TAKSHASHILA INSTITUTION

Regulating Genetically Engineered Insects in India

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1 Executive Summary

Genetically engineered insects have applications across vector control, sericulture, biological control of crop pests and insect-derived protein for animal feed. The Department of Biotechnology's Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023 focusses on contained rearing, and the Ministry of Environment, Forest and Climate Change, which would oversee the commercialisation of these products, has not issued a complementary guidance document that captures the vision for insects. Rule 7 of the 1989 Rules already bars the use or sale of genetically engineered products without the consent of the Genetic Engineering Appraisal Committee, and Rules 8 to 11 extend that requirement to production, release and products. However, these rules need to be updated to account for the emerging technologies in genetic engineering that now allow the designing of a wide variety of insects with different benefit-risk profiles.

This document proposes a risk-tiered commercialisation pathway for genetically engineered insects developed under the 2023 research guidelines, confined to beneficial applications and consistent with India's obligations under the Cartagena Protocol and the Biological Weapons Convention. For insects, mobility, mating with wild populations and the difficulty of recall make persistence— rather than genetic novelty— the key determinant of ecological risk.

We recommend three measures: a conditional exemption from Rules 7 to 11 for the lightest tier, handled by institutional certification and a public registry entry; delegation of the middle tier to the Review Committee on Genetic Manipulation; and retention of the Appraisal Committee for release and for transgenic cases, with the evidence expected set out in advance. An insect or its biomass entering the food or feed chain faces a second approval to establish whether it is fit for consumption.

2 Introduction

Insects can be genetically engineered to provide various benefits. Engineered mosquito strains can limit the spread of dengue and malaria, silkworms could produce desirable properties in silk, predators can control crop pests to reduce reliance on pesticides, and black soldier flies can substitute for fishmeal in aquaculture and poultry feed. Even more simply, engineered insects could become a platform to make desired proteins. Yet, despite the benefits of genetically engineered insects being apparent, the regulatory roadmap to their commercialisation and adoption hasn't been updated to reflect new technological changes.

India regulates genetically engineered organisms under the Rules for the Manufacture, Use/Import/Export and Storage of

Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989, framed under the Environment (Protection) Act, 1986 [1]. Oversight is tiered across Institutional Biosafety Committees at the level of the institution, the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology (DBT), and the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEFCC), supported by state and district level committees.

Rule 7 bars the manufacture, use, import, export, transport or sale of genetically engineered products without GEAC approval, Rule 8 governs production involving discharge into the environment, Rule 9 governs deliberate release, and Rules 10 and 11 govern products and foods containing engineered organisms. The difficulty is therefore not that commercial use is unregulated. However, the requirement is undifferentiated, so a contained rearing facility and an open release of a self-propagating construct are treated at the same level, thereby disincentivizing innovation that may be low-risk.

For insects, the DBT's 2023 research guidelines provided a vision for how genetically engineered insects may be used in India[2]. Given DBT's research mandate, the guidelines only cover limited research phases, while further confined field trials and commercialisation are routed to the GEAC and other authorities. The gap was recognised when the guidelines were framed and has not since been filled.

Current advances in engineering technologies demand a proactive regulatory pathway to incentivise more innovation in this field. A parallel to harmonising regulation across government departments can be found in 2022, when the regulatory architecture was updated for genome-edited plants. The environment ministry exempted genome-edited plants in the SDN-1 and SDN-2 categories— which are free of exogenous introduced DNA— from Rules 7 to 11 of the 1989 Rules, in concert with guidelines issued by the Department of Biotechnology that provide such plants a light-touch regulatory route[3].

Unlike plants, where the primary application is food, insects have other applications that are not food related. It is therefore important to create regulatory pathways specific for food and feed, as well as for other applications, where the perceived risk may be lower but benefits to the economy may be significant. Looking at the plant example, India does allow genetically modified varieties of cotton to be grown. A similar differentiation for insects could also be made.

In the following sections we set out the two axes on which we propose to tier authorisation, describe how each of the three tracks would work with a case study for each, and identify which authority clears the organism, which clears the product, and which monitors both.

3 Framework

The first axis is persistence and spread, and it characterises the organism, not the product. P0 covers organisms that are non-viable or sterile, which remain living modified organisms for regulatory purposes; P1 covers self-limiting modifications, where the trait declines out of the population over successive generations; P2 covers self-sustaining modifications, where the trait persists; and P3 covers self-propagating modifications, where it spreads beyond the released cohort.

