

# Gene Drives and the Issue of Governance

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# Disclaimer

The views expressed in this presentation are my own and do not necessarily reflect the official position and policy of the DOST Biosafety Committee nor the Philippine Government.

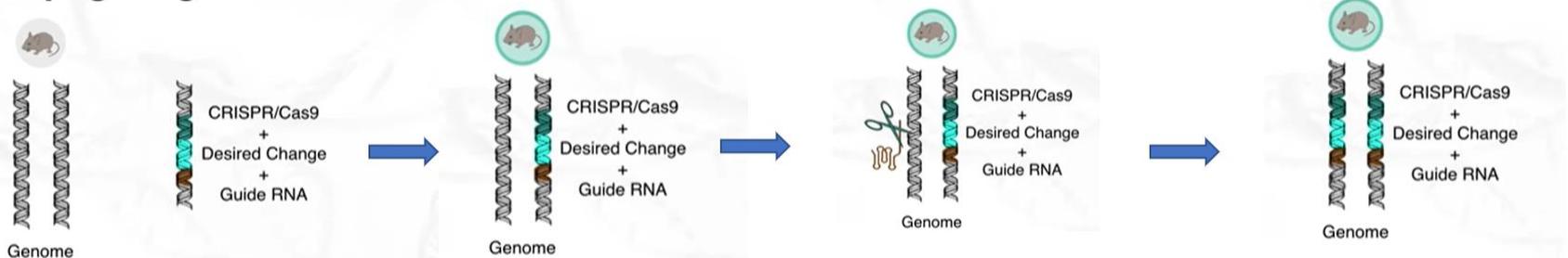
# Outline

- Rationale for governance
- Landscape of governance mechanisms
- Ideal governance framework

# Gene Drives

- Gene drives are ubiquitous in nature, but we will limit our discussions on synthetic, self propagating gene drives:
  - CRISPR Cas9 + desired change + guide RNA in reproductive cell

## Self-Propagating Gene Drive



Cassette inserted into reproductive cell

# Rationale for governance

- Genetic modification could affect the species in unexpected ways
- Genetic modification could spread beyond the target population or species – designed to spread
- Gene drive organism can affect ecosystems, and restoration may be difficult
- Gene drive organisms may cross international borders
  - Infringe on state's rights for self determination
  - Loss of opportunity to do risk assessment and management
  - May compromise state's protection goals

# Landscape of governance mechanisms

- Institutional level
- National levels
  - Local and tribal (indigenous peoples) levels
- Global levels

# Institutional level:

- Within institutions
  - Best practices followed
  - Adherence to research standards, guidelines and existing regulations
  - Personnel qualifications, professional standing and commitment
  - Ethical considerations
  - Adequate physical, administrative, and procedural infrastructure
  - Safeguards in place for accidental releases, force majeure disruption and breach of containment
  - Transparency

# National governance

- At present, no regulatory pathway that is specific for gene drive organisms
- Many look towards existing governance in more advanced countries, international guidance
- Most consider including gene drive organisms in existing governance pathways
  - Standard regulations for pests, drugs, pest control agents, phytosanitary regulations
  - Specific regulations for GMOs
  - May consider local restrictions and concerns, and tribal laws and protection goals

# National/Regional governance

- EU law: reference for many states
  - regulated by numerous existing provisions including endangered species, habitat protection, ‘traditional’ GMO, veterinary medicine, animal welfare, biosafety, toxins, and intellectual property
  - states are obligated to take steps to prevent harm arising from activities within their jurisdiction
  - Under directive 2001/18/ EC, central directive regarding GMOs, also known as the “release directive”
- US: no specific law
  - Joint regulatory activities by FDA, APHIS, EPA,
  - For research, NIH and NAS provide guidance

# National governance

- Australia: under Gene Technology Act administered by OGTR
  - GT Act is amended to currently oversee research on gene drive organisms,
  - Considers gene drive organisms a higher risk endeavor requiring dealings not involved in intentional release licensing for contained research
- India: no specific law
  - Special consideration for gene drives → DBT created special task force on genome engineering technologies to promote initiatives
  - Takshashila Institution in India provided risk assessment report on testing and deployment of gene drives (emphasis on safety standards for field releases)

# National governance

- African Union
  - gene drive regulation placed under the biotechnology framework of the Commission of Economic Community of West African States
  - gene drive techniques recommended for malaria control are population suppression (sterile males) and population replacement (mosquitoes resistant to the malaria parasite).
  - elements of governance including risk analysis, management, policy, regulatory systems, and research and development are being discussed in detail
  - Also discussing regulatory approaches on transboundary issues, and the benefits of working jointly at the regional level.

