

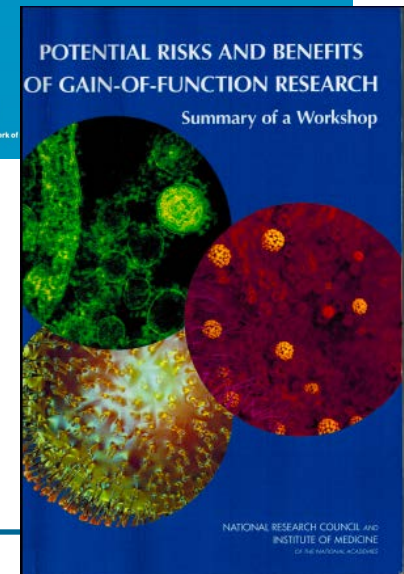
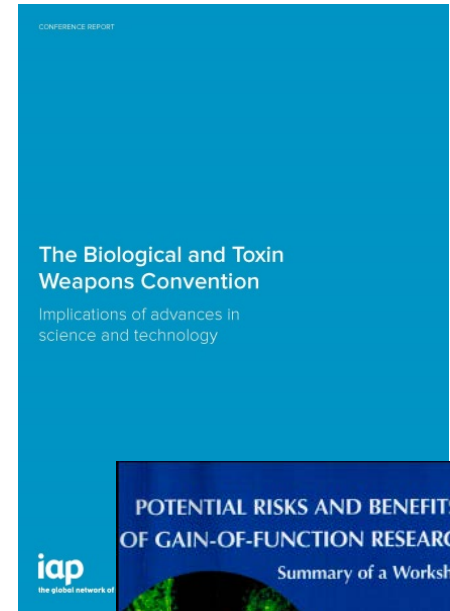
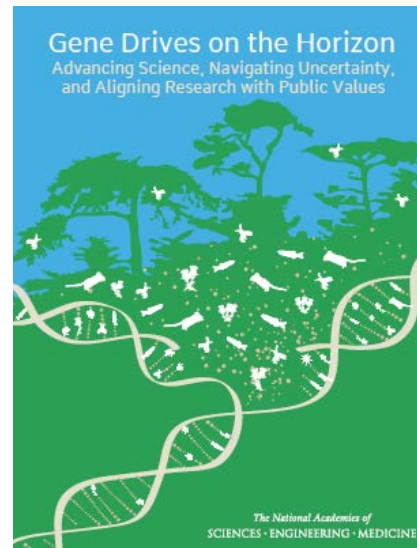
The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Advances in the Life Sciences

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Board on Life Sciences
BWC Review Conference: Prospects and Plans

Recent Activities Engaging Scientific, Ethics, Policy Communities on Emerging S&T

- IAP “Trends” Workshop for BWC 8th Rev Con
- Gene Editing
- Gain of Function Discussions



IAP Report: Developments in S&T Relevant to BWC (8th Review Conference)

- Background white papers identifying recent developments
- Workshop at Polish Academy (Sept. 2015)
 - 72 participants from 30 countries & international orgs.
 - Detecting and responding to disease & investigating alleged violations (microbial forensics)
 - Developing, producing, and delivering biological agents
 - Models for bringing S&T analysis into BWC
- Report prepared by Royal Society (Dec. 2015)
 - 2-page executive summary, non-technical conference report, and longer technical report - English, Spanish and Arabic
 - <https://royalsociety.org/topics-policy/projects/biological-toxin-weapons-convention/>

Selected Findings

- Global ability to detect and treat disease has been enhanced
 - Significant logistical, economic, technical and political barriers remain to achieve this objective
- Recent advances could facilitate the development of biological weapons
 - Technological barriers have been eroded
 - Improvements in techniques for modifying and ‘optimizing’ existing biological agents
 - Overcoming issues in synthesizing novel agents
 - Less time and space may be required for manufacture
 - At present most advances still require well-funded, sophisticated laboratories but this will change

Selected Findings

- Workshop did not identify any developments that would not be covered by the treaty
- BWC should continue to monitor S&T developments:
 - Would be aided by a mechanism to formulate relevant questions, identify applicable S&T capabilities, consider implications for the BWC, and support informed decisions about further actions, if required
- Need for education/outreach to promote the aims and objectives of the BWC among the scientific community

U.S. NAS Gene Editing-Related Activities

- Genetically Engineered Crops (2016)
<https://nas-sites.org/ge-crops/>
- Gene Drives in Non-Human Organisms (2016) ←
- Human Gene Editing (est. late 2016)
<http://nationalacademies.org/gene-editing/index.htm>
- Future Products of Biotechnology (est. late 2016)
<http://nas-sites.org/biotech>

