Governing Gene Editing: A Policy Framework

An open regulatory environment to manage a rapidly emerging technology

Takshashila Policy Proposal

September, 2017

Prepared by:

Anirudh Kanisetti

Madhav Chandavarkar

Ajay Patri

Shambhavi Naik

The need for a governance framework

Gene editing comes with great benefits – but also with great risks. A governance framework is necessary to capture the opportunities while managing the risks.

India's policy framework should be guided by the national interest rather than prevailing international narratives in this emerging field.

Gene editing technologies are an opportunity for India

Research into gene editing, especially with cost-effective technologies such as CRISPR-Cas9, can act as a strong foundation for an indigenous biotechnology sector. This could pave the way for everything from addressing India's food security problems to improved medical treatments.

The technology should be allowed to develop

The policy framework must enable India to be at the forefront of the advances in this rapidly developing technology. Otherwise, India's significant genetic resources and technical capacity will remain underutilised.

India must not impede the commercialisation of gene editing

India should pursue a policy which is in its national interest and not bow down to pressure from interest groups abroad. A robust indigenous gene editing industry will further India's interests abroad through trade advantages and will also enable it to coalesce an independent gene editing stance on the international stage.

Guiding Principles

The policy deliberations leading up to the proposed framework are centred around five principles

1. Scientific progress must be encouraged

Scientific progress has provided tangible benefits for human beings. Unless there is compelling reason to do otherwise, the pursuit of scientific knowledge and development must be encouraged.

2. The technology should be viewed independently of its use

While the application of scientific knowledge might have adverse effects, the knowledge itself cannot be branded undesirable.

3. Global and national interests must be balanced

Global and national interests may not always be complementary to one another. India must balance these while formulating its policy around gene editing.

4. Regulation is better than outright prohibition

Rather than drive the entire industry underground, it is better to have a well-regulated framework with appropriate checks and balances.

5. Policymaking must be scientific but still inclusive

Gene editing is a highly technical field - scientists must be given primacy in determining the contours of any regulatory framework. Given its far-reaching consequences and ethical complications, other stakeholders must also be consulted.

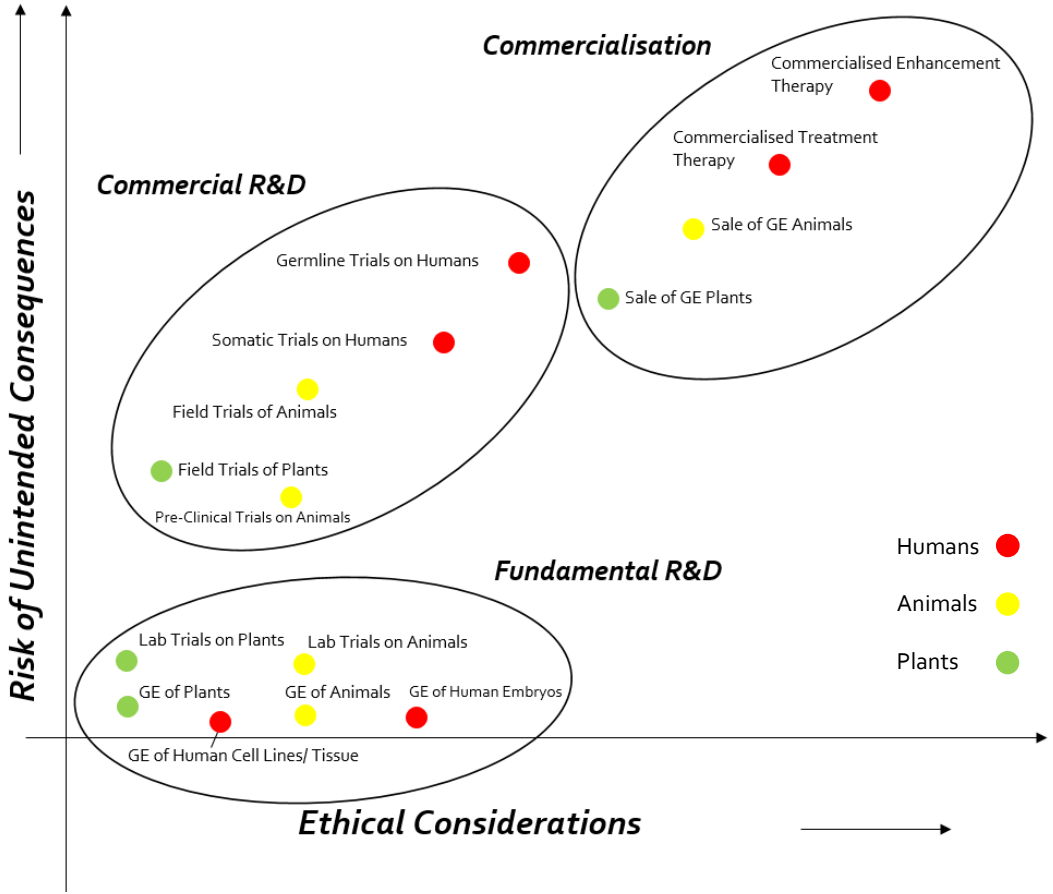
An analytical model for policymaking

Gene Editing applications are assessed based on their scientific and ethical risks. This provides three broad groupings, each of which requires a different type of governance principle.

