Emerging biotechnologies and public engagement: Reflections on the NASEM report on gene drives

Center for Science and Technology Policy Research | CIRES
University of Colorado-Boulder | March 8, 2017

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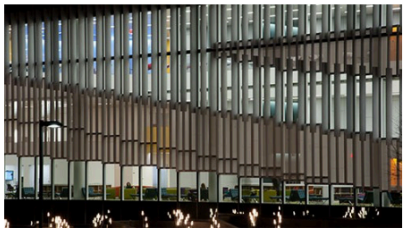

For Stakeholders

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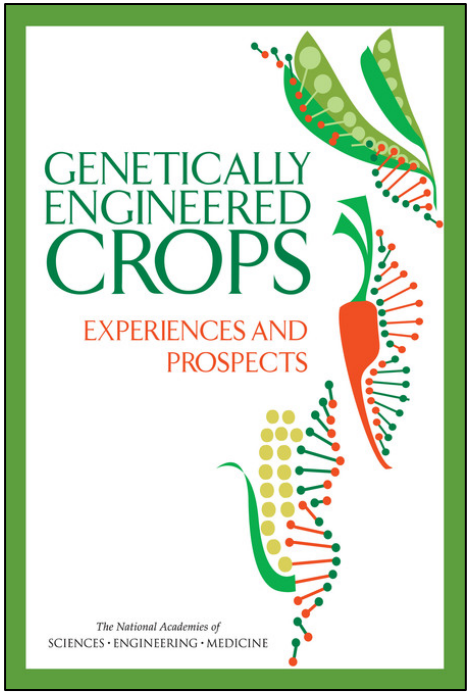

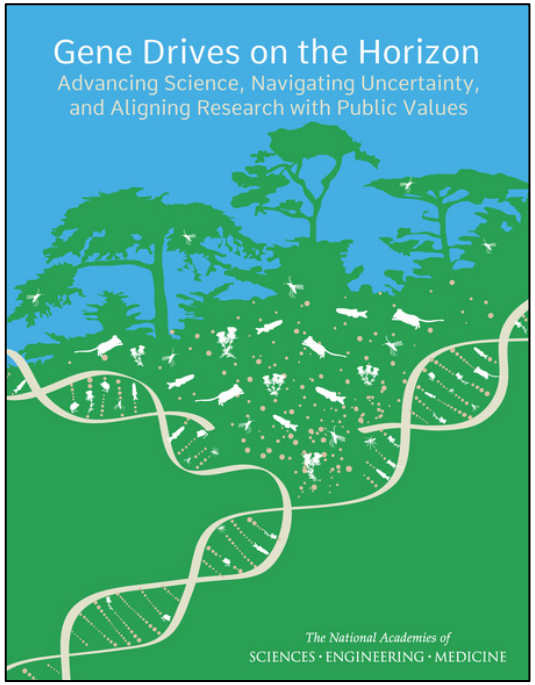

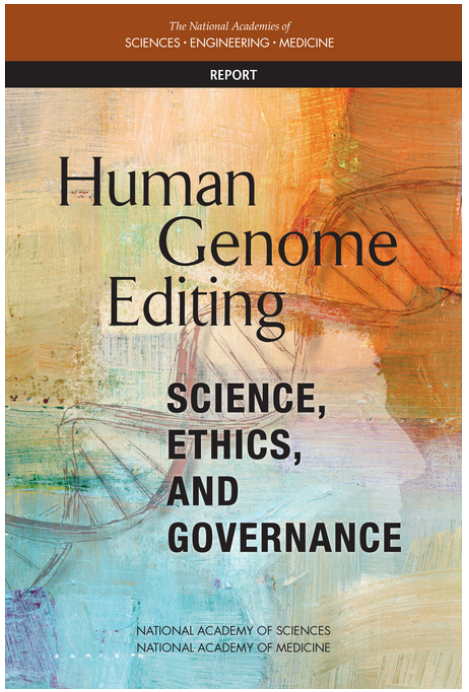

Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System

Welcome to the National Academies of Sciences, Engineering, and Medicine study examining the future products of biotechnology. Rapid scientific advances are expanding the types of products that can be generated through biotechnology. A committee of experts will identify the kinds of products that may be produced with biotechnology in the next 10 years. The U.S. regulatory system for biotechnology products was originally designed in the 1980s, so the committee will also provide advice on the scientific capabilities, tools, and expertise that
forthcoming products. The committee's report is expected to

This study is sponsored by the US Environmental Protection
and the US Food and Drug Administration.

Advances in gene editing have prompted four related studies (formerly the National Research Council)

