Capacity Building: Are we ready to regulate Gene Drive organisms?

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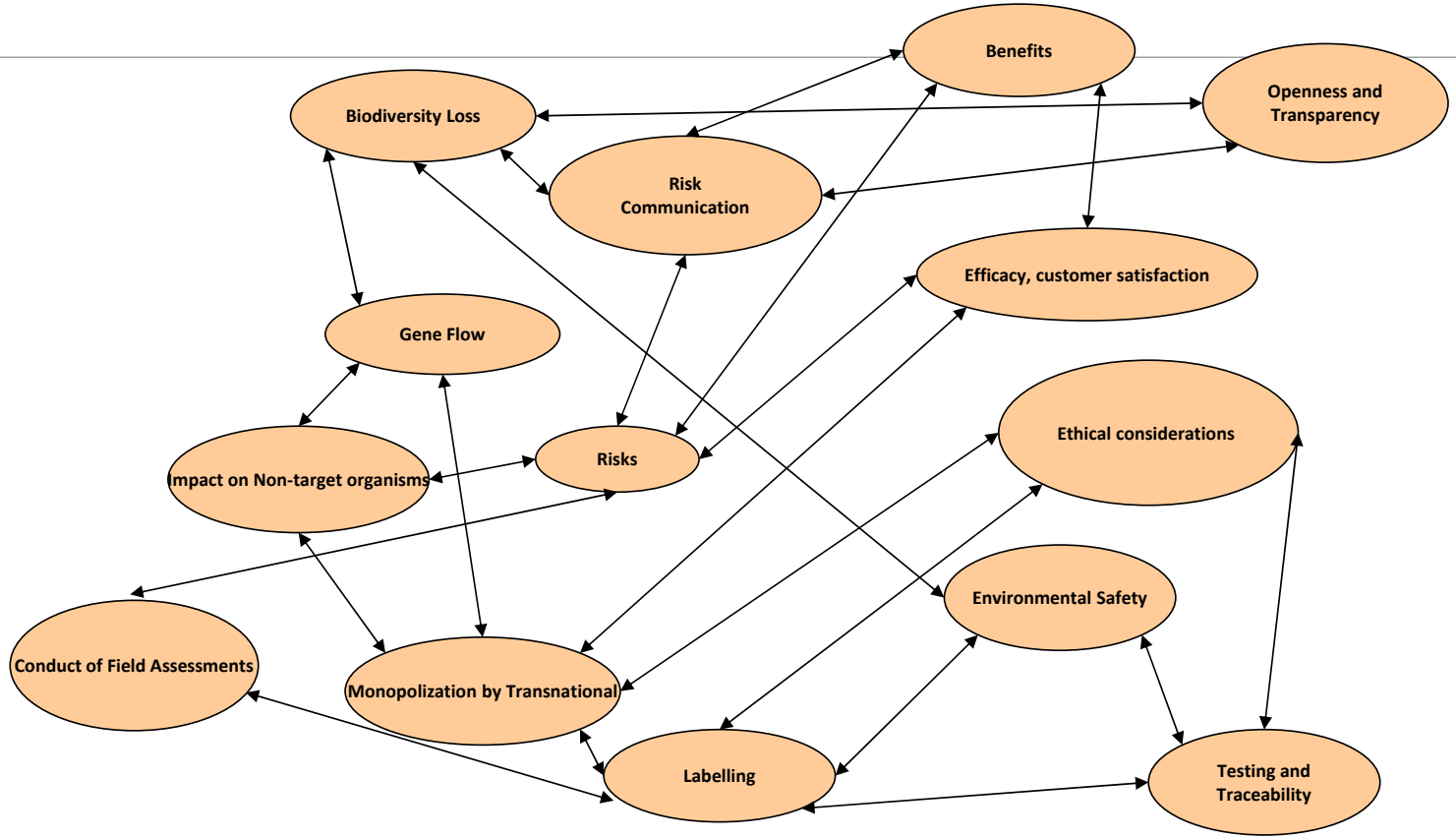
Capacity building for innovative technologies

- Regulating for innovation is a multi-faceted and multi-stakeholder endeavour
- Innovations raise a lot of questions for policymakers and regulators, which ultimately inform their decisions
- Capacity-building is the key to implement appropriate regulations and facilitate decision making