The second axis is containment and exposure, in three tiers. E1 covers contained use in an enclosed facility with no intended release; E2 covers confined release into outdoor cages, or screened enclosures that are bounded and reversible; and E3 covers deliberate release into the open environment.

3.1 The Decision Matrix

Crossing the two axes yields twelve combinations, each routing to one of three tracks. The tracks differ in where an application goes, and how it is assessed.

Persistence	E1 · Contained	E2 · Confined	E3 · Open release
P0 · Non-viable or sterile	A · Exemption	A · Exemption	B · Delegated
P1 · Self-limiting	A · Exemption	B · Delegated	B · Delegated
P2 · Self-sustaining	B · Delegated	B · Delegated	C · Full appraisal
P3 · Self-propagating	C · Full appraisal	C · Full appraisal	C · Full appraisal

Two consequences are worth noting. Self-propagating systems require full appraisal including under containment, because for these cases containment failure is itself the hazard. A product gate then applies wherever an insect, or its biomass, enters the food or feed chain; that gate is separate from these tracks, and is outlined in the final section.

3.2 Track A: Exemption

Track A is a conditional exemption from Rules 7 to 11, similar to the route the environment ministry has already accepted for genome-edited plants, under which the Institutional Biosafety Committee certifies and the RCGM receives that certification.

First, the applicant files with its Institutional Biosafety Committee the persistence and exposure classification, along with the data supporting it; the molecular evidence that no exogenous DNA remains; containment standard operating procedures; and a contingency plan covering escape and recall.

Second, the Committee confirms the classification, certifies the absence of exogenous DNA and issues a certificate, as it does under the plant SOP.

Third, the certificate and the Committee's minutes are filed with the RCGM through the Indian Biosafety Knowledge Portal—the channel the plant route already uses—and the application is entered in a public registry.

Fourth, the exemption takes effect on that entry. Nothing is pending before GEAC and no order issues, because the prohibition in Rules 7 to 11 has been lifted for the class rather than waived for the applicant.

The exemption is conditional—contingent upon* periodic* re-verification at defined generation intervals, maintenance of the certified containment standard, notification of any escape, and entry of monitoring results in the registry. Breach of a condition voids the exemption and the application can be subjected to the full appraisal process. The RCGM retains the power to refer a registered application up a track at any time.

Example: An edited silkworm reared for silk. A silkworm line carrying a self-limiting modification, reared in an enclosed facility, with the silk rather than the insect entering trade, is an application at the intersection of P1 and E1. The modification declines out of the population over successive generations, so an escaped insect cannot expand into a biodiversity threat. Containment is complete, and silk is neither food nor feed, thus reducing risk.

3.3 Track B: Delegated Review

The RCGM decides on the application falling in Track B. It applies where an organism persists but is contained, and where a self-limiting organism is released in an open environment.

An applicant files everything required for Track A— together with tier-appropriate efficacy data and a focused environmental risk assessment covering dispersal, mating competitiveness, non-target effects and persistence. The RCGM decides, advised by a standing expert sub-committee on engineered insects, within a fixed period. The decision may be an approval, an approval on conditions, a referral to the GEAC with reasons, or a refusal.

Example: Insect protein for aquaculture feed. The insects in a black soldier fly production facility are a fertile breeding colony, whose modification persists from one generation to the next. This places the organism at P2 rather than P0, while containment places it at E1. The matrix routes it to Track B.

3.4 Track C: Full Appraisal

Track C retains the GEAC and the appraisal it has already conducted, with the difference being that the evidence expected is set out in advance. It applies to open release of anything that persists, and to self-propagating constructs wherever they are held.

An application carries a full environmental risk assessment, a food and feed safety review where relevant, public consultation, advance informed agreement under the Cartagena Protocol where movement across a border is foreseeable, and long-term monitoring and stewardship obligations.

Example: A self-sustaining mosquito for vector control. A line engineered so that the modification persists in the wild population, released into the open environment to reduce transmission of dengue or malaria, sits at P2 and E3 and goes to Track C. The modification is intended to remain in the population after the release programme ends, which is what makes full appraisal appropriate.

