GENE CONVENE
GLOBAL COLLABORATIVE
Advancing Best Practices in Genetic Biocontrol Technology

FNIH
Foundation for the National Institutes of Health

Advances in Gene Drive Policy and Oversight

NExTRAC Nov 9-10, 2020

Stephanie James
Foundation for NIH

geneconvene@fnih.org
www.fnih/geneconvene

State of the conversation

France

New Zealand

Australia

CBD

Norway

Netherlands

2017	Scientific Opinion of French High Council for Biotechnology on Use of Genetically Modified Mosquitoes for Vector Control	France, with consideration of RA criteria	http://www.hautconseildesbiotechnologies.fr/sites/www.hautconseildesbiotechnologies.fr/files/file_fields/2018/04/opinionmosquitoes180228.pdf
2017	Report of the Royal Society Te Aparangi Gene Editing Panel on Use of Gene Editing to Create Gene Drives for Pest Control in New Zealand	drive-modified organisms to	.nz/assets/gene-editing-pest-control-technical-paper.pdf
2017	Synthetic Gene Drives in Australia: Implications for Emerging Technologies	synthetic gene drives in an Australian context, with considerations for containment,	://www.science.org.au/support/analysis/reports/synthetic-gene-drives-australia-implications-emerging-technologies
2017	Report of the Ad Hoc Technical Expert Group on Synthetic Biology, Montreal, Canada, 9 December 2017; CBD/SYNBIO/AHTEG/2017/1/3	engineered gene drives fell under the definition of LMOs as per the Cartagena Protocol	https://www.cbd.int/doc/c/aa10/9160/6c3fcedf265dbee686715016/synbio-ahteg-2017-01-03-en.pdf
2017	European Academies Scientific Advisory Council Policy report 31: Genome Editing: Scientific Opportunities, Public Interests and Policy Options in the European Union	Reviews applications of gene editing in a range of organisms, including gene drive applications where it supports	https://easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Report_31_on_Genome_Editing.pdf
2017	Statement of the Norwegian Biotechnology Advisory Board on Gene Drives	gene drive technologies and provides recommendations for	http://www.bioteknologiradet.no/filarkiv/2017/02/Statement-on-gene-drives.pdf
2018	Netherlands Commission on Genetic Modification Report on Experiences with Gene Drive Systems that may Inform an Environmental Risk Assessment (CGM 2018-03)		systems-that-may-inform-an-environmental-risk-assessment/
2018	National Institute for Public Health and the Environment RIVM Letter report 2018-0090 Risk assessment	Provided recommendations specifically tailored to the system in the Netherlands for authorising research with gene	https://www.rivm.nl/bibliotheek/rapporten/2018-0090.pdf

African Union

Brasil

UK

IUCN

Austria

	method for activities involving organisms with gene drive under conta use	drive-modif	
2018	Report of the High Le African Union Panel on Emerging Technologies (APET) on Gene Drives for Malaria Control and Elimination in Africa	drive technology for malaria in Africa, with recommendations for	.nepad.org/publication/gene-drives-malaria-control-and-elimination-africa
2018	National Biosafety Technical Commission of Brasil (CTNBio) Normative Resolution No. 16 of January 15, 2018	Up precision breeding innovation techniques, including gene drive	https://agrobiobrasil.org.br/wp-content/uploads/2018/05/Normative-Resolution-16-of-January-15-2018.pdf
2018	Statement of The Royal Society, UK, on Gene Dri Research: Why It Matters	technologies, and recommends continued research	https://royalsociety.org/~/media/policy/Publications/2018/08-11-18-gene-drive-statement.pdf
2019	Office of Gene Technology Regulator, Department of Health, Australian Government, Guidance for IBCs: Regulatory requirements for contained research with GMOs containing engineered gene drives	Provides guidance to Institutional Biosafety Committees and researchers on the regulatory requirements for physical confinement and licensing of contained research on GMOs containing engineered gene	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/53139D205A98A3B3CA257D4F00811F97/$File/Guidance%20on%20gene%20drives.pdf
2019	International Union for th Conservation of Nature Report on Genetic Frontier for Conservation: An Assessment of Synthetic Biology and Biodiversity Conservation	conservation, including biodiversity implications of synthetic biology applications not intended for conservation benefit such as gene drive approaches for malaria suppression in Africa	tps://portals.iucn.org/library/efiles/documents/2019-012-En.pdf
2020	Environment Agency Austria Report on Gene Drive Organisms Implications for the Environment and Nature Conservation	for technology assessment	https://www.google.com/url=t&rct=j&q=&esrc=s&sou web&cd=12&ved=2ahUKEwjSrserw7XpAhXcTxUIHWuZDHcQFjALegQIARAB&url=https%3A%2F%2Fwww.bafu.admin.ch%2Fdam%2Fbafu%2Fde%2Fdokumente%2Fbiotechnologie%2Ffachinfo-daten%2F2019-technical-report-gene-drive-organisms-implications-for-the-environment-and-nature-conservations-ig-gmo-technical-report-on-gene-drives.pdf.download.pdf%2Fi

