

Environmental, Socio-economic, and Health Impact Assessment (ESHIA) for Gene Drive Organisms

ISAAA Inc. and the Outreach Network for Gene Drive Research

Introduction

Understanding the possible positive and negative impacts that gene drive organisms could have on the environment and people is essential before these technologies are considered for release, whether for research purposes or for use. Different impacts are assessed through different tools and methodologies. While environmental risks are evaluated through specific risk assessments, other dimensions, such as positive and negative impacts on a social, economic, and health level can be assessed through impact assessments. These environmental, socio-economic and health impact assessments can complement the information provided by environmental risk assessments.

What is environmental, socio-economic, and health impact assessment (ESHIA)?

One way to evaluate gene drive organisms' potential consequences is to undertake an environmental, socio-economic, and health impact assessment (ESHIA). The process involves conducting a systematic analysis and evaluation of the potential effects the release of an organism involving a gene drive could have, taking into account what is being released as well as how and where it is being released. In other words, the possible impacts of releasing any given gene drive organism must be assessed on a case-by-case basis.

For example, while you can apply a broadly similar ESHIA methodology to evaluate two different cases, the results are likely to be very different. Doing an ESHIA to evaluate the possible impacts of using a gene drive mosquito that aims to reduce malaria in India through a population replacement approach would likely be very different from an ESHIA for the proposed use of a population suppression gene drive to control rat populations in an island setting in Australia. The methodologies would be largely comparable as they would still be within a global ESHIA framework, but the outcomes are driven by each case and its specificities.

An ESHIA lays out the challenges posed by the issue that the proposed intervention is seeking to solve,



What are considered IMPACTS?

Impacts can include changes to one or more of the following: people's way of life, their culture, political systems, environment, health and wellbeing, economy, personal and property rights and even their fears and aspirations.

the burden of the current situation, the available tools to address the issue, their benefits and limitations, and the impacts these tools might have. The ESHIA will then assess what the proposed intervention could do to address the issue, and what other impacts it could have. For example, in the case of invasive alien rodents, an ESHIA would describe the “status quo” and the impact that invasive rodents have in this current situation on environmental, socio-economic and health (ESH) dimensions. It would also map out the existing tools that exist to deal with this problem of invasive alien rodents and what impact these tools are having on “ESH” issues.

In the case of invasive alien rodents, this would likely include the impact of the rodents on crops or as disease vectors, and the positive and negative impacts of the current tools to control rodents and mitigate their impact, such as rodenticides. The ESHIA will then seek to assess what a gene drive technology could do to mitigate or eliminate the negative impacts that invasive alien rodents have, as well as mitigate or eliminate the negative impacts that other tools such as rodenticides may have. It will also consider what additional impacts the use of gene drive rodents could have.

In effect, an ESHIA offers an analysis of the impacts that implementing the proposed intervention could have, as well as an alternate analysis of conserving the status quo and the risks and benefits of doing so. This can help inform decision making because it offers alternative scenarios to consider, acknowledging that all courses of action have impacts (whether choosing to stay ‘as is’ or to implement a new tool or action). ESHIA can also help identify where some of the trade-offs might be, and how positive impacts can be maximized while negative ones are mitigated or minimized.

ESHIA requirements are often part of the national regulatory requirements. ESHIA also enables public participation in decision-making as they include structured public consultation throughout the

ESHIA is helpful because it offers an analysis that helps assess the advantages and disadvantages of action and inaction, which is important to inform decisions.

process. These complement the analysis by ensuring that concerns or expectations from the potentially affected stakeholders can be integrated into the impact assessment.