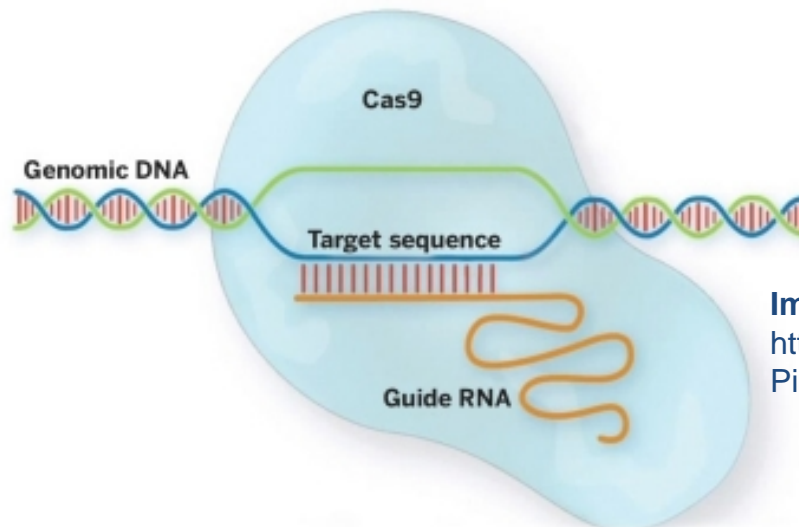
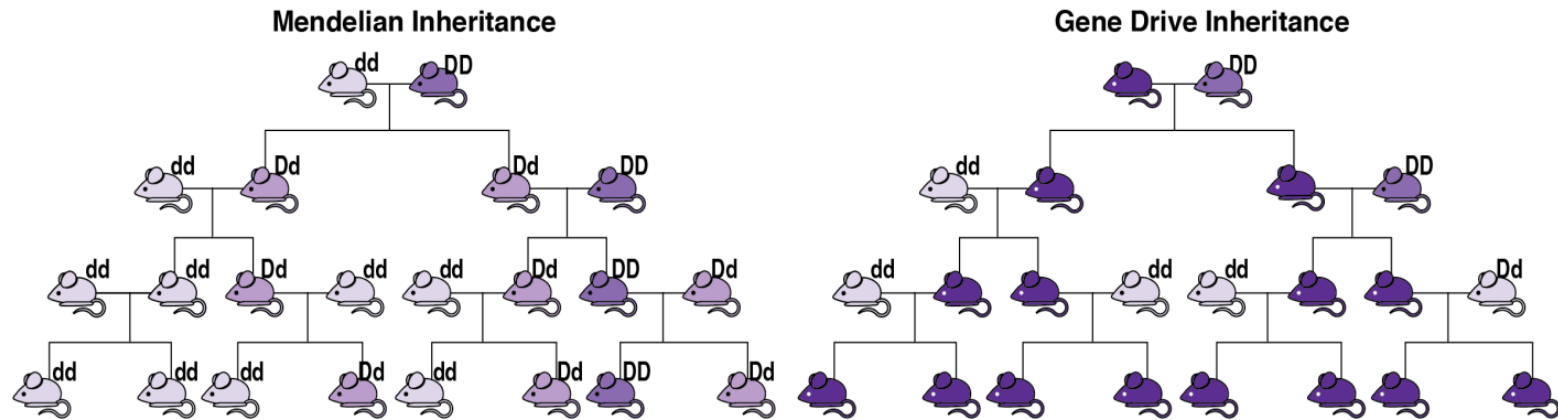


Image:

<http://cen.acs.org/articles/92/i39/Patent-Picks-CRISPRCas9-Gene-Editing.html>

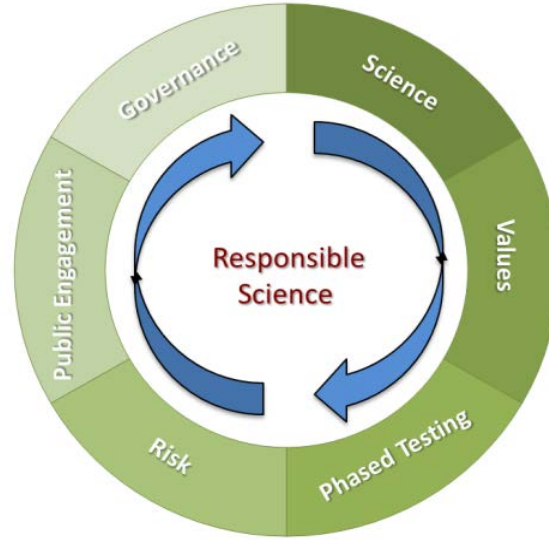
Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values



- Not all organisms suitable for gene drive modification
- Responsible governance, case-by-case analysis, phased testing
- Confinement and containment protocols
- International issue

Potential Biosecurity Concerns

- Unintended consequences of release
- Intentional misuse
 - Technical challenges; but could, for ex., possibly develop mosquito capable of transmitting pathogen more efficiently or transmit a pathogen or toxin not normally vector borne
- Active awareness and dialogue about potential for misuse



Recommendation 8-7

Researcher institutions, regulators, and funders should

- collaborate to develop oversight structures to regularly review the state of gene drive science and its potential for misuse.
- recommend or develop educational programs about biosecurity concerns, the potential for dual-use research, responsible practices and gene drive funding

Oversight of Gain of Function Research

- Gain of function research of concern due to pandemic potential
 - Enhanced pathogenicity or respiratory transmissibility in mammals, for ex. certain strains influenza, MERS, SARS
- Governance mechanisms to address questions about the biosecurity implications of research
- Advice provided by NSABB; ongoing US policy process
- Workshops to provide stakeholder input
 - Risk-benefit calculus is not simple
 - Publication stage too late
 - International issue
- NSABB #7: Engaging international community in dialogue about responsible conduct and appropriate oversight

A Few Final Points

- Biosciences are developing rapidly
 - Recent attention around genetic manipulation technologies
- Need for responsible governance in context of complex risk-benefit discussions
- Need for international dialogue - BWC as one forum
- Process for identifying & discussing scientific issues and implications for BWC
 - Various mechanisms could be envisioned or have been proposed
 - IAP convened discussion at April BWC Preparatory Committee Meeting: What would a BWC science advising mechanism need to achieve
 - Summary of discussions (IAP) forthcoming