The National Academies of
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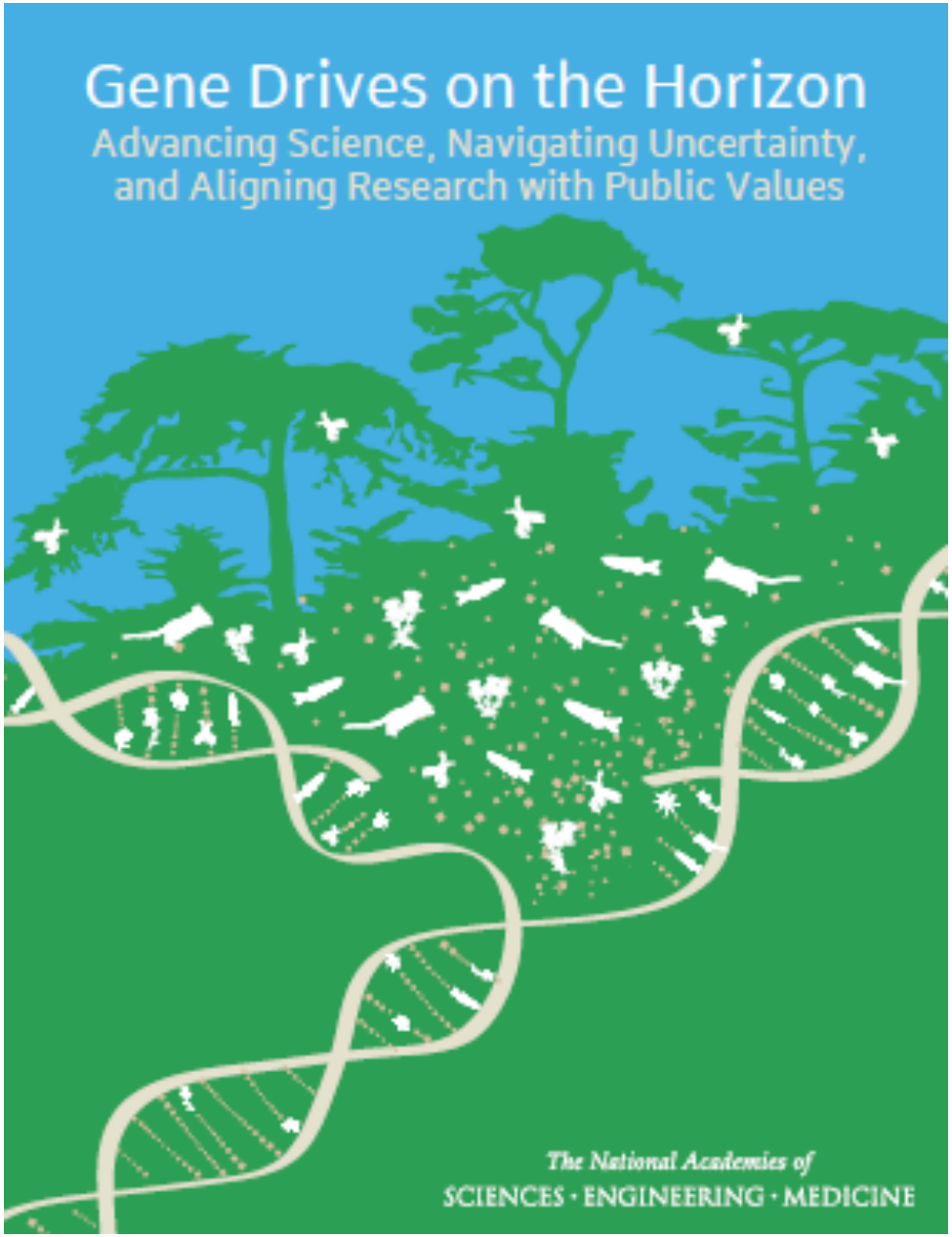

The National Academies of
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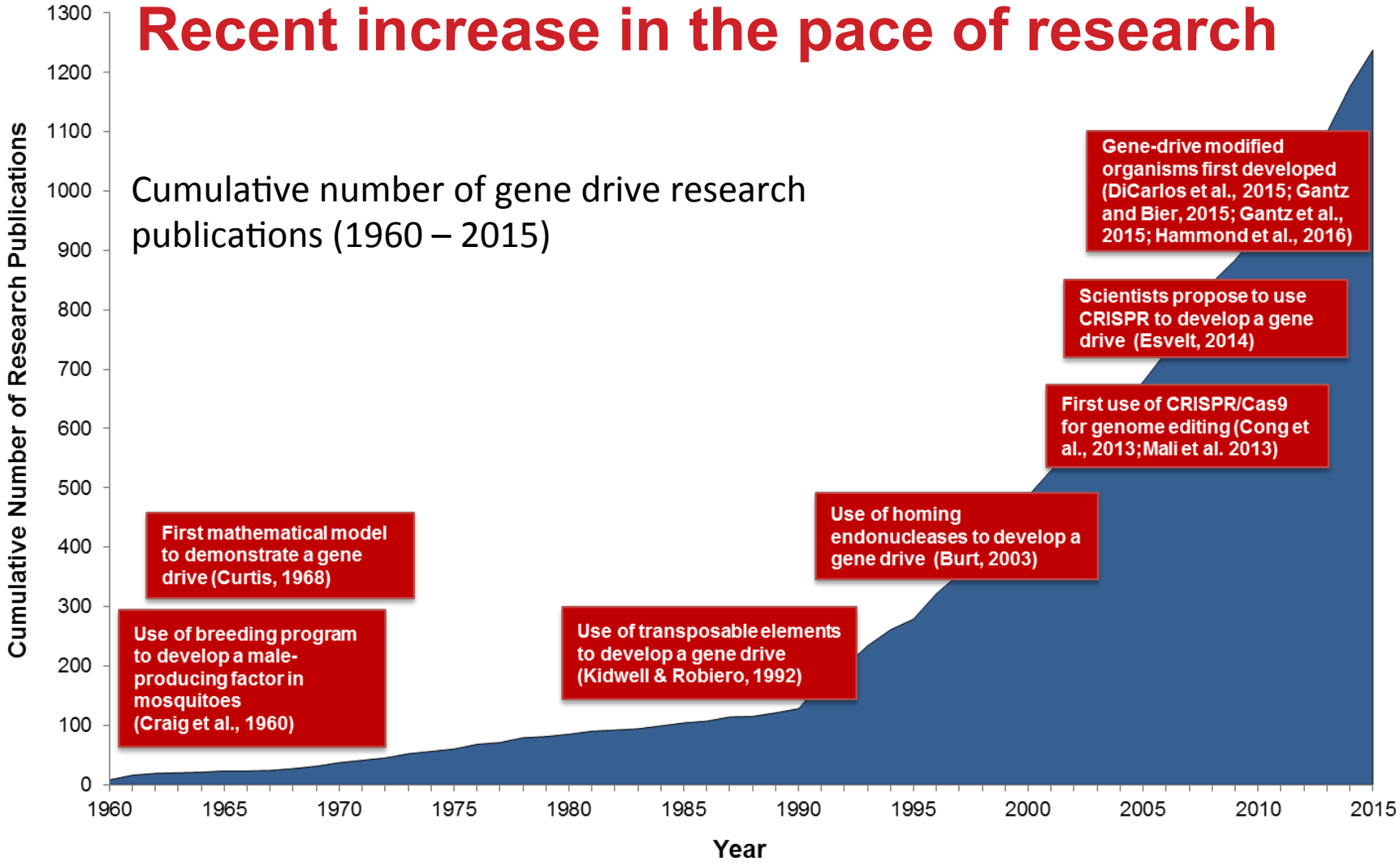
Released June 2016

