Overview of regulatory frameworks for gene-drive organisms

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Web-conference “Research and innovation for biodiversity: What role for gene drive ?

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Gene drives still at early stage evaluation

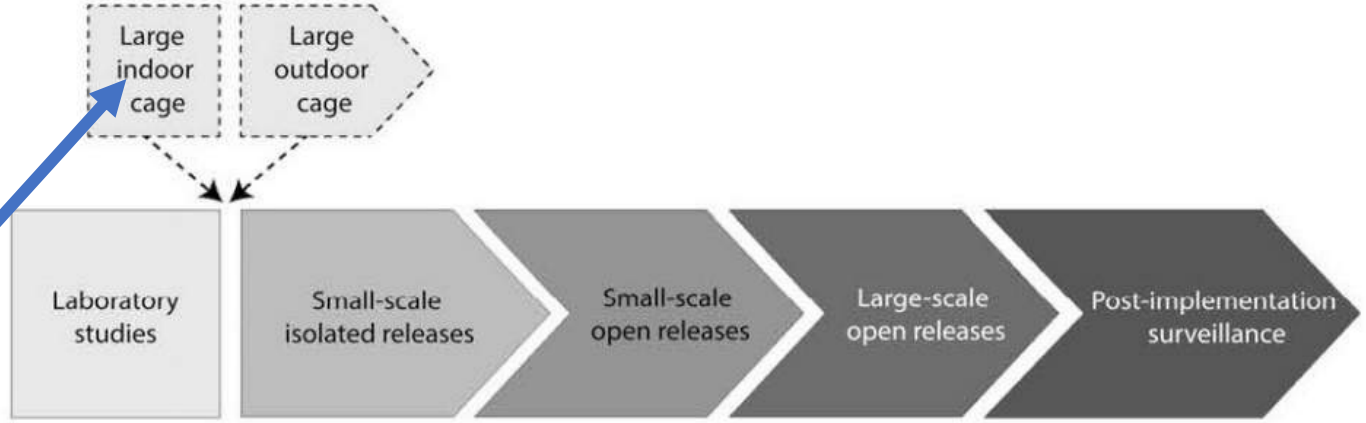


FIGURE 3. Pathway to deployment of gene drive mosquitoes.