Regulation of gene drive organisms

- Gene drive organisms are developed using modern biotechnology
- Biosafety regulatory systems are responsible for regulating products of modern biotechnology
- These systems are implemented through regulatory instruments viz. acts, rules, policies etc.
- Review of applications and decision making supported by scientific guidelines updated from time to time
- Review process includes consideration by technical experts as well as interministerial committees
- Public consultations are generally held prior to decision making

Issues and concerns with modern biotechnology (including gene drives)



Addressing biosafety and ethical concerns

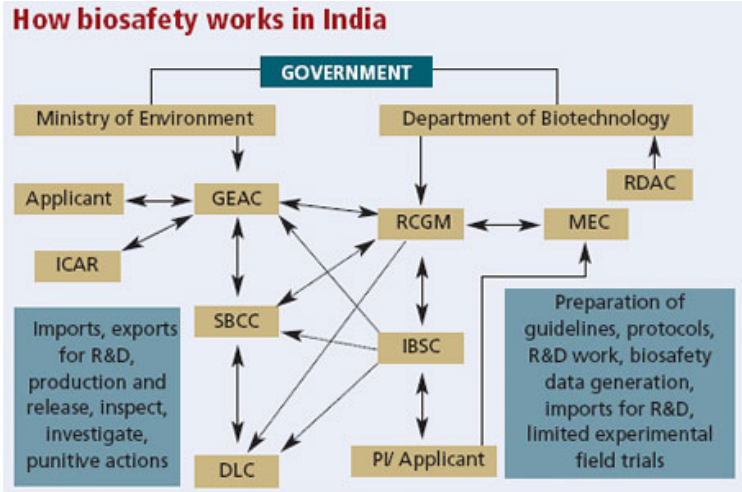
- **Scientific**
  - Potential harm to people
  - Potential harm to the environment
- **Non Scientific**
  - Ethical concerns

Key requirements for regulating gene drives

1. Functional biosafety regulatory systems in the country
2. Scientific guidelines and resources for baseline information
3. Trained human resource
4. Community engagement

1. Biosafety regulatory framework

- Most countries have biosafety regulatory framework, as a result of initiatives at the national level or support being a Party to the Cartagena Protocol on Biosafety
- Competent authorities are designated for receiving applications by researchers/ technology developers
- Biosafety regulations more inclined for plants; limited experience with other categories of organisms such as mosquitoes



Challenges in developing countries

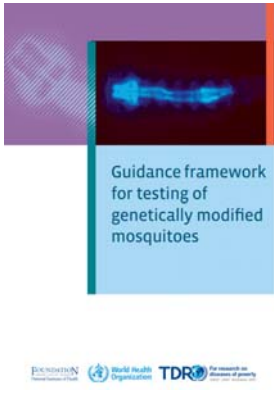
- Regulatory system mostly consist of committees as compared to dedicated secretariat
- Change in members during the course of product development
- Guidelines and study requirements are sometimes interpreted differently by committee members.
- System of formal consultations with regulators prior to submitting an application not in place

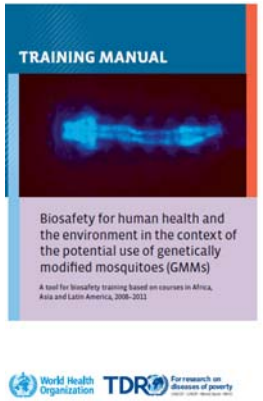
2. Scientific guidelines and resources

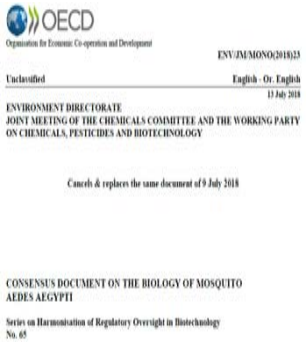
- Internationally accepted safety assessment methodologies for products of modern biotechnology
- Data requirements for pre-market safety assessment
- Baseline information

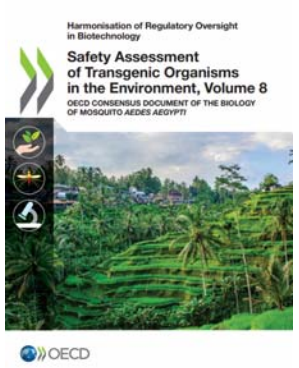
Example: Guidance documents for genetically modified mosquitoes

- WHO *Guidance framework for testing genetically modified mosquitoes* published in 2014 (Revised in 2021)
- WHO Training Manual for *Biosafety for human health and the environment in the context of the potential use of genetically modified mosquitoes (GMMs)*
- OECD Consensus document on the biology of mosquito *Aedes aegypti*