nas-sites.org/gene-drives

- PDF of the full report
- Report in Brief
- Webinars with experts
- Archived webcast of public release at NAS
- Slide presentation

Motivations for the Study:
Recent increase in the pace of research

Cumulative number of gene drive research publications (1960 – 2015)



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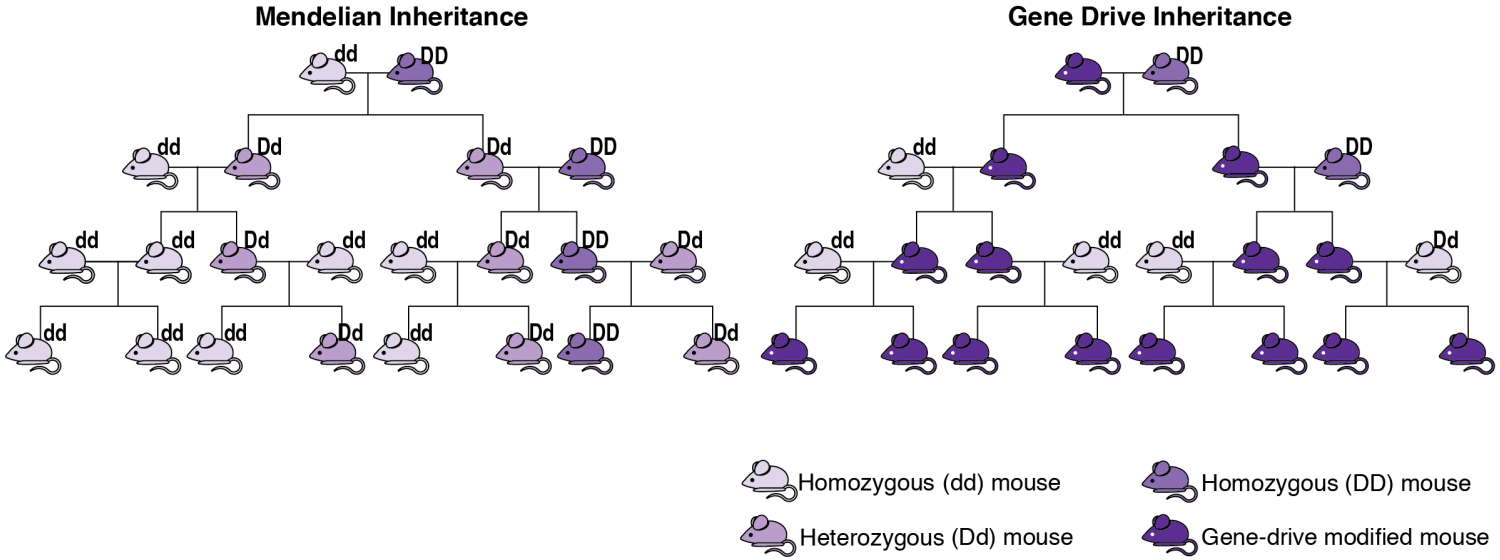
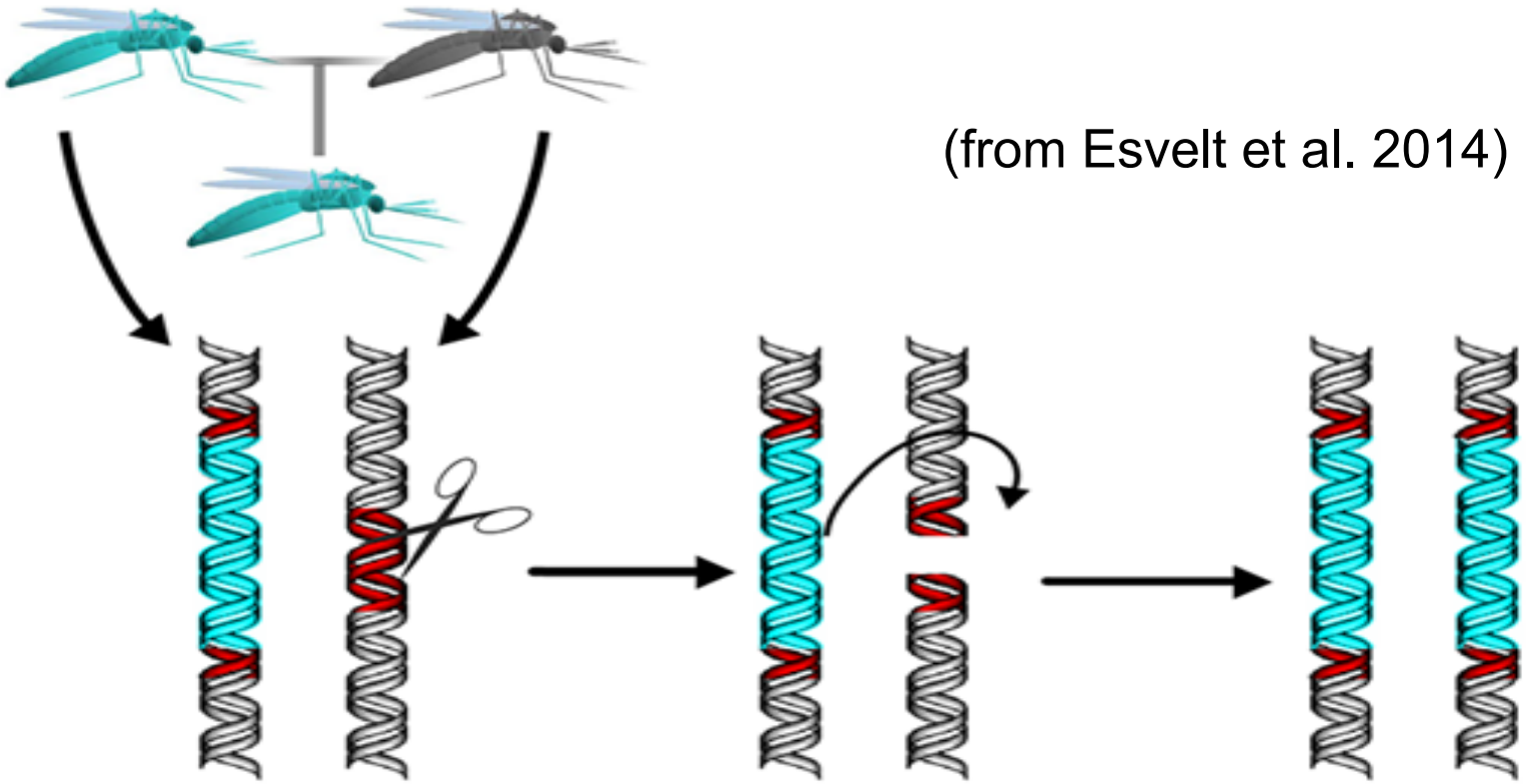
What Are Gene Drives?

