

# Comments on draft document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment

The Network of Rural and Agrarian Studies (NRAS)

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The Department of Biotechnology (DBT), Government of India has sought comments on the draft regulatory framework and guidelines for risk-assessment for genome-edited organisms on 9<sup>th</sup> January 2020.

On behalf of the Network of Rural and Agrarian Studies – a collective of academics, researchers, writers, teachers, journalists, civil society members, and citizens concerned about rural and agrarian issues – we write to express grave reservations about the framework, but more importantly, about the way the rules have been framed and comments sought. We begin with the latter aspect, before offering comments on the framework and guidelines.

## 1. Exceeding the mandate of the Department of Biotechnology

Gene drives are genetic modifications “[designed to spread through a population at higher-than-normal rates of inheritance](#).” Whereas plant breeding, radiation breeding and the recombinant-DNA technology alters crop genomes, gene drives allow changes to a much larger sets of organisms including microbes, plants, insects, animals and human beings. In brief, gene drives allows us to change *living organisms and ecosystems*, in ways more complex and uncertain than earlier technologies.

The Department of Biotechnology is therefore not the appropriate department for framing risk assessment guidelines for genome edited organisms, given its mandate is to [promote large scale use of biotechnology](#). Genome-edited organisms raise a wide range of concerns – ecological impacts, biodiversity, human and animal health, farmers’ welfare, socio-economic considerations, intellectual property rights, among others. These are areas that fall within the mandates of other ministries and departments of the Union Government as per the Government of India (Allocation of Business) Rules, 1961. Since the DBT lacks expertise and the legal mandate in these areas, the regulatory framework for genome edited organisms should be devised by other line ministries. In our view, the Ministry of Environment, Forests and Climate Change, the Ministry of Health and Family Welfare, and the Ministry of Agriculture and Farmers’ Welfare should together frame regulatory policies for genome-edited crops.

## 2. Public participation

For a technology with wide range of uses and applications, placing a document in English on the DBT website and asking for written comments, that too only on the specific provisions and not the overarching framework, is not good enough – there needs to be much wider consultation with citizens, citizen groups, political leaders, state governments and policymakers before pushing any regulatory framework forward. The Union Government must publicize existing scientific and commercial knowledge about genome edited crops in multiple Indian

languages, and then seek public comments and feedback. The model of public hearings envisaged under the Forest Rights Act, 2006, can serve as a useful starting point for public consultations. The regulatory framework for genome edited organisms also needs a debate in the Parliament, and at a minimum, within the Standing Committee on Science & Technology, Environment and Forests and the Standing Committee on Agriculture.

### **3. Comments on the proposed regulatory framework**

The Department of Biotechnology proposes to regulate genome edited crops via the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 (Rules, 1989), notified under the Environment (Protection) Act, 1986. These are the rules that presently govern genetically modified (GM) crops via different regulatory committees, with the Genetic Engineering Appraisal Committee as the apex decision-making body.

We believe that this is a fundamentally unsound idea. Rules 1989 are skeletal and outdated. They have repeatedly proven inadequate to the task of regulating GMOs – whether it is the breakdown of resistance to Bollgard-II cotton or the easy availability of unapproved traits like herbicide tolerance. The working of the regulatory regime has also been severely criticized by the Parliamentary Standing Committee on Agriculture, the Parliamentary Standing Committee on Science & Technology, Environment and Forests, and a majority of the Technical Expert Committee (TEC) appointed by the Supreme Court in Aruna Rodrigues’ and Gene Campaign’s public interest litigations.

In the last 30 years, many advances have been made in our understanding of agrarian issues, agro-ecosystems, health and molecular biology. The climate crisis, environmental crisis and agrarian crisis are already upon us, with no satisfactory resolution in sight. In this context, using the threadbare Rules, 1989 to regulate a complex and uncertain technology that can result in permanent shifts in living organisms and ecosystems is myopic and irresponsible.

We urge the Government of India – through the Ministry of Environment & Forests, the Ministry of Agriculture & Farmers’ Welfare and the Ministry of Health and Family Welfare – to take up the task of devising a regulatory framework for genome edited organisms afresh.

In our view, the regulatory framework must incorporate the following elements at a minimum.

