Australian Government
Department of Health
Office of the Gene Technology Regulator

ISAAA Webinar 2: Key considerations for risk assessments of gene drive technologies

Do we need a new regulatory framework to ensure gene drives are safe?

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Overview

- Australian gene technology legislation
- Risk assessment of GMOs
- Risk assessment of gene drives
- Discussions in international organisations

Study the past, if you would divine the future Confucius

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Australia's Gene Technology Regulatory Scheme

- National scheme – specific legislation

  - *Gene Technology Act 2000*

- Integrates with product regulators
- Independent decision-maker (Gene Technology Regulator)
- Independent, science based assessment
- Regulate work from lab to trials to commercial releases for microbes, plants and animals

Object of the *Gene Technology Act 2000*

To protect the health and safety of people,

and to protect the environment,

by identifying risks posed by,

or as a result of, gene technology

and by managing those risks

through regulating certain dealings with GMOs

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Environmental release of GMOs

- Licences issued for 129 trials
- 37 licences for commercial release – plants + vaccines

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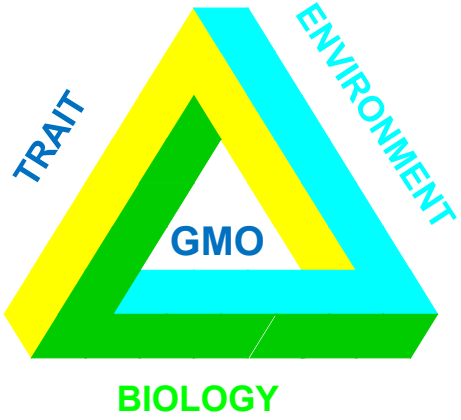
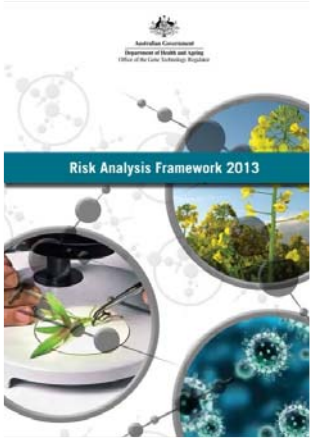
OGTR risk analysis

- Adapt / adopt existing guidance
- Qualitative, comparative assessments vs baseline
- Focus on harm and plausible pathways to harm
- Distinguish events vs harm
- Regulatory science and data to support decision making





Australian gene drive targets ?

Red Fire Ant

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Contained work with gene drive GMOs in Australia

Determine if gene drives can be used to control plant pathogenic fungi

Develop a genetic method to control invasive pest mice by spreading mutations that cause infertility, embryonic death or bias the sex of offspring 25-09-202

Develop and explore split gene drive designs to confer sex biased progeny and insecticide sensitivity in model organism Drosophila as a proof-of-concept

Gene drives and risk assessment

Implicit messages from debate:

- unprecedented ?
- nothing comparable ?
- dread consequences ?
- previous experience not helpful ?
- containment challenges ? (physical and geographical)

... need completely different set of tools?

Gene Drive risk analysis – challenges

- (ir)reversibility & containment – molecular, geographic
- conflicted values
  - environment vs human health
  - native vs exotic
- *Δ* risk GMO vs *Δ* risk overall
- Deep understanding of biology of populations, reproduction, food webs, ecological functions

Guidance from other risk analyses?

- GMOs (eg gene flow)
- biological control
- sterile insect release (ɣ- irradiation)
- pest / weed / disease (biosecurity, quarantine, SPS)
- biosafety - containment of pathogens

Lessons for:

risk assessment, risk management, risk communication

Why spend a day in the library when you can learn the same thing by working in the laboratory for a month? Frank Westheimer

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Convention on Biological Diversity 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 XIV/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
- In parallel, Cartagena Protocol Parties made a decision at COP-MOP9 in 2018 recognizing that risk assessment guidance for organisms containing engineered gene drives may need to be developed to assist regulators (Decision IX/13).
- Next meeting in late 2022

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World Health Organization (WHO) on gene drives

Key points

- Risk analysis frameworks used for other technologies provide useful precedents for the risk analysis of GMMs (genetically modified mosquitoes).
- Risk analysis of GMMs focuses on evaluating the potential to cause harm with respect to relevant protection goals, such as health and the environment, and should be conducted before each new phase of testing; risks should be considered in the context of appropriate comparators.
- RA and related RM must be conducted on a case-by-case basis, focusing on the particular GMM system, receiving environment, and objectives within the phase of testing under evaluation; the goal is to achieve a level of safety considered acceptable by decision-makers and other stakeholders.
- Opportunities for consultation with and input by relevant stakeholders are included in the risk analysis and impact assessment processes.
- Safety oversight will be provided at multiple levels, including by national regulatory authorities and institutional or national committees dealing with ethical and biosafety issues, as well as by external groups such as a DSMB for studies on disease impact; international and regional agreements may also be applicable for GMMs anticipated to cross national boundaries.

Guidance framework for testing genetically modified mosquitoes, World Health Organization; 2021.

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International Union for Conservation of Nature (IUCN) on gene drives

The IUCN World Conservation Congress (2021):

- 1. REQUESTS the Director General, Commission Chairs and Members to initiate an inclusive and participatory process to develop an IUCN policy on the implications of the use of synthetic biology in nature conservation to be debated and voted on by the next 2024 Conservation Congress. This should follow the process described in Annex section I and for the proposed policy;
- 2. REQUESTS the Council to, for this purpose, create a working group composed of IUCN Members (NGOs, governments and indigenous peoples' organisations) ensuring a balance among genders, regions, perspectives and knowledge systems, as defined in Annex section II;
- 3. REQUESTS the Council to establish a drafting and participatory review process for the working group to undertake the development of the IUCN policy on synthetic biology in relation to nature conservation, as defined in Annex section III; and
- 4. CALLS UPON the Director General and Commissions to remain neutral on all aspects of synthetic biology until the formal adoption of an IUCN policy on synthetic biology, remaining cognisant as new understanding develops during the process.

30 Sept 2021

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Use existing regulatory frameworks for gene drive risk assessments

- Build on existing frameworks for risk analyses
- ‘Borrow’ from other disciplines
- Carry on talking and sharing knowledge

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