Gene drives are systems of biased inheritance in which the ability of a genetic element to pass from a parent organism to its offspring through sexual reproduction is enhanced.



CRISPR-based Gene Drives

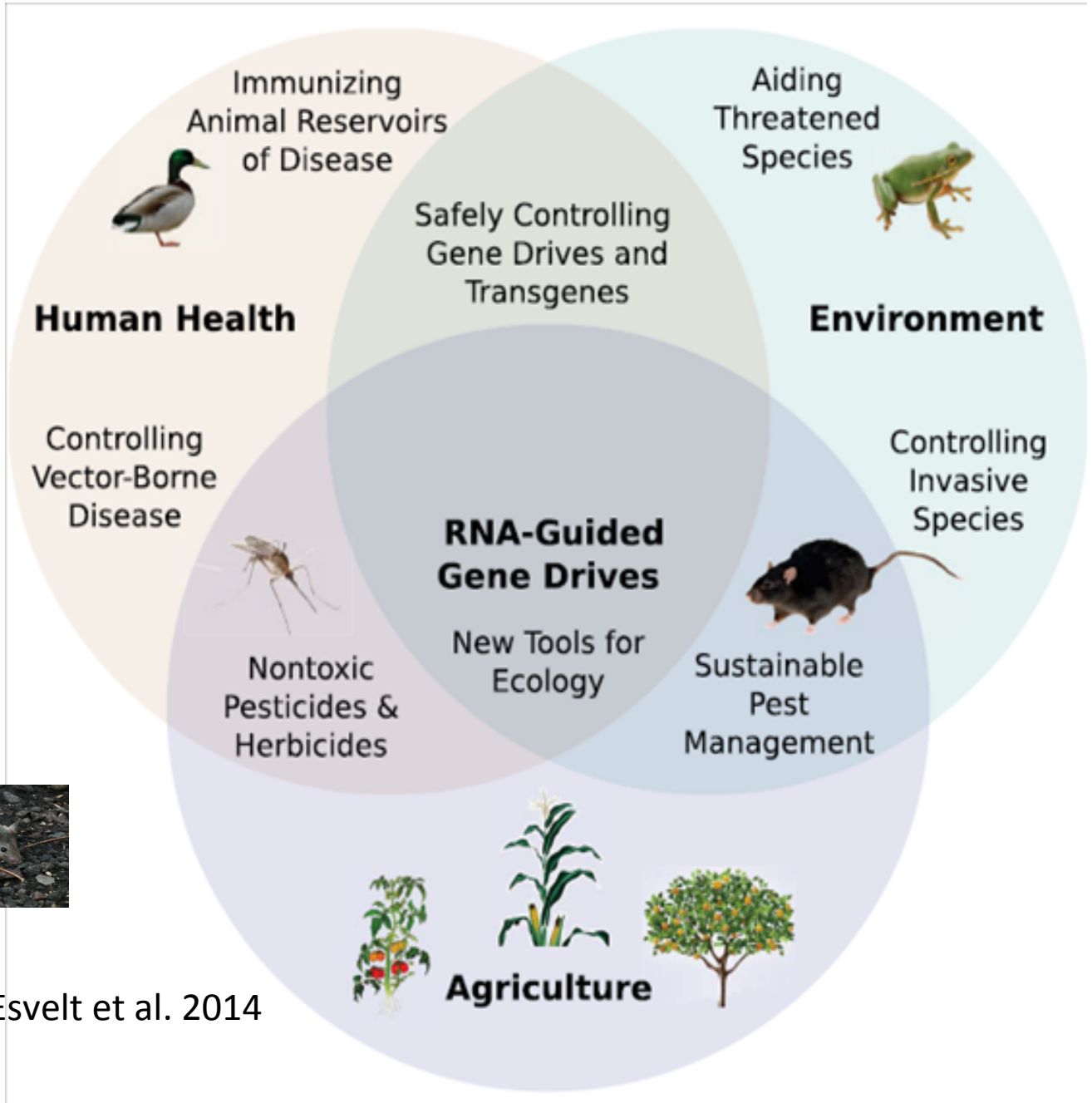


(from Esvelt et al. 2014)