			g-gmo-2020-IG%2520GMO%2520technical%2520report%2520on%2520gene%2520drives.pdf&usg=AOvVaw3XF9Z9-7oV4heW_rGGXDFt
2020	Guidance Framework for Testing the Sterile Insect Technique as a Vector Control Tool against Aedes-Borne Diseases	Guidance issued by the International Atomic Energy Agency and World Health Organization on requirements for testing and deployment of the sterile insect technique	https://www.iaea.org/sites/default/files/aedes-who-iaea-2020.pdf
2020	Report of the Ad Hoc Technical Expert Group on Risk Assessment, Montreal, Canada, 15 April 2020, CBD/CP/RA/AHTEG/2020/1/5	Reaffirmed that LMOs containing engineered gene drives fall within the scope of the	https://www.cbd.int/doc/c/a763/e248/4fa326e03e3c126b9615e95d/cp-ra-ahteg-
2020	Swiss Academies Fact Sheet Gene Drives: Benefits, Risk and Possible Applications	Sciences containing recommendations for technical assessment and ethical considerations	ences.ch/uuid/0d56b3a2-be56-5b53-b83b-e9d2ac66d830?r=20200527115808_1591352186_247ab218-d398-5151-b026-a858af7cc3d2

Switzerland

State of the conversation – self governance

Gene Drive Research Forum

- Encouraging a community of practice
  https://fnih.org/what-we-do/geneconvene/working-with-geneconvene/research-forum

Principles for gene drive research, *Science Dec 2017*

- Commitment to abide by 5 guiding principles
  - Advance quality science to promote the public good
  - Promote stewardship, safety, and good governance
  - Demonstrate transparency and accountability
  - Engage thoughtfully with affected communities, stakeholders, and publics
  - Foster opportunities to strengthen capacity and education
- Signed by 16 organizations to date

Current projects: definitions, registries, engagement

https://science.sciencemag.org/content/358/6367/1135

Investigators' Core Commitments - submitted

- Addresses similar issues for conduct of field trials

State of the conversation - multinational venues

Environment - CBD, IUCN
Public health - WHO

2020 WHO Position Statement

- New tools to control both pathogens and their vectors are urgently needed
- All potentially beneficial new technologies, including GMVs (GDVs), should be responsibly investigated

2017 WHO Evaluation Process for new vector control interventions

- Advise on trial design
- Review evidence to substantiate public health claim(s)
- Guide hazard/risk assessments where applicable and to develop product specifications

Advances since the NASEM report

Deeper consideration of specific issues and use cases - examples

- 2017, 2019 Problem formulation exercises
  - Relevant protection goals, pathways to harm
- 2018 “Pathway to deployment of gene drive mosquitoes…”
  - Implications of low threshold drive on phased testing pathway
  - Efficacy, safety, monitoring, ethics, partnerships, engagement, regulation
- 2020 “Toward definition of safety and efficacy criteria…”
  - Minimal performance characteristics to move to first field testing
- 2020 “WHO report on Ethics and Vector-borne Diseases”
  - Includes gene drive modified vectors
  - Recommendations on informed consent, engagement
- 2020(exp) EFSA opinion on guidelines for risk assessment of gene drive modified insects
  - https://www.efsa.europa.eu/en/consultations/call/public-consultation-gmo-panel-scientific-opinion-evaluation
- 2021(exp) Update of “WHO Guidance Framework…”
  - Reviews new developments: efficacy, safety, ethics, regulatory
  - Expands recommendations on testing pathway for GDMs

GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

Advances since the NASEM report

Regional harmonization: African Union

AU High Level Panel on Emerging Technologies
2018 Report on "Gene Drives for Malaria Control…"

- Africa should invest in the development and regulation of gene drive technology, whose greatest and most urgent application will be in malaria control and elimination
- Interaction between different agencies mandated to regulate emerging technologies
- Regional approach to the harmonization of policies across African countries

2020 AUDA-NEPAD Position Paper on Integrated Vector Management

- Complementary tools are urgently needed to ensure effective elimination of malaria
- Commitment to supporting Member States in building necessary regulatory systems

West African Integrated Vector Management program

- "…five IVM guidelines have been so far developed and validated …next steps are now to consolidate progress in West Africa and scale up the initiative to continental process…"