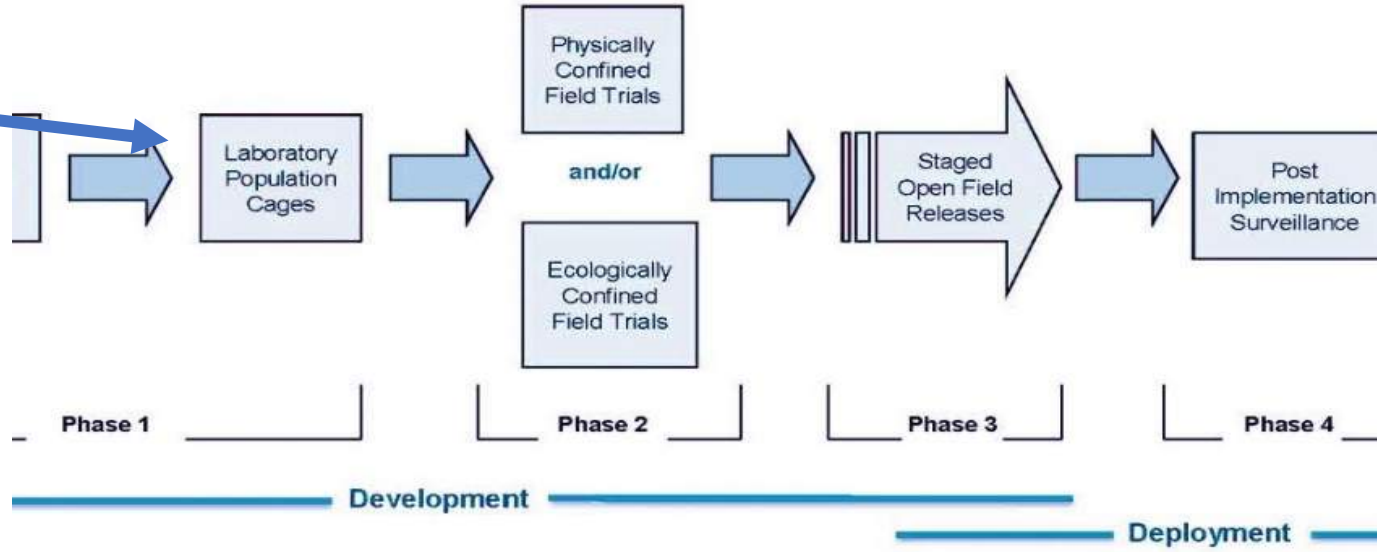
James et al, 2018

2018

nature biotechnology
OPEN

A CRISPR–Cas9 gene drive targeting *doublesex* causes complete population suppression in caged *Anopheles gambiae* mosquitoes

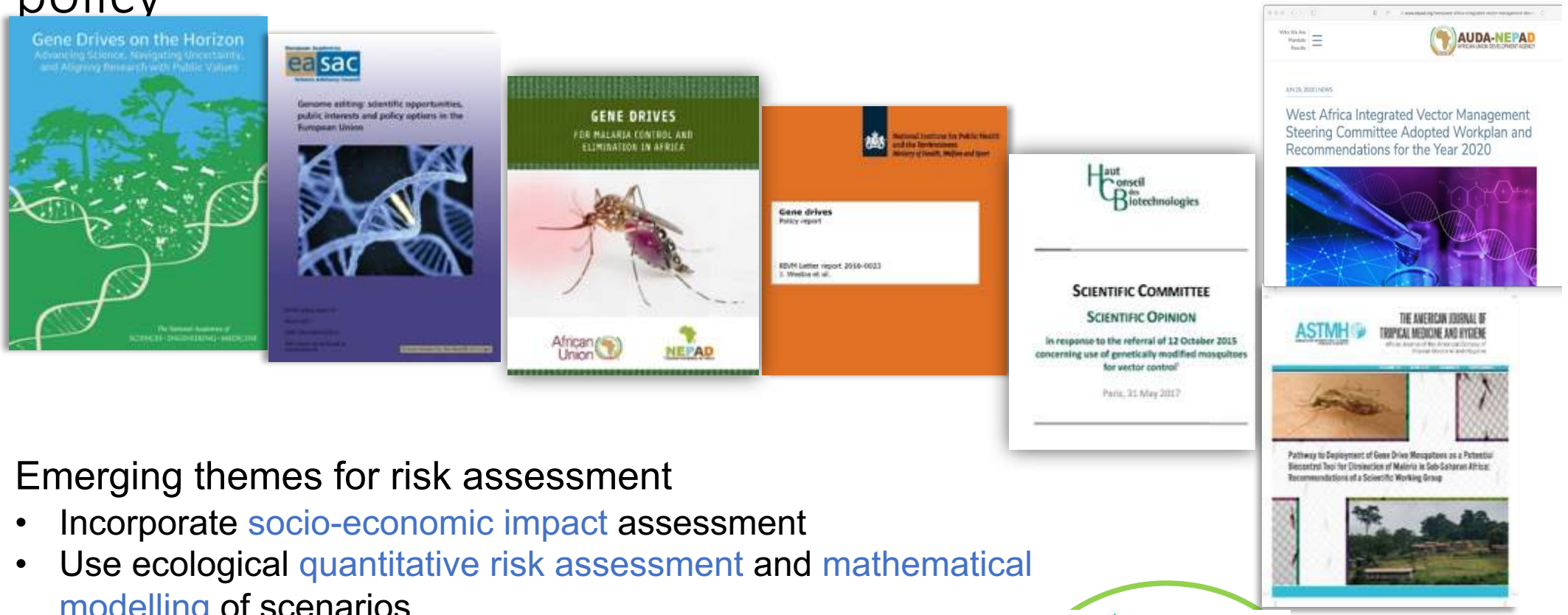
Kyros Kyrou[1,2], Andrew M Hammond[1,2], Roberto Galizi[1], Nace Kranjc[1], Austin Burt[1], Andrea K Beaghton[1], Tony Nolan[1] & Andrea Crisanti[1]