Key Features and Potential Uses of Gene Drives

- Defining features:
  - Spread and persistence
  - Potential to cause irreversible ecological change
- Two potential uses:
  - Population suppression: Decrease numbers
  - Population replacement: Change genetic characteristic(s)

Proposals to Use Gene Drives



Esvelt et al. 2014

Motivations for the Study
Many questions about science, ethics, and governance

- Could gene drives have unintended consequences for public health and the environment?
- Do we know enough to consider releasing gene-drive modified organisms into the environment?
- *Should* a gene drive be used to suppress or eliminate a pest species?
- How do we decide where gene-drive modified organisms could be released? What should be governments' role?

Statement of Task

- 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 this 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 release sites.

- Provide general principles that will guide **responsible practices** in gene drive research

Committee Composition

Developmental Biology
Lisa A. Taneyhill, University of Maryland

Ecological Risk Assessment
Wayne Landis, Western Washington Univ.

Entomology & Vector-Borne Diseases
Nicole L. Achee, Univ. of Notre Dame
Lynn Riddiford, Howard Hughes Medical Institute

Ethics & Scientific Integrity in Research
Elizabeth Heitman, *Co-Chair,* Vanderbilt University Medical Center
Gregory E. Kaebnick, The Hastings Center

Public Interfaces with Controversial Science
Jason A. Delborne, NC State University

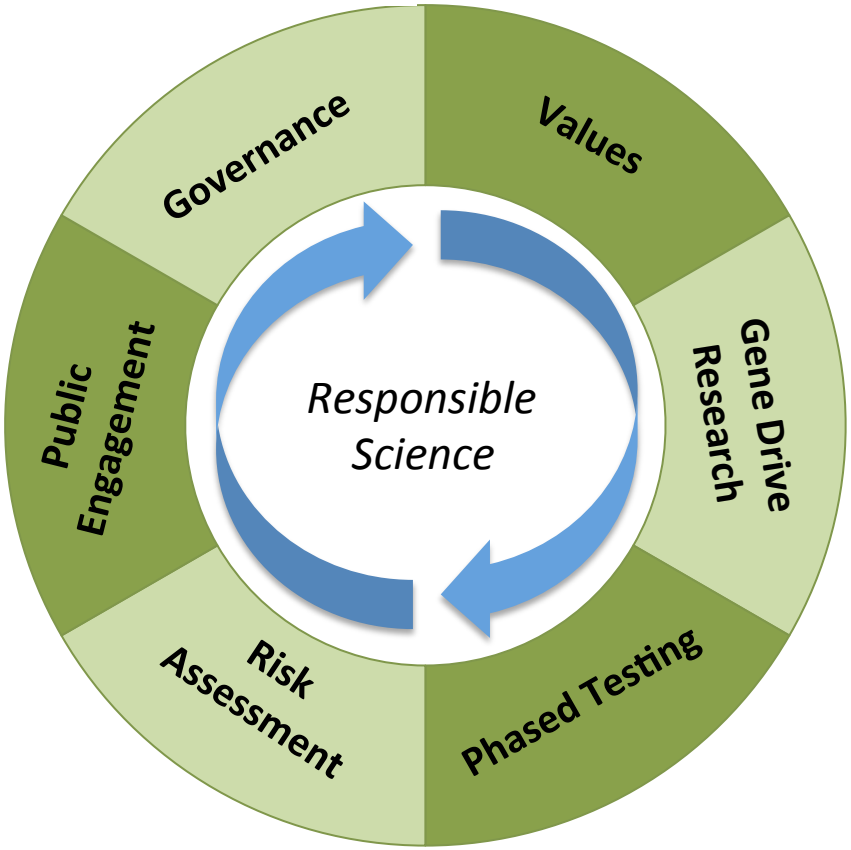
Biosafety & Biosecurity
Stephen Higgs, Kansas State University

Plant Biology & Ecology
Vicki Chandler, Minerva Schools at Keck Graduate Institute
Brandon S. Gaut, Univ. of California, Irvine

Population Ecology
James P. Collins, *Co-Chair,* Arizona State University
Joseph Travis, Florida State University
Paul E. Turner, Yale University

Science & Technology Policy, Law
Ann Kingiri, African Centre for Technology Studies
Joyce Tait, University of Edinburgh
David E. Winickoff, University of California, Berkeley

Responsible Science to Develop Gene Drive Technologies



A responsible science approach calls for continuous evaluation and assessment of the social, environmental, regulatory, and ethical considerations of gene drives.

(NASEM, 2016)

State of the Science

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.

(NASEM, 2016)

Values Are Important at Every Step

Questions about responsible science, from why and how research should be conducted to whether, when, and where a gene-drive modified organism could be released into the environment, *rest on values at every step* (NASEM, 2016).