A self-limiting line released for the same purpose sits at P1 and E3, in Track B, because the modification declines and the population returns to its prior state. The two applications may target the same disease in the same district, and differ only in whether the change they make is permanent.

3.5 Monitoring and the Conditions

The 1989 Rules already establish a monitoring tier beneath the approval bodies. Under Rule 4(5) the State Biotechnology Coordination Committee has powers to inspect, investigate and take punitive action in case of violations, and to periodically review the safety and control measures at institutions handling engineered organisms, while Rule 15(3) allows it to take samples for closer examination. Under Rule 4(6), the District Level Committee— working under the District Collector— monitors safety regulations at installations engaged in the use of genetically modified organisms, visits those installations, maps hazards and reports to the State Committee or to the GEAC. Rule 15 allows either body to act at the expense of the person responsible where an order is ignored, and Rule 18(1) permits authorised persons to enter premises for supervision.

However, a defined post-authorisation role for these committees with respect to engineered insects is missing. The District Level Committee could conduct the periodic verification of mass rearing applications, the State Committee could hold the field-monitoring obligations attached to authorised release, and either could refer a case to the RCGM or GEAC when a population behaves outside the tier on which it was authorised.

4 Food and Feed as a Special Case

The framework to this point concerns the organism. A separate question arises the moment the insect, or anything derived from it, is sold for consumption: which is whether that product is safe to eat or to feed. The practical consequence, and the point on which the framework would otherwise be misread, is that an application sitting in Track A still requires product approval before anything reaches the market. It establishes that the insect may be reared under containment on a light-touch filing, but the resulting protein meal would still require further clearance.

Under the 1989 Rules, Rule 10 requires GEAC approval for substances and products containing engineered organisms; and Rule 11 requires GEAC approval for food, food ingredients and additives that contain or consist of them. Under the Food Safety and Standards Act, 2006, Section 22 gives the Food Safety and Standards Authority of India the power to regulate genetically modified food. In proceedings before the Jaipur Bench of the Rajasthan High Court the Union Government accepted that no regulations, standards or guidelines regulating GM food have been framed under Section 22. Consequently, in October 2025, the court directed the Centre and the Authority to frame and notify them within six months. Until they are notified, the court restrained both the Authority and the GEAC from permitting the sale, manufacture, distribution or import of GM food. Any pathway for engineered insects intended for human consumption is therefore being designed against an unsettled and presently restrictive backdrop.

Further, the Delhi High Court has held that the Food Safety and Standards Act, 2006 extends only to food intended for human consumption and that animal feed falls outside the statutory definition of food, thus placing it beyond the Authority's mandate. The consequence for this framework is direct. The application closest to commercial readiness, insect protein for aquaculture and poultry feed, has no food-safety regulator at all, with its only product gate being GEAC's approval under Rule 10— an environmental-release instrument. We recommend that the Department of Animal Husbandry and Dairying assess the safety of engineered insect-derived feed, and that GEAC's Rule 10 approval for such products be confined to the environmental question.

5 Conclusion

India has a research framework for genetically engineered insects but no anticipatory route for putting its outputs to use. Research capacity built with public funds, therefore, has no route to public benefit.

Tiering on persistence and containment, rather than on genetic novelty, places the evidentiary burden where the risk actually

lies—in an organism that moves, mates with wild populations and cannot easily be recalled. It exempts the lightest class from Rules 7 to 11 on stated conditions, delegates the middle tier to the RCGM under a published procedure, and leaves the Appraisal Committee the cases that require it.

For India to truly develop world class capabilities in this field and benefit from the scientifically appropriate use of a genetically engineered organisms, the governance ecosystem has to take a whole-of-government approach in setting the vision and regulatory routes for varied applications.

Endnotes

1. Ministry of Environment, Forest and Climate Change, Government of India. The manufacture, use, import, export and storage of hazardous micro organisms genetically engineered organisms or cells rules, 1989. Link

2. Department of Biotechnology, Government of India. Guidelines and Standard Operating Procedures for Research on Genetically Engineered Insects, 2023 [Link]

3. Ministry of Science and Technology, Government of India. Notification of Standard Operating Procedures (SOPs) for regulatory review of Genome Edited Plants under SDN-1 and SDN-2 categories, 2022. [Link]



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