

Genetically engineered mosquitoes

Legislation and permitting

- Are regulations/legislation in place governing research and other activities with recombinant DNA, etc.?
○ If so, what are the key relevant regulations/legislation?
- What is the status of the Cartagena Protocol on Biosafety (<http://bch.cbd.int/protocol/>) in the country and how is it being implemented?
○ If relevant, identify the in-country CPB contact point.
- Were any relevant legislation or policies in place prior to Cartagena obligations and what is their current status?
- Are there any specific laws/norms/guidance, etc., regarding vector control where project activities (*e.g.*, baseline monitoring/surveying) might interact with these regulations?
○ Any conventional control plans (*e.g.*, IVM, barrier treatment, risk mitigation plans) will need to take account of any such regulations.
- Are there other known regulatory/legal issues that may affect project operations? Examples may include:
 - Restrictive customs regulations or delays,
 - Immigration (visas, work permits),
 - Restrictions on exporting samples (for example, biodiversity/bioprospecting law).

Regulatory processes

- Has the country had previous experience importing GE mosquitoes for laboratory research?
○ If not, what about other GE insects (*e.g.*, *Drosophila* for research purposes), plants or other animals?
- What are the relevant national, state, municipal and local agencies and their specific roles?
- Is there a clear process for application and approval for the proposed research?
○ If so, provide an outline of the structure and process.
○ What are the estimated time-lines for completing each of the regulatory steps?
○ What is the basis for this estimate?
- Is a risk assessment/risk management plan required? If so, who develops it, the applicant or the authority?
- What are the opportunities/mechanisms/requirements for public engagement in the regulatory process?
○ Some regulatory processes are fully confidential, some open to the public, some are a mix (for example, applications become publicly available but information identified as confidential by the applicant is redacted).
- What are the inspection and audit regimens for compliance with granted permits?
○ These may be described in the legislation, but in some instances may not be known in advance of the permit being granted, for example, they may be attached as conditions of permits.
- What are the internal approval procedures of the proposed in-country collaborating institution?
○ Are there precedents for prior use of these procedures?
○ What committees/structures are involved?
○ Is this a public or confidential process?
○ Are there interactions with governmental approval/permitting processes? With ethical, social, and cultural?
○ Is there sufficient capacity for regulatory compliance and reporting?

Other regulated research

- Describe the Institutional Review Boards (IRBs)/Institutional Ethics Committee (IECs) responsible for oversight of Human Subjects research at the institutions to be involved in the trials.
 - Describe the Institutional Biosafety Committees (IBC) or equivalent review bodies responsible for oversight of research involving biohazardous agents.
 - Describe the Institutional Animal Care and Use Committee (IACUC) or equivalent institutional review bodies responsible for oversight of research involving vertebrate animals.
 - Does the country have national guidelines for research with recombinant DNA?
 - Does the in-country collaborating institution have an established research review procedure for research with recombinant DNA?
○ If so, what are the procedures, structures, informational requirements and projected timescale(s)?
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