- Fairness (distribution of benefits and harms)
- Justice (who makes decisions and how)
- Knowledge (to advance human capacities and for its own sake)
- Nature (control, stewardship, intrinsic vs. extrinsic values, purposeful extinctions)
- Precaution

ILLUSTRATION: DAVIDE BONAZZI/@SALZMANART

TECHNOLOGY GOVERNANCE

Precaution and governance of emerging technologies

Precaution can be consistent with support of science

By **Gregory E. Kaebnick,[1] Elizabeth Heitman,[2] James P. Collins,[3] Jason A. Delborne,[4] Wayne G. Landis,[5] Keegan Sawyer,[6] Lisa A. Taneyhill,[7] David E. Winickoff[8,9]**

Precautionary approaches to governance of emerging technology call for constraints on the use of technol- irrational fears of unproven risks—"risk panics" (*1*)—and would paralyze development and use of beneficial new technologies (*1*, *2*). Advocates give credence to this view when they suggest that precaution leads necessarily to moratoria (*3*). Progress in the debate over precaution is possible if we can reject the common assumption that precaution can be explained by a simple

the protection and restoration of environments threatened by nonindigenous organisms. Gene drives also might have harmful effects, especially to the environment. A drive designed to eliminate a non-native mouse population from an island to protect native species might pose threats to related species, to populations of the mouse elsewhere in the world, or to other species on the island that depend on the mouse population. The range of effects due to hybridization, geographic dispersal, and predator-prey interactions, for example, would need to be studied and the probabilities quantified. These are a few possible harms for one hypothetical use; given the present state of knowledge for gene drives, the outcomes and their probabilities are not yet well understood.

INTERPRETING PRECAUTION

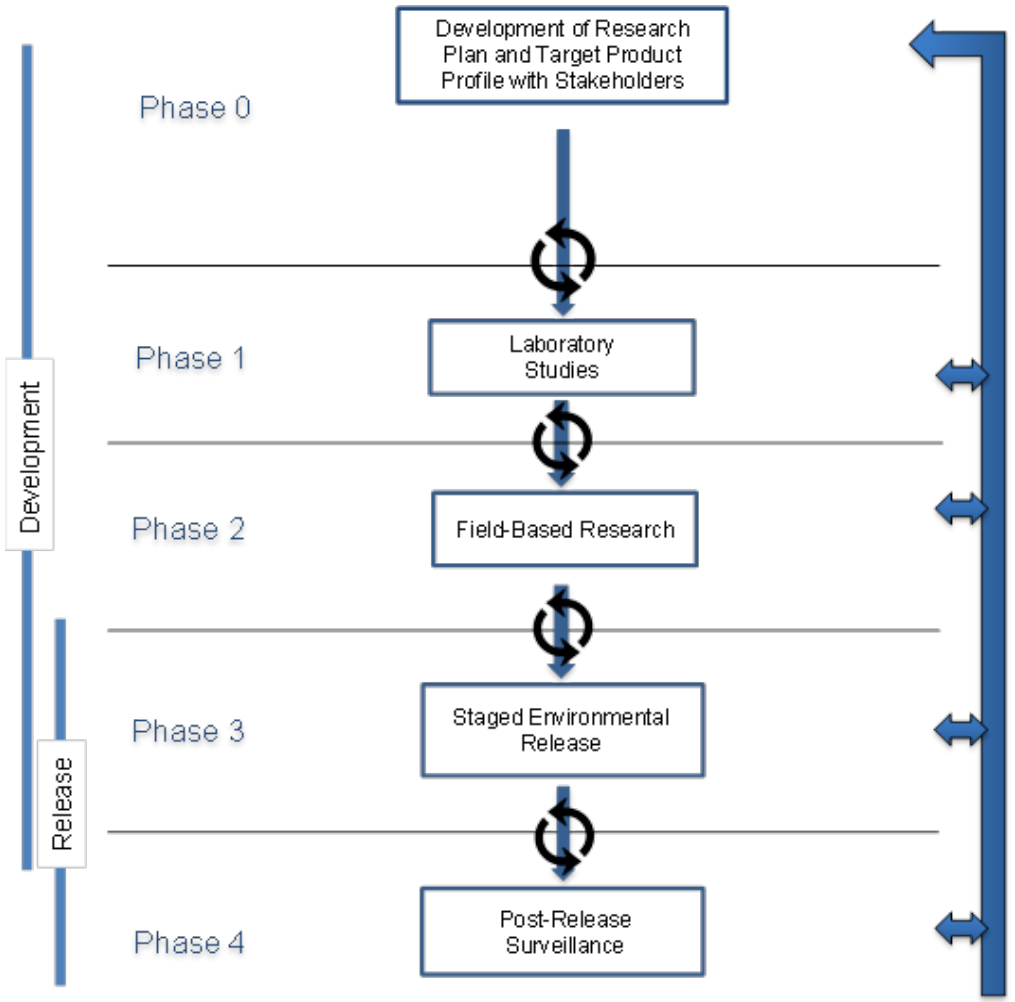
At least four common objections to precaution underlie critics' claims that precaution is irrational and paralyzing. First, precaution is said to be too vague and ambiguous to provide useful guidance. In response, some advocates hold that precaution is not meant to provide a decision-making algorithm that is able to identify appropriate precautionary measures for each and every technology. Precaution is better described at a high level not as a principle but as an attitude or approach that consists in sharpening or broadening the scrutiny of a proposed project (*5*, *6*). Deciding whether precautionary measures are appropriate, and then determining what they are, depends on examining details of the technology and its potential impacts (*2*).