# Global governance

- Differences in national approaches to governance may create gaps in the protection of human health and environment,
- Differences in national approaches may impede research, especially basic researches whose benefit to society may be yet unclear
- → responsible governance must incorporate clear mechanisms for international dialogue on potential use and on comparable standards
  - Formal and informal agreements
  - Treaties

# Global governance

## Convention on Biological Diversity (CBD)

- Main international regulatory instrument on the development and use of genetically modified organisms
- Multilateral treaty
- Objectives
  - conservation of biological diversity;
  - sustainable use of the components of biological diversity; and
  - fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

# CBD

- Requires parties to “establish or maintain means to regulate, manage, or control the risks associated with the use and release of LMOs likely to have adverse environmental impacts on conservation and sustainable use of biological diversity, taking also into account the risks to human health”
- Implemented through Cartagena Protocol on Biosafety, the supplementary Nagoya-KL protocol on Liability and Redress, and Nagoya protocol on access and benefit sharing

# CBD on gene drives

- Decision X/13, 2010): invites countries to submit relevant information and to apply the precautionary approach to the field release of living synthetic biology organisms
- Decision XII/24, 2014 created AHTEG, and urged states to take five specific actions concerning synthetic biology: have risk assessment and management procedures in place for any environmental release, and cooperate in capacity building
- Decision XIII/17, 2016 encouraged countries to facilitate public and multi-stakeholder dialogues and awareness-raising activities, and cooperate in developing guidance and capacity
- Decision 14/19, 2018 called for a precautionary approach and conditions limiting release of gene drive organisms into the environment. Prior to release, risk assessment and risk management should be in place and public involvement in decision making

# CITES

## Convention on International Trade in Endangered Species of Wild Fauna and Flora

- Aims to protect the survival of listed species from being further threatened by international trade
- Gene Drive species NOT likely to be part of the list

# International bioweapons and environmental weapons law

## UN Biological Weapons Convention

- requires countries to prohibit bioweapons

## Environmental Modification Convention (ENMOD)

- Prohibits hostile or military use of environmental modification
- Parties should facilitate information exchange on peaceful environmental modification

# IUCN

The International Union for Conservation of Nature

- hybrid intergovernmental and nongovernmental organization
- WCC-2016-Res-086 initiated a process toward developing guidance for synthetic biology and gene drives
  - Outcome is expected at the IUCN's next Congress, scheduled this year

# WHO

- Vector Control Advisory Group (VCAG) is advisory body on vector control methods
  - VCAG input critical for moving gene drive mosquitoes into field trials.
  - Currently supports gene drive technology and encourages further development, requiring extensive cage trial testing to gather substantial evidence to support field trial release
  - Will incorporate existing standard GMO regulations and adopt novel regulatory details to account for the special circumstances inherent in gene drive systems.

# FAO

- Commission On Genetic Resources for Food and Agriculture 9<sup>th</sup> session in Rome 2018
  - Included Gene Drive on revised list of proposed thematic studies
    - Articulated concerns that genome edited gene drive plants “could skew permanently the genetics of an entire population of the organism and by extension the overall ecosystem dynamics. “
    - Expressed concern that limited dedicated policies or global mechanisms exist for regulating gene drive technology, despite its demonstrable environmental and ethical issues

# Desirable features of governance

1. Thorough risk assessment that involved diverse expertise
2. Mechanisms for engagement of affected communities and general public
3. Clear lines of authority, delineation of responsibility and methods for accountability
4. Balance between oversight impositions and level of risk
5. Adaptability to science and social developments
6. Ability to predict trans-boundary movements

# Parting shot:

- Should there be specific governance for gene drives or could this development be addressed by existing laws, guidance documents and standards?
- Concern : creating a specific governance path for gene drive may set a precedent in that each novel technology will consistently require unique governance strategies.
  - May be difficult to meet
  - May require resources
  - May be disincentive to regulation

Thank you