During an ESHIA for a gene drive organism, some of the questions that experts would consider are:

- Beyond its role in a given ecosystem, does the target organism hold social, cultural, or economic significance for potentially affected (local) stakeholders?
- Do the target organism or the proposed activities related to its release have the potential to affect the local economy?
- What are the potential impacts of the presence of research teams on local governance within communities?
- If any environmental impact is envisaged on other species, do these species have a cultural or religious role? What ecosystem services do they provide?
- What is the potential impact of gene drive interventions on the health of potentially affected (local) stakeholders?
- Would any indigenous people’s land, resources, and cultural practices be potentially affected by the proposed activities?
- What are the alternatives to gene drives? What are the positive and negative impacts of those? Could tools containing gene drive organisms offer a better result?

So far, no impact assessment has been done for any proposed activity involving engineered gene drive organisms, as no gene drive organism has been proposed for release yet.

How is an ESHIA different from an environmental risk assessment (ERA)?

While ESHIA and environmental risk assessment (ERA) may be undertaken separately and use distinct methodologies, they are complementary and may overlap. Both are project specific, but an ERA will generally focus only on potential harms and mitigations posed by the organism and its genetic insert in regard to the biosafety of the activities being undertaken (e.g contained use or field trials). On the other hand, an ESHIA will look at the broader impacts of human or environmental activities, such as socio-economic dimensions, and will consider both positive and negative impacts.

ERAs are a legal requirement in all countries that have a biosafety framework for the release of genetically modified (including gene drive) organisms but ESHIAs are not always required by the regulatory authorities.

Guidelines and oversight

Generally, conducting an ESHIA can be a legal requirement in some contexts or can be mandated by development organizations and other funders of projects. In the absence of a legal requirement, it can also be initiated directly by the technology developers.

In recent years, several attempts have been made to propose a comprehensive and unified framework for assessing various impacts of any research or infrastructure project. Some global guidelines have been established by institutions such as the [International Finance Corporation](#) (IFC, part of the World Bank Group), which is used by IFC and other development banks to decide whether to fund projects. Another example is the guidelines by the influential [International Association for Impact Assessment](#) (IAIA), which review best assessment practices on a yearly basis. Country-specific or sector-specific guidelines are also widely available.

For gene drives, the WHO's [Guidance Framework for Testing Genetically Modified Mosquitoes](#)

stresses the importance of taking into account environmental, socio-economic, and health impacts during assessments. However, it does not point to any specific methodology.

The Convention on Biological Diversity (CBD) has produced a narrower set of [Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol](#), applicable to the impacts of living modified organisms. These guidelines deal strictly with the socio-economic aspects of an assessment and intend to incorporate socio-economic dimensions to ERA on a voluntary basis. Parties' experience using this guidance will be reviewed at the next Meeting of the Parties to the Cartagena Protocol.

How is an ESHIA undertaken?

The first step of an ESHIA is usually to define its terms of reference (ToR), which would include both the thematic areas of potential impacts and the geographical and temporal scopes. At this stage, experts will define what exactly is being assessed and how that assessment will be undertaken, determining what are the relevant aspects to investigate. These ToR are usually informed by public consultation. If the ESHIA is mandated by the national authorities, the ToR will be submitted to the appropriate national authorities for approval.