- a) Needs assessment – As with GMOs, the DBT proposes to restrict the role of regulation to risk assessment, without setting priorities for what genome edited organisms are important for the country. As the majority of the Technical Expert Committee (mentioned above) recommends, regulation should begin with a needs assessment of whether genome edited organisms are needed at all. There is no point debating risk assessment frameworks without settling this prior question.
- b) Public participation – It is at the stage of needs assessment, that public participation is most meaningful and necessary. It has been amply demonstrated that the agrarian crisis is not a crisis of production, and in fact the obsession with productivity is contributing to the linked crisis of farming and the environment. Therefore, the public must be involved in framing the priorities for research and development of genome edited organisms, if

they are required. As mentioned earlier, the model of public hearings envisaged under the Forest Rights Act, 2006, can serve as a useful starting point for public consultations, participation and consent. Consultations should be region-wise and must include a range of farmers, especially small and marginal farmers and landless farmers, and civil society groups.

- c) Precautionary Principle – The needs assessment must exhaust the potential of existing technologies and practices of integrated pest management, agro-ecological farming, biodiversity-rich agriculture, public health, biodiversity conservation etc. before turning to genome editing. The needs assessment itself should be guided by the precautionary principle.
- d) Devise and demonstrate safe containment protocols – Gene drives are designed to persist and spread in the environment. Before permitting research, the Union Government must notify rigorous containment protocols and demonstrate their efficacy. The Indian experience with illegal Bt cotton, HT cotton and Bt brinjal does not lend confidence in existing containment protocols.
- e) Devise monitoring and assessment mechanisms and demonstrate reversal methods – Before allowing research and development, the government must demonstrate that there are a) functioning monitoring mechanisms and b) methods to reverse the spread of gene drives in case of accidental release. The DBT proposal to leave on-site regulation to institutional biosafety committees is totally inadequate and irresponsible. As the Sopory Report on the failure of Bikaneri Narma Bt cotton observed, institutional committees failed to detect even the contamination of BN Bt cotton with Monsanto’s Bt event. Their capacity to oversee subtler changes to the genome is simply non-existent.
- f) Ensure free, prior, informed consent of all communities where research & development work is planned/proposed.
- g) Conduct an ecological assessment of gene drives – We have a poor grasp of how gene drives will spread through and alter the ecosystem. There are serious unaddressed issues in regard to plant genome editing furthered by methods like CRISPR-Cas9. Despite claims about precise and targeted DNA modifications, issues of off-target mismatches that can give rise to unintended changes within plant genomes remain poorly researched. Bioengineered crops would require “[greater clarity as to target specificity, the potential for mismatched edits, unanticipated downstream effects of off-target mutations, and assurance that genome reagents do not occur in finished products](#)”.
- h) It is vital that before research & development of gene drives is permitted, a panel of expert ecologists assess the risks to ecosystems from gene drives. The GEAC and the RCGM are simply not equipped for this task, as these are bodies largely staffed by biotechnologists, ex-officio bureaucrats, agricultural and medical scientists.

## Conclusion

Advances in ecology indicate that killing organisms (mosquitoes, pests, weeds, etc.) is an inefficient and myopic strategy of managing ecosystems, and that the road to sustainable food and agriculture requires reversing ecological degradation, biodiversity erosion, and building the health of soil and farmers’ creative capacities. Genome editing goes against these principles by

offering yet another [magic bullet](#) to solve problems triggered by previous ‘magic bullets.’ It is very important for India to focus on retaining its rich agro-biodiversity of seeds, microbes, and animals, rather than submitting to genomic manipulation of cultivars, animals, insects and microbes, indigenous and non-native.

Moreover, scientists and policymakers in India need to contribute responsibly. We must adapt the European framework of Responsible Research and Innovation (RRI), which advocates [anticipation, inclusion, reflexivity, and responsiveness](#). There are fundamental ethical, economic, ecological and political questions raised by genome editing. India’s experience with the non-approval of Bt brinjal underlines widespread reservations by the public. Public participation and inclusion in deciding about the necessity and introduction of genome editing for crop development is a must. Bureaucratic steering of genome editing that does not adhere to principles of responsible innovation and public participation may well be disastrous especially because genome editing will have long term consequences on Indian agriculture, ecology, and society. Fast-tracking regulations through this draft that facilitates the introduction of new genome editing technology is a premature move.

We strongly urge the Government of India to go back to the drawing board, and prepare a policy framework for holistically addressing the multiple crises plaguing the country. At this point, the risks of genome editing are too poorly understood to prepare a risk assessment framework, especially in light of the failure of Rules, 1989 to regulate GMOs. Nor is it clear that as a matter of policy, we need genome editing in India. Therefore, we urge the government to impose a moratorium on genome editing, pending wide public consultation and a thorough needs assessment, keeping in mind the potential of ecological solutions to agricultural and other problems and the precautionary principle.

Signed,

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