Moving towards gene drive field trials? (who, what, when, where and why)

Todd Kuiken, Ph.D.
Genetic Engineering & Society Center
tkuiken@ncsu.edu
@drtoddoliver

GES CENTER
NC STATE

Additional International Deliberations/Guidance

- WHO Guidance framework for testing of genetically modified mosquitoes (October 13th)
  (https://www.who.int/publications/i/item/9789240013155)
  - WHO takes the position that all potentially beneficial new technologies, including GMMs, should be investigated to determine whether they could be useful in the continued fight against diseases of public health concern.
    - Such research should be conducted in steps and be supported by clear governance mechanisms to evaluate the health, environmental and ecological implications.
  - Existing governance mechanisms should be backed financially to ensure that they are effective.
  - Internationally recognized risk assessment tools and procedures should be used for evaluating safety.
  - Community engagement is essential in developing effective approaches to combating VBDs.
    - Communities must be engaged in planning and conducting field trials before any new public health intervention is introduced. WHO considers that tools for engaging populations affected by VBDs are a priority in field research on GMMs.
- International Union for the Conservation of Nature
  - World Congress - January 2021 (postponed)
  - Motion on synbio/gene drives will be negotiated/voted on
    - https://www.iucncongress2020.org/motion/075

U.S. Progress since 2016 NASEM report: Lessons to learn

- Diamondback moth (Upstate NY) [completed] Not a gene drive
  - first open field release of a genetically engineered self-limiting insect in North America
  - Regulated under US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)
  - Results published Jan 2020 - https://www.frontiersin.org/articles/10.3389/fbioe.2019.00482/full
- American Chestnut [contained field trials underway] Not a gene drive
  - Public comment period just ended for deregulation status for field release
  - Food and Drug Administration, examine the food safety of the transgenic nuts (if being sold)
- Oxitec mosquitos (Florida Keys/Texas) [potential release 2021] Not a gene drive
  - Was bounced from USDA → FDA → EPA
  - EPA Experimental use permit approved: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0274
- Genetic Biocontrol of Invasive Rodents Would be a gene drive
  - Still unclear who would have final jurisdiction (US FWS/EPA/Endangered Species Act?)
  - Heard earlier from Antoinette Piaggio, PhD (USDA) on latest efforts underway
  - https://www.geneticbiocontrol.org/

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Assessment Tools for Biotechnology Products

COVID-19 Update: EPA is providing flexibilities to applicants experiencing challenges related to COVID-19. **Please see the Flexibilities Available to Organizations Impacted by COVID-19** clause in Section IV of EPA's Solicitation Clauses.

U.S. Environmental Protection Agency
Office of Science Advisor, Policy and Engagement
Office of Research and Development
Science to Achieve Results (STAR) Program

Assessment Tools for Biotechnology Products
CLOSED – FOR REFERENCES PURPOSES ONLY

This is the initial announcement of this funding opportunity

Funding Opportunity Number: EPA-G2020-STAR-C1, Assessment Tools for Biotechnology Products

Funding Opportunity Number: EPA-G2020-STAR-C2, Early Career: Assessment Tools for Biotechnology Products

Catalog of Federal Domestic Assistance (CFDA) Number: 66.509

Solicitation Opening Date: May 6, 2020
Solicitation Closing Date: July 15, 2020: 11:59:59 pm Eastern Time

The United States Environmental Protection Agency (EPA), as part of its Science to Achieve Results (STAR) program, is seeking applications proposing research to support the development of improved science-based human health and environmental risk assessments of new biotechnology products, including those developed through synthetic biology, genome editing, and metabolic engineering.

For more information, and how to apply, please click on the link provided below

Total - $4.4 million (not clear how much, if any will go towards gene drives)

In comparison, DARPA's Safe Genes program was $65 million*

*https://www.darpa.mil/news-events/2017-07-19

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https://www.epa.gov/research-grants/assessment-tools-biotechnology-products

IISD Experimental Lakes Area (IISD-ELA) is an exceptional natural laboratory comprised of 58 small lakes and their watersheds set aside for scientific research. Located in a sparsely populated region of Northwestern Ontario, Canada, the lakes in the region are not affected by human impacts. By manipulating these small lakes, scientists are able to examine how all aspects of the ecosystem—from the atmosphere to fish populations—respond. Findings from these real-world experiments are often much more accurate than those from research conducted at smaller scales, such as in laboratories.

https://www.iisd.org/ela/

Take Away Message…

- Is there a difference between “field release research” and a “release”?
  - This should be considered in the regulatory review
- U.S. should evaluate whether it should officially join (or re-join) international treaties/deliberations
  - Some applications being funded are intended to be used outside U.S.
  - Some applications may cross borders from U.S. to other countries
  - Harmonize guidance with international treaties/organizations (including FPIC)
- U.S. regulations can probably handle the eventual review of gene drive applications
  - Some clarifications will be needed for which applications go where
- The “field work” cannot be left for someone else to do after the fact
- U.S. should establish ecological risk research station(s) (ELA type reservation) for gene drives
  - Establish a coordinated research strategy that co-funds ecological research with gene drive development
  - This will require more involvement from the ecological sciences community (with funding)