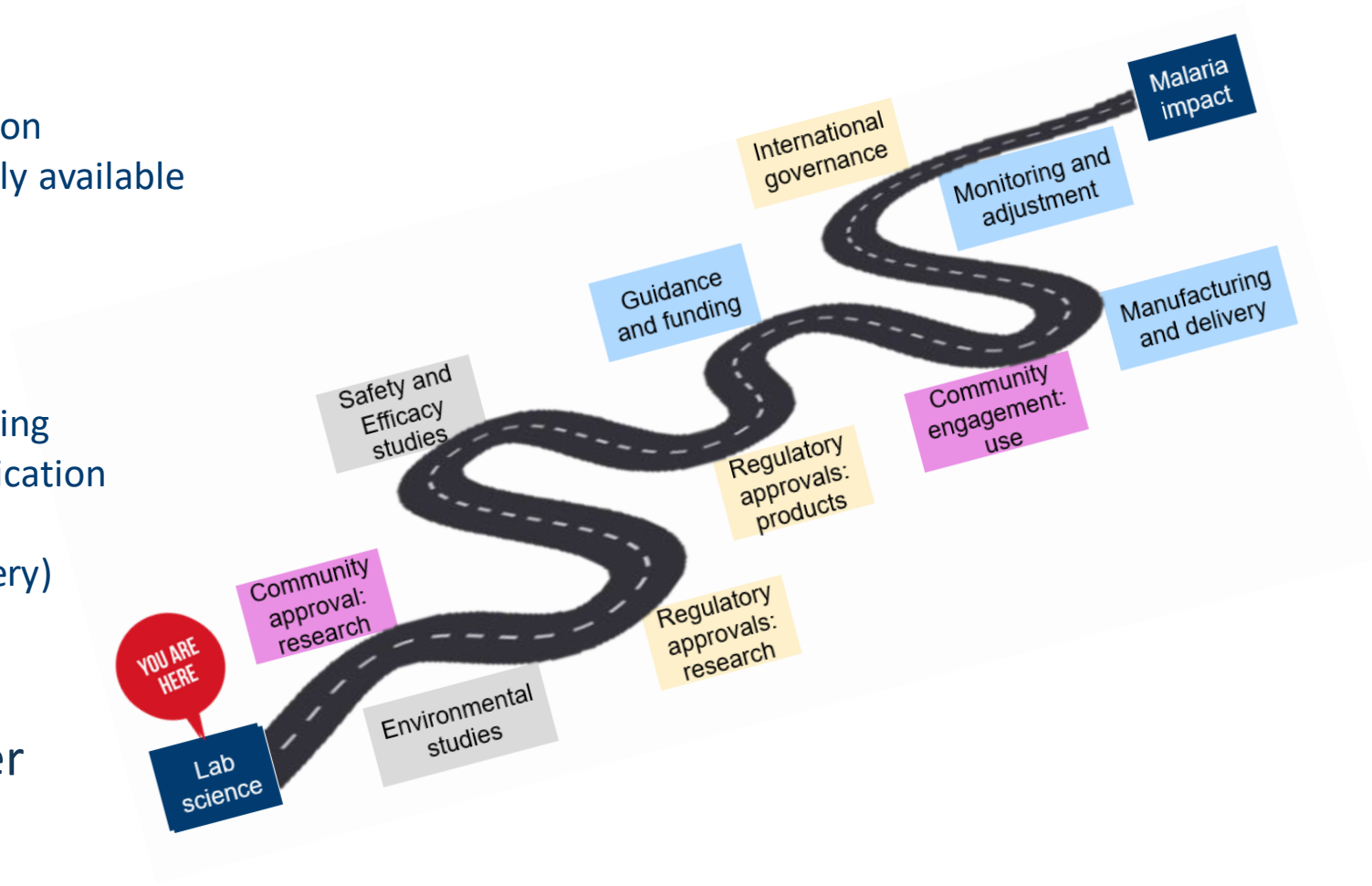
What gaps still exist?

Challenges and uncertainties remain

- Preferred product characteristics
- Containment requirements/facility certification
- Risk and impact assessment; external, publicly available
- Field testing protocols
- Monitoring requirements and methods
- Remediation options/liability
- Co-development/ technology transfer
- Technical and regulatory capacity strengthening
- Best practices for engagement and communication
- Consent and authorization requirements
- Implementation plans (manufacturing, delivery)
- Post-implementation surveillance

These must be addressed in a coordinated, systematic, targeted manner

- Different gene drive systems, organisms, locations



GENE CONVENE GLOBAL COLLABORATIVE

FNIH Foundation for the National Institutes of Health

- Promote coordination, collaboration, resource sharing
- Provide consensus guidance on key questions for responsible research and development
- Strengthen technical and regulatory capacity
- Address information gaps

www.fnih/geneconvene : *Forum activities; External risk assessments; Recommendations and guidance*

- Simplify access to timely information

www.geneconvenevi.org : *Technical advances; Regulatory and policy updates; Webinars*

GENE CONVENE GLOBAL COLLABORATIVE FNIH Foundation for the National Institutes of Health

Email: geneconvene@fnih.org