The NASEM report demonstrates this contextual approach to precaution. It starts from an understanding of the science, how the science might be used, and downstream effects of attempts to use it. Some general

Published by AAAS

Phased Testing Pathway

Risk assessment
Public engagement
Governance



Stepwise, iterative approach to scientific evaluation

Guides research and supports evidence-based decision making

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Challenges to Governance of Gene Drive Research and Development

Existing mechanisms of governance may be inadequate to address potential immediate and long-term environmental and public health consequences because they:

- Do not consider gene drives' intentional spread and potential irreversible effects on ecosystems
- Lack clarity in their jurisdiction of oversight
- Provide insufficient structures for public engagement
- Do not address the potential for misuse
- Lack policies for collaborating with other countries with divergent systems of governance

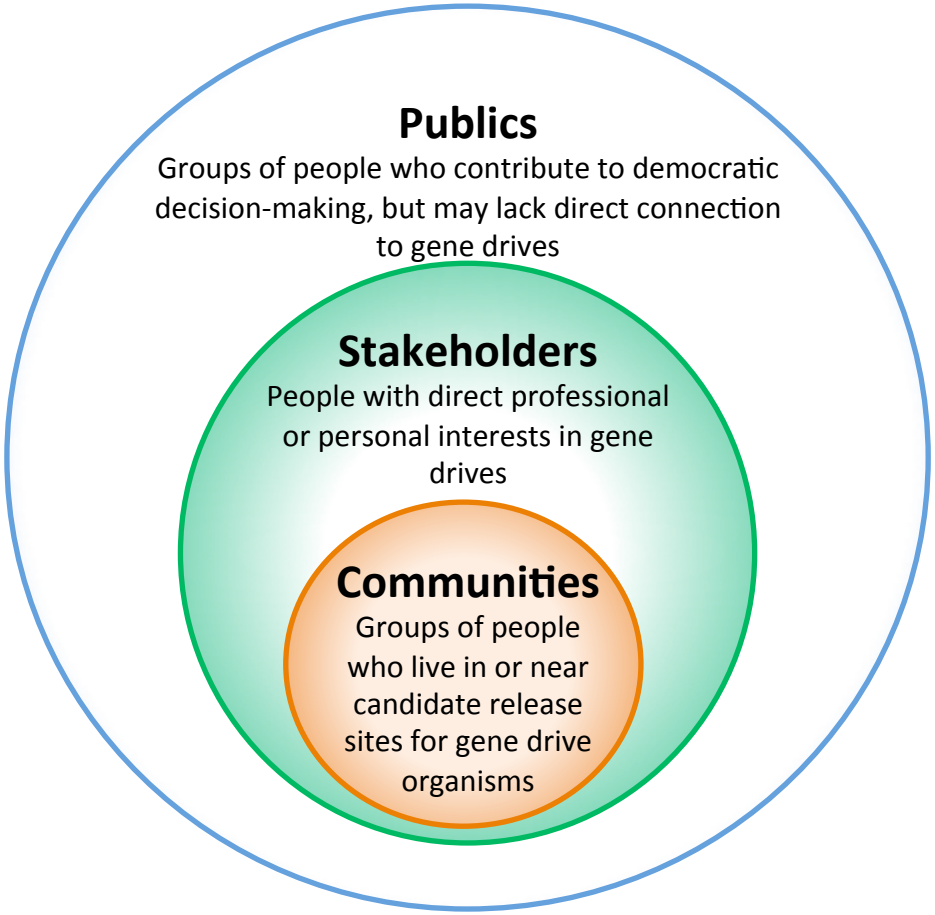
From Environmental Assessment to Ecological Risk Assessment

Advantages of ecological risk assessment:

- Quantify the probability of specific outcomes
- Trace cause-and-effect pathways
- Identify sources of uncertainty
- Incorporate concerns of relevant publics
- Compare benefits and harms
- Compare alternative strategies
- Inform research and public policy decisions

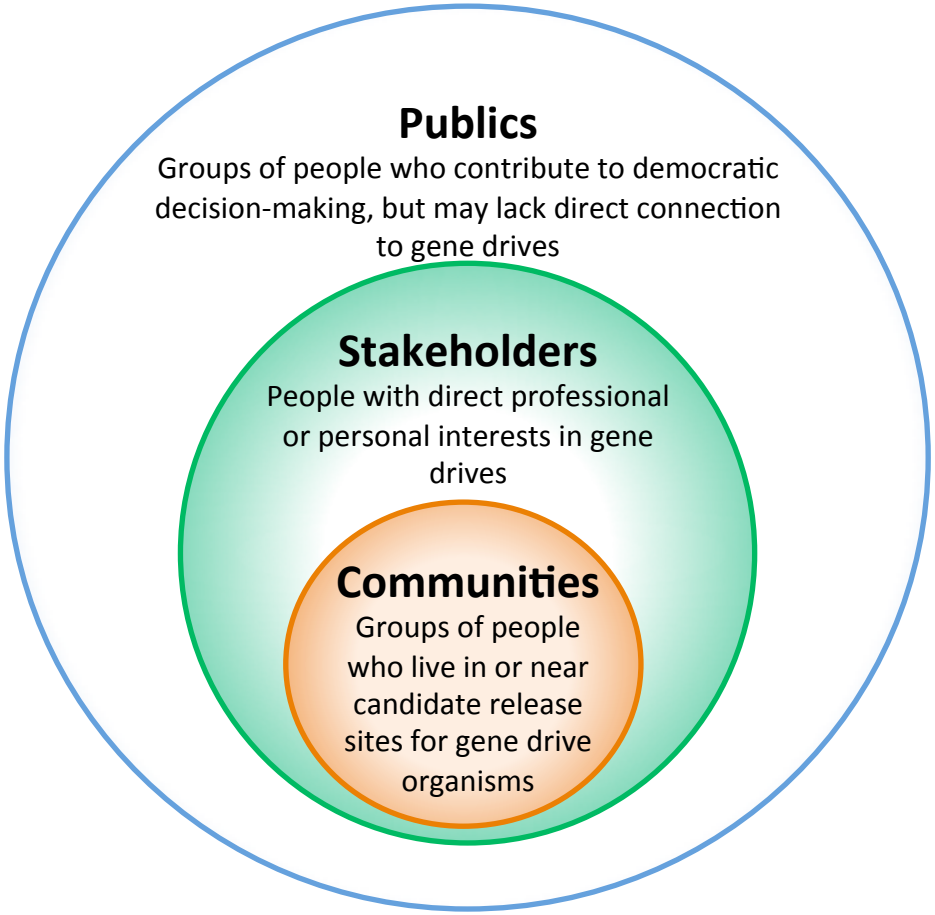
Relevant U.S. guidelines and technical documents are not yet sufficient on their own to guide ecological risk assessment for gene drive technology.