No gene drive has entered field trial stages

WHO,2014

Gene drive – Increasing guidance for risk assessment and policy



Emerging themes for risk assessment

- Incorporate socio-economic impact assessment
- Use ecological quantitative risk assessment and mathematical modelling of scenarios
- Learn from existing pest control programs
- Include potential benefits for risk –benefit assessment

Convention on Biological Diversity

OECD

efsa European Food Safety Authority

World Health Organization

Convention on Biology Diversity: Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment

Convention on Biological Diversity

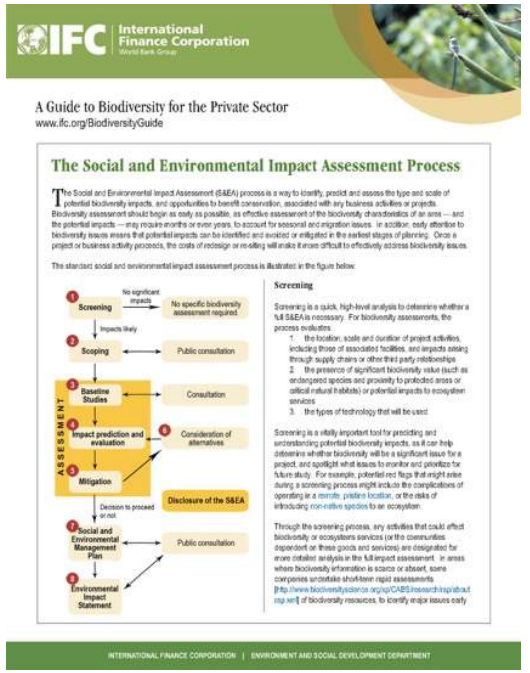
- Cartagena Protocol on Biosafety Annex III risk assessment methodology principles apply
- Additional guidance for Genetically modified mosquitoes published in 2016
- AHTEG on risk assessment convened to examine whether additional guidance was needed for gene drives
  - Report published April 2020 (CBD/CP/RA/AHTEG/2020/15 – April 15, 2020)
  - Recognised risk should be balanced with benefit in decision-making
  - Gene drives are LMO's and fall within the scope of the Cartagena Protocol on Biosafety
  - Existing risk assessment frameworks may be applicable, although some areas require further attention.
  - Analysis should be case by case and a thorough risk assessment conducted prior to release
  - Public consultation, including indigenous peoples and regional co-operation should be included
  - AHTEG recommended preparation of additional guidance on specific technical issues
- Further discussion at COP/MOP15 on preparation of additional guidance materials for synthetic gene drives.

EFSA gene drive risk assessment activities

- Mandate from Commission June 2018
  - Identify potential risks that gene drive modified organisms could pose
  - Identify novel hazards and appropriate comparators
  - Determine whether existing risk assessment guidance documents are sufficient and where updates are required
- Stakeholder engagement
  - May 2019 (Workshop) and Oct 2019 (*ad hoc* meeting)
- Draft opinion for public consultation April 2020
  - Environmental risk assessment (ERA) for gene drive can build on the existing framework
  - Follow a case by case approach based on systematic problem formulation methods framed by relevant protection goals and experiences with other pest control activities
  - Guidelines should be updated in specific areas including the use of modelling, molecular characterization, assessment of persistence and invasiveness and post market monitoring
  - *https://www.efsa.europa.eu/sites/default/files/consultation/consultation/gene-drive-document-for-consultation.pdf*
- Final opinion expected to be published Dec 2020.

Legal requirements beyond biosafety risk assessment: Environmental Impact Assessment

- Environment, Health, Social and Economic Impacts assessed
- Existing well established guidance from World Bank and IFC
- Includes structured public participation and feedback
- Outcomes
  - Identifies impacts positive and negative
  - Identification of information gaps
  - Identification of benefits
  - Management options
  - Follow – up audit



Summary

- Conduct case by case evaluation
- Regulatory approach can build on existing regulatory frameworks for GMO's and biocontrol control solutions
- Transparent and scientifically rigorous risk assessment methods should be used
- Additional guidance needed in some areas: e.g use of mathematical models, persistence in the environment
- Include benefits, socio-economic impacts and public consultation in decision making
- Increasing number of guidance documents available to guide research