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A Vector Control Research Alliance

Assessing gene drive's potential social, economic and health impacts

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A question needing reformulation

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Assessing a specific gene drive organism and not “gene drive”

Gene drive organisms are very diverse and therefore any assessment would have to be **case-by-case**

- **Different purposes**
- **Different molecular systems that have different characteristics**
- **Different contexts**
- **Different protocols**

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A methodology to approach case-by-case assessment

- The assessment will be specific to a research protocol for a specific construct, in a specific environment
- That is the basis of an Impact Assessment, that will define for the specific protocol:
  - What the area of impact will be
  - What the impacts could be
  - How the positive impacts can be maximised and how the negative impacts can be avoided, minimised or mitigated
  - How to engage potentially affected people in this assessment

To date, there has been no impact assessments done for engineered gene drive organisms

Which assessment?

Impact assessments

- Impact assessments are usually part of the environmental code, and apply to different project, not specifically LMOs.
- They look at positive and negative impacts
- They include environmental aspects but also social, economic, health and increasingly human rights (IFC and WB standards)
- They have a defined structure for public consultation in international standards
- Numerous standards and good practice codified – e.g. IFC, but also development banks

Risk assessments (ERA)

- Environmental risk assessments are part of biosafety processes
- They look at risks
- They focus on environmental aspects, though countries "may take into account" (on a voluntary basis) "social and economic consideration" (Art. 26 of the Cartagena Protocol)
- The public consultation is part of Art.23 of the Cartagena Protocol

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Considerations for future impact social, economic and health impact assessments of gene drive organisms

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An analysis in context

- The starting point for the analysis of the social, economic and health impacts of gene drive organisms, is to know the context. What happens in the absence of those:
  - What is the burden of the current situation?
  - What are the current tools to fight this problem and what are their own impacts?
  - How efficacious are the current tools and how acceptable are the current impacts
- This is part of the alternative analysis that needs to look at
  - Other interventions not involving gene drive organisms
  - The case of "no intervention"

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Identifying specifically the sources of impact

1

Impact of the gene drive organism

Any impact related to the presence of the construct on the target population

2

Impact of the protocol activities

Any impact related to the protocol implementation: presence of team members, monitoring activities

3

Impact of the outcome

Any impact related to the expected outcome (e.g. disease reduction, increased resilience of a species, eradication of invasive alien species

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A hypothetical example: using gene drive mosquitoes to reduce malaria burden in sub-Saharan Africa by reducing malaria vector mosquito population

Impact of the gene drive organism

- Will depend of the specific characteristics of this construct and of the mosquito species.
- We can ask the questions:
  - Does the target mosquito have a cultural or religious importance or role?
  - If any environmental impact is identified on other species, do these species have a cultural, religious role? What is their ecosystem services?
  - Can the gene-drive mosquito increase human or animal allergic reactions above those of the wild-type mosquito ?

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A hypothetical example: using gene drive mosquitoes to reduce malaria burden in sub-Saharan Africa by reducing malaria vector mosquito population

Impact of the protocol activities

- Will depend of the specific activities of this protocol
- We can ask the questions:
  - Will the presence of the team or the activities proposed create any disruption for the communities livelihood activities
  - If the protocol involves local employment, will this new income generated create positive impacts for the community?
  - Can the presence of the team lead to local inflation?
  - Can the protocol activities lead to a reduction in vector borne disease prevention measures from communities?
  - Can the increased car movements generate any road accidents with humans or livestock?
  - Can the question of whether to allow or not the project lead to some social conflicts within the community?

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A hypothetical example: using gene drive mosquitoes to reduce malaria burden in sub-Saharan Africa by reducing malaria vector mosquito population

Impact of the outcome (here malaria reduction)

- Will depend of the magnitude of the outcome
- We can ask the questions:
  - Will the malaria reduction in this area lead to population flux?
  - Will malaria reduction (thus lives saved) have an impact on environmental resource uses?
  - Will malaria reduction have an impact on access to education?
  - Will malaria reduction have an impact on the health system?
  - Will malaria reduction have an impact on the population of other species that might have been affected by malaria?
  - Will malaria reduction have an impact on women empowerment?