Defining engagement



Seeking and facilitating the sharing and exchange of knowledge, perspectives, and preferences between or among groups who often have differences in expertise, power, and values (NASEM, 2016)

Public Engagement as a Priority



Public engagement cannot be an afterthought.

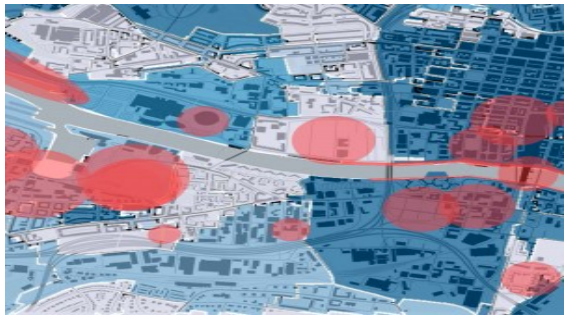
The outcomes of engagement may be as crucial as the scientific outcomes to decisions about whether to release a gene-drive modified organism into the environment (NASEM, 2016)

Motivations for Engagement

- Local knowledge
- Principles of justice
  - Transparency
  - Informed consent
- Opportunities for mutual learning
  - Scenario development
  - Reflective deliberation
- Building of trust

(NASEM, 2016)

Dps.mn.gov/divisions/ojp



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Designing Information Flow

Type of Engagement
Public Communication
Public Consultation

Public Engagement Sponsor ← → Public Representative

Rowe, G., & Frewer, L. J. (2005). A Typology of Public Engagement Mechanisms. *Science, Technology and Human Values*, 30(2), p. 255.

Challenges of Engagement

ECAST Network

- **Who** should be engaged?
- What are the **goals** of engagement?
- **When** should engagement occur?
- How can **cultural differences** among those involved in engagement be recognized and respected in ways that enhance deliberation?
- What are potential triggers for **polarization**?
- How should the results of engagement feed into practical and formal **decision making** about research and technological deployment?

(NASEM, 2016)

Experimenting with engagement

Project is being led by Kevin Esvelt, an assistant biology professor at MIT. *Mark Lovewell*

Genetically-Engineered Mice Explored as New Tool in Fight Against Lyme Disease

Alex Elvin *Wednesday, July 27, 2016 - 5:50pm*

Scientists at MIT are hoping to prevent Lyme disease on the Vineyard by releasing large numbers

The Vineyard Gazette
July 27, 2016

Those who attended generally supported the proposal, but peppered speakers with questions. —

CTIONS HOME SEARCH The New York Times

SCIENCE

Fighting Lyme Disease in the Genes of Nantucket's Mice

Trilobites
By AMY HARMON JUNE 7, 2016

NC STATE UNIVERSITY

Expert & Citizen Assessment of Science & Technology

A Distributed Network of Institutions for Peer to Peer Public Deliberation

https://ecastnetwork.org/

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ECAST
EXPERT AND CITIZEN ASSESSMENT OF SCIENCE AND TECHNOLOGY

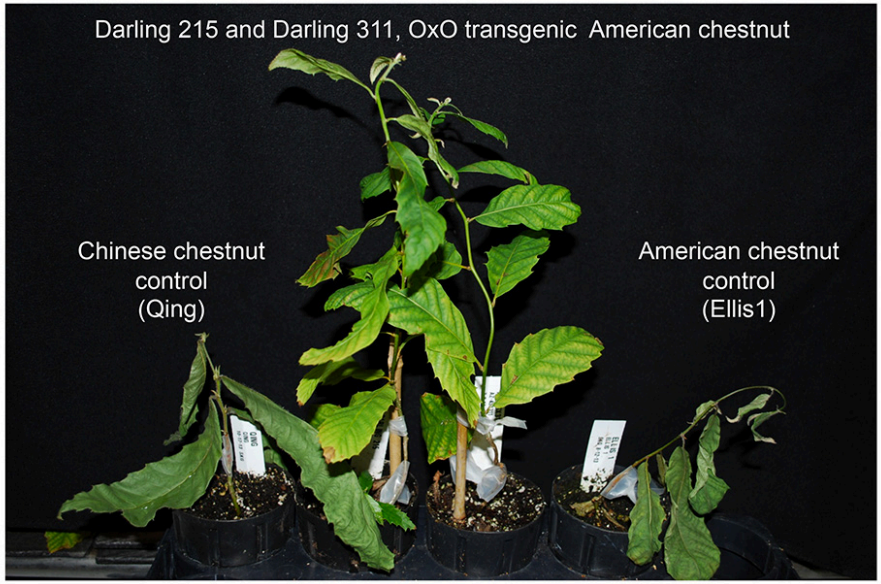
CATEGORIES

Event (15)

USING PUBLIC ENGAGEMENT TO INFORM POLICY DECISIONS

Very small stem blight resistance assay showing significant blight resistance enhancement using the OxO gene.

ESF



All plants were produced from tissue culture. Non-transgenic & transgenic Americans are clonal (Ellis 1 cell line). Pictured 8 days post inoculation with *C.parasitica* strain EP155. American stem diameters were ~1.5mm, Chinese ~2.0mm. Darling 215 OxO expression level is the threshold for high resistance in leaf assays and Darling 311 has higher expression levels than 215.

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ALGAE INDUSTRY, ALGAL SCIENCE

EPA POSTS INFORMATION ON GM/SYNBIO ALGAE PROJECT

AUGUST 12, 2015 ALGAEWORLD LEAVE A COMMENT

Thank you!

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