Preparation of guidance documents

- Led by credible scientific international agencies
- Harmonized documents with participation of experts from various countries
- Consultative process, years of discussions
- Based on science (peer reviewed literature)

3. Trained human resource

- Limited expertise in risk assessment and risk management requirements
- Technical expertise in multiple disciplines
- High turnover of regulators (members of regulatory committees) and scientific staff
- Representatives of ministries, not well-versed with novel technologies

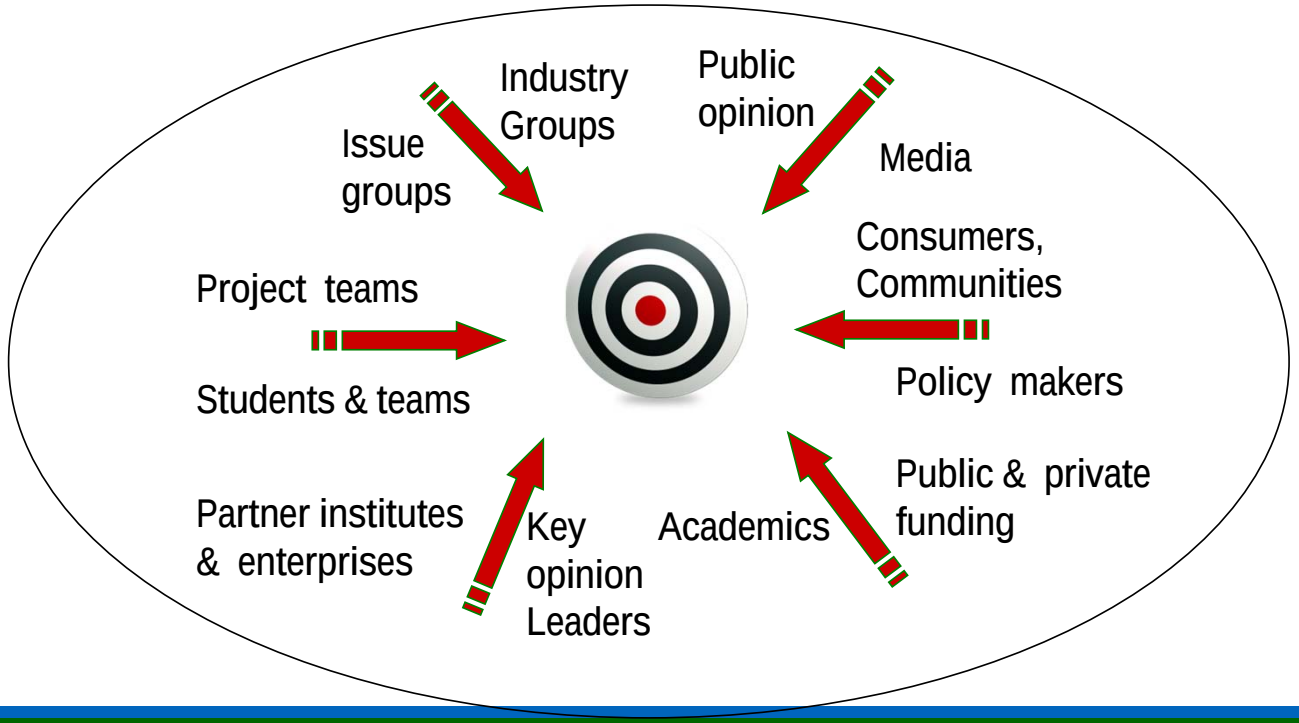
4. Public awareness

- Public debate over the use of modern biotechnology influenced by misperceptions, inaccurate and sometimes false information.
- Strategic communication plans are extremely important
- These include skilled communicators and spokesperson, developing key material, identifying delivery formats as per the local needs

How will GMM affect local ecosystems?
How do the risks of GM compare with increased dengue incidence / insecticide pollution of environment?
What restrictions should be placed on the use of GMM?

Identify your target audiences

"The public" is not a homogeneous population. Each of these groups constitutes a distinct audience seeking information that answers their questions and concerns with an appropriate level of detail.



Regulations of gene drives: Status and capacity building needs

- Biosafety frameworks are in place in most countries
- Guidelines and resource documents are available
- Trained human resource is urgently required for effective decision making to permit testing and release
- Public awareness is extremely important and needs to be undertaken in a planned manner

Thank you!