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Target Malaria and social, economic and health assessments

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A regulatory requirement

- In Burkina Faso, where the project operates, prior to the release of **non-gene drive** genetically modified mosquitoes the regulation requires:
  - An environmental risk assessment
    - Biosafety regulation – reviewed by the National Biosafety Authority
    - Ministry of Higher Education and Research
    - Leads to a decision to grant or not a release permit
  - An impact assessment
    - Environmental regulation – reviewed by the National Agency for Environmental Evaluations
    - Ministry of Environment, Green Economy and Climate Change
    - Leads to a favorable or not favorable opinion to proceed to a release

- The two processes are parallel.

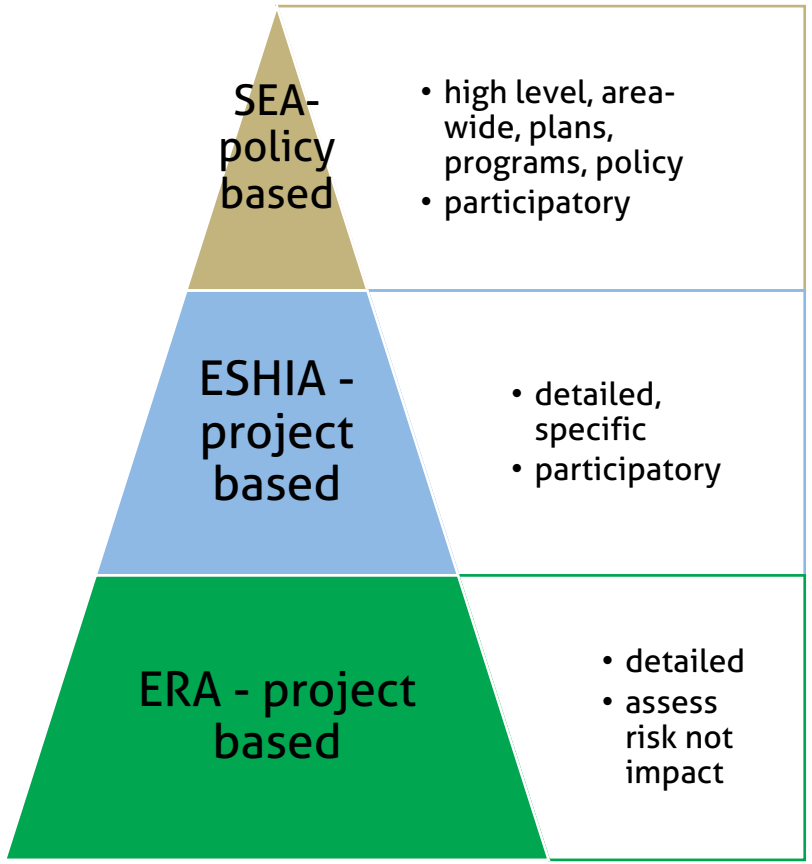
First ESHIA for the release of genetically modified mosquitoes

- The project commissioned the implementation of an ESHIA for its intermediary step
  - Release of **non gene drive** genetically modified male bias mosquito strain
- No clear precedent in this field for ESHIA implementation
- But wealth of precedents from other fields, which can be learned from
- Starting from a scoping phase to identify what are the key issues
- ESHIA also linked to the community agreement model – identifies who is impacted and who will give agreement

Taking a strategic step: the Strategic Environmental Assessment

- High level strategic framework tool
- Conducted early in development
- Systematic process for the evaluation of environmental implications of a proposed policy, plan or program.
- Despite its name, it also addresses social, economic and health considerations

Evidence-based tools to inform decision making



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Key takeaways

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- The assessment of social, economic and health impacts of gene drive organisms will depend on the specific project and context and have to be case by case
- Any assessment will have to be done in context: what is the alternative to the use of gene drive and the impacts of that situation
- Impact assessments should look at: the impact of the organism itself, the impact of the protocol activities, and the impact of the intended outcome
- Impact assessments will complement Environmental Risk Assessment, usually done in parallel for different authorities/ministries.

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Thank you

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