The axes of our analytical framework are

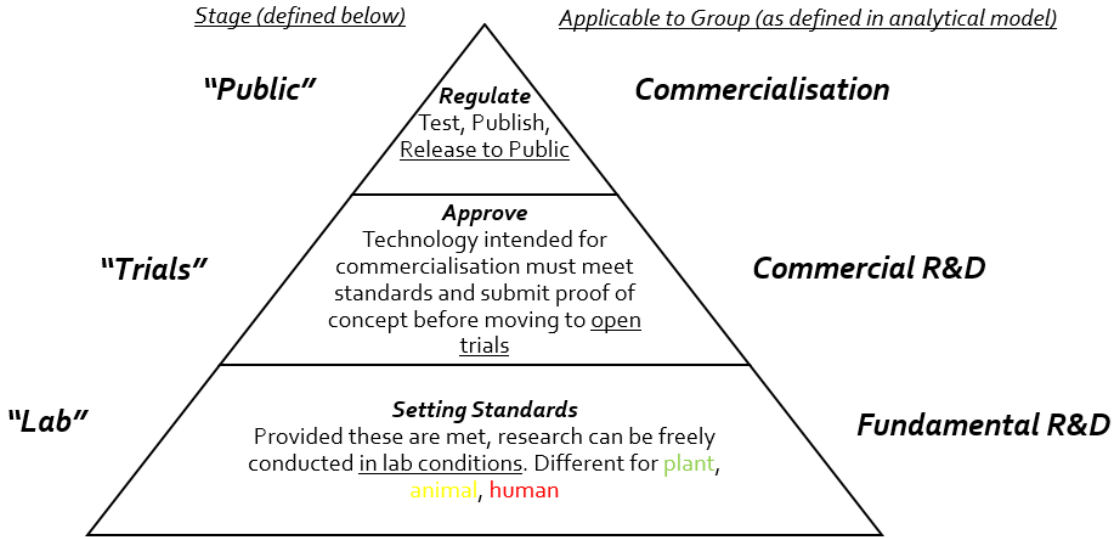
Risk of Unintended Consequences: Represents unintended eventualities *deriving* from the use of the technology, such as increasing inequality.

Ethical Considerations: Represents the ethical considerations *inherent* in the use of the technology, such as the "order of nature".



A three-level framework

The risks associated with the groupings defined above can be managed with layered regulations **that become stringent as the application moves from R&D to commercialisation.**



1. "Laboratory" Stage – Compliance with Standards. Research organisations free to conduct lab experiments as long as they adhere to scientific standards and protocols for different technologies. Government to set standards in collaboration with research and industry groups.

2. "Trials" Stage – Subject to Conditions. Clinical/open field trials on a demonstrated product cannot be carried out without prior approval. The approval will be granted by an agency based on standards set by the government in collaboration with research and industry groups.

3. "Public" Stage – Verify Safety. Product can be sold on the market only after government has independently verified that the product meets safety and disclosure standards.

How does the framework address concerns and objections?

The framework is designed with safeguards that minimise unintended consequences and misuse of gene editing.

Scientific Limitations

Gene editing technologies are still relatively imperfect. Rigourous scientific standards ensure that research in lab settings will be conducted safely, allowing field trials only the once safety and effectiveness have been proven.

Unintended Consequences

By providing a barrier before release to the public, the framework prevents unintended environmental or public health effects. Products will only be available on the market once their effects are fully understood and certified by an independent body.

Ethical Considerations

Disclosure requirements at the human trial and public release stage ensure that end users will be able to give informed consent to the use of gene edited products. Approval and oversight over the various stages also ensure other ethical considerations like confidentiality are addressed.

Other objections

The framework does not address the question of gene editing being *unnatural* - humans have been tinkering with genes through selective breeding for millennia. Claims such as GMO imperialism are broader systemic issues and should be addressed independently of gene editing regulations.

Notes on Implementation

The Three-Level Framework can be achieved in many ways, but it is only a beginning. The standards must be continually updated. A forward-looking regulatory environment is the first step towards developing India's scientific capabilities and industries.

In order to create a conducive *regulatory environment* that facilitates scientific progress, the following steps are proposed.

One way to implement the framework in a way that ensures timely approvals would be to create independent accreditation firms that approve trials and certify adherence to standards. Violators of the standards should be penalised. Broad non-binding guidelines, as currently established by the Indian Council for Medical Research, are not enough.

These standards should be set by a formal tripartite committee incorporating the government, the research community, and the biotechnology industry. The standards must be constantly updated as the technology evolves.

The government should protect the exclusive license of patent holders in order to encourage research but still maintain exemptions, such as allowing research to be conducted on a patented technology. These exemptions should be employed reasonably and with discretion; for example, efforts should be made to secure reasonable compensation to patent holders if the government employs the technology for public use.