed.

Action items for the research community include a series of guidance documents about best practices to be followed at each stage of development, including updating existing guidance developed by professional societies to address previous generations of engineered insects. Foremost among these is guidance to help product developers to engage and work with communities when pursuing field testing of these new approaches to control insect-borne disease and agricultural pests. Researchers and research funders alike were also encouraged to pursue new and varied gene drive designs so that products could be better tuned to the needs of specific applications.

Relevant Federal agencies are urged to update their guidance to product developers, and to clarify the relative roles of the Food and Drug Administration, U.S. Department of Agriculture, and Environmental Protection Agency for regulating genetically engineered insects. Participants also suggested that the U.S. Government establish a single office or point of contact to help guide developers to the appropriate Federal agency, as other countries have done.

Although much of the research related to gene drive insects is and will take place in the U.S. and other developed countries, many of the products will have applications in the developing world. The workshop participants urged the World Health Organization (WHO) in particular to play the leading role to help developing countries build the regulatory capacity to oversee this next generation of engineered insects to help control devastating insect borne diseases. The WHO was also urged to update its guidance documents on field testing genetically engineered mosquitoes.

Copies of full report available at <http://www.jcvi.org/cms/research/groups/policy-center/>.

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