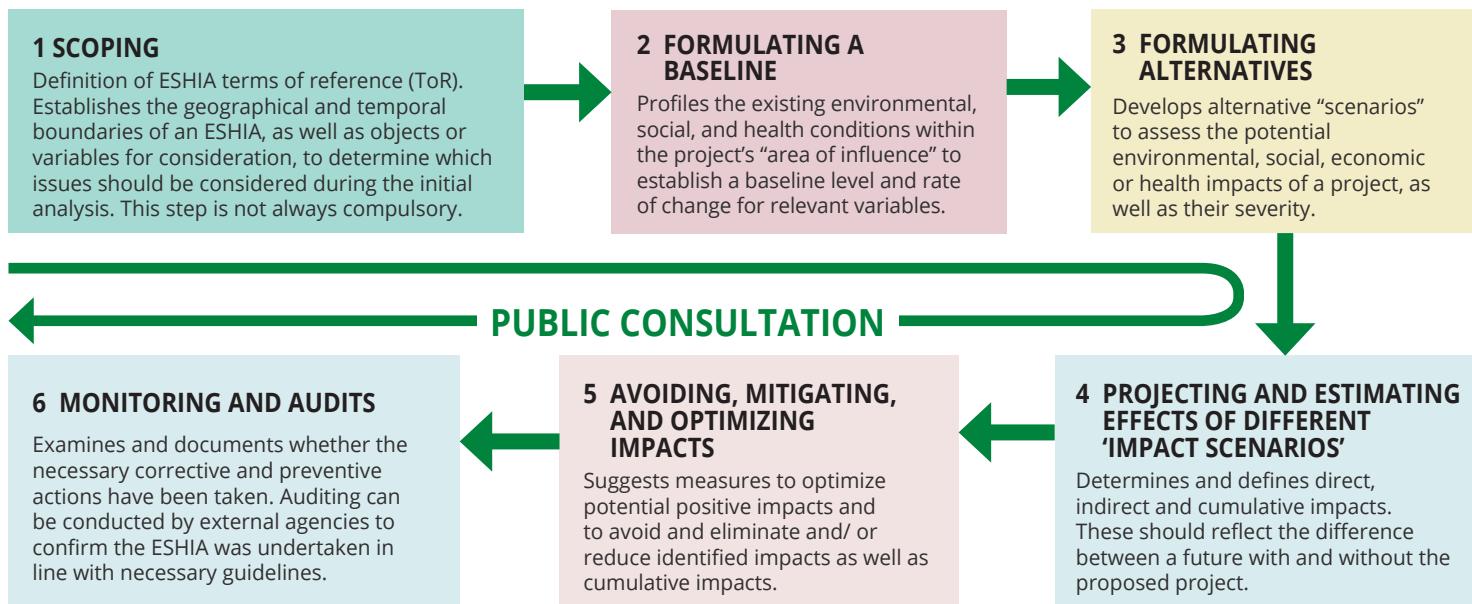


Quantitative and qualitative data can be used for a well-rounded assessment, from interviews with stakeholders to sampling, and data analysis. Examples of tools and methodologies that can be used include oral or written evidence from traditional or local knowledge holders, cause/effect matrices, flow charts, diagrams, and map overlays.

The methodology used is informed by the scope defined in the ToR and international standards for ESHIA.

Approaches to ESHIA can vary from one case to another, but assessment tends to develop along the steps listed below:

Steps in Conducting Environmental, Socio-economic, and Health Impact Assessment ^{1,2}



¹ McHugh, S., Maruca, S., Lilien, J. and Manning, A., 2006. Environmental, Social, and Health Impact Assessment (ESHIA) Process. All Days, [online] Available at: <https://onepetro.org/SPEHSE/proceedings-abstract/06HSE/All-06HSE/SPE-98224-MS/140791>

² International Finance Corporation, 2018. The Social and Environmental Impact Assessment Process. A Guide to Biodiversity for the Private Sector. [online] World Bank Group. Available at: <https://www.ifc.org/wps/wcm/connect/9608497e-56e8-4074-bab6-45c61a36a4ad/ESIA.pdf?MOD=AJPRES&CVID=jkCYZ3G>

Policy recommendations

ESHIA and ERA are complementary and both their findings should be considered in decision-making. An ESHIA can strengthen the evidence base to inform governmental decision-making processes, as it takes into account positive and negative potential environmental, socio-economic, and health impacts of a technology. The public engagement required by an ESHIA also enables public participation and information sharing with numerous stakeholder groups across a wide array of relevant topics.

Decisions regarding the release of gene drive technologies, whether for research or use, should consider the findings of ESHIA in addition to the findings of ERA. These assessments should be evidence-based, consistent with the principle of case-by-case assessment, and make provisions for the consideration of both risks and benefits and public consultation.



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OUTREACH NETWORK FOR GENE DRIVE RESEARCH

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ISAAA POLICY BRIEFS

Environmental, Socio-economic, and Health Impact Assessments (ESHIA) for Gene Drives

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