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ENTOMOLOGY

Science of Biopesticides and Critical Analysis of Indian Legal Frameworks Regulating Biocontrol Agents

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ABSTRACT

The unsustainable application of chemical pesticides has resulted in a steady decline in food productivity worldwide. Biopesticides hold the potential to maintain agricultural productivity, while safeguarding agroecosystems and microclimates. There are three broad categories of biopesticides: microbial biopesticides, botanical biopesticides, and semiochemical biopesticides. While the development and consumption of biopesticides is at a record high in a number of places, including Canada, the USA, the EU, Australia, and Brazil, India has shown slow growth, due in part to inadequate legislation, a lack of capacity, and the weak implementation of policies related to biopesticides and biocontrol agents. Biopesticides and biocontrol agents in India are still largely regulated by legal frameworks originally designed for chemical insecticides and pesticides. As a result, manufacturers and importers of biopesticides and biocontrol agents face multiple legal and procedural challenges. This paper provides a critical analysis of Indian legal frameworks regulating biopesticides, concluding that a reform in legal apparatus is necessary to promote the uptake of these substances in the country. A shift in the legal framework from a focus on chemical substances to biological agents would also complement the country's environmental and sustainability goals.

Highlights

- Indian Insecticides Act is inadequate to deal with biopesticides. Consequently, manufacturing, trade and use of biopesticides is affected by legal barriers.
- A reform is needed in regulations, registration and licensing process.

Keywords: Biopesticides, Biocontrol Agents, Legal Framework, Agroecosystem, Sustainability

Biopesticides are defined as mass-produced agents manufactured from living microorganisms or natural products and used for the control of pests (OECD 2009). An estimated 67,000 crop pest species exist worldwide, including plant pathogens, weeds, invertebrates, and some vertebrate species. Together they cause an approximately 40% reduction in the world's crop yield (Oerke *et al.* 1994). Pest management techniques seek to combat this reduction in yield. However, the unsustainable application of chemical fertilizers and plant protection chemicals has resulted in the steady decline of soil and crop productivity. In order to address this challenge, agricultural practices must evolve to sustainably meet the growing global demand for food without irreversibly damaging the world's natural resources – especially soil. Simply put, rising food yields must be decoupled from the unsustainable use of water, energy, fertilizers, chemicals, and land. Investing in sustainable agriculture is one of the most effective ways to simultaneously achieve the sustainable development goals (SDGs) related to poverty and hunger, nutrition and health, education, economic and social growth, peace and security, and the preservation of the world's environment (Earth Alive 2017). To this end, biopesticides hold tremendous potential to increase farmers' agricultural productivity, while also contributing to more sustainable soil. Several countries including Canada, Argentina, South Africa, Australia, the USA, and Brazil, among others, have already begun to embrace these technologies, and the list of potential commercial products promising increased crop yields continues to grow (Simiyu *et al.* 2013).

The global biopesticide market has been growing rapidly. More than 200 products are currently sold in the US market, compared to only 60 comparable products in the EU. Indeed, more than 225 microbial biopesticides are manufactured in 30 OECD countries (Hubbard *et al.* 2014). Countries like Canada, the USA, and Mexico use about 45% of the biopesticides sold worldwide, while Asia lags behind, consuming only 5% (Bailey, Boyetchko and Längle 2010). In India, the uptake has been particularly slow. Biopesticides have low single digit market share in India (Urs 2015). Along with neem (*Azadirechta indica*) derived products, antagonistic fungi *Trichoderma* strains and *Pseudomonas fluorescens* bacteria dominate the Indian market. Moreover, existing producers of biopesticides in India have been losing credibility among farmers because their products have proven to be ineffective in serious pathogenic outbreaks. The supply chain is also problematic, as minor changes in temperature, humidity, and exposure to the UV spectrum can severely affect biopesticide performance.

In most countries, the challenges concerning biopesticides revolve around inadequate legislation, a lack of capacity, and weak policy implementation (Urs 2015). Many countries have amended their policies to minimize the use of chemical pesticides and promote the use of biopesticides; however, biopesticides are still largely regulated by systems that were originally designed for chemical pesticides. This has created barriers to market entry by imposing burdensome costs on the biopesticide industry (Kumar and Singh 2014). One of the major obstacles in promoting biopesticides as an alternative to chemical pesticides is the lack of appropriate recognition of biopesticide, reflecting the weakness of the underlying policy framework in India (Kumar and Singh 2015). The relative immaturity of the policy framework, limited resources and capabilities, and a lack of trust between regulators and producers are also serious problems.

Investment risks involved in opting for biofertilizers and biopesticides on farmers' fields, and farmers' confidence in the quality and performance of the products, continue to be debated in India (Bhide 2013). While there is ample evidence of the microbiological and biotechnological aspects of biofertilizers and biopesticide production (including insecticides, fungicides, herbicides, and termicides), there is no critical analysis of the laws and regulations governing the use of biofertilizers and biopesticides in India. Yet unless the practical impact of these laws or rules is known, there is little chances of reforming the legal framework. The present paper analyses the Indian law concerning biopesticides under conventional pesticide legislation, and proposes reforms in legal framework.

The Science of Biopesticides

The biopesticides are obtained from organisms including plants, bacteria and other microbes, fungi, and nematodes (Copping 2009; EPA 2012). They are often important components of integrated pest management (IPM) programmes, and have received a great deal of attention as substitutes to synthetic chemical plant protection products (PPPs).

There are three broad categories of biopesticides: microbial biopesticides, botanical biopesticides, and semiochemicals. Microbial biopesticides are derived from fungi, bacteria, algae, viruses, nematodes and protozoa, and other compounds produced directly from these microbes such as metabolites (Van Lenteren 2012). The names of some microbial biopesticides are shown in Table 1. More than 3000 kinds of microbes that cause diseases in insects have been recorded (Nawaz, Mabubu and Hua 2016). Amongst these microbial biopesticides, over 100 bacteria have been identified as insect pathogens, including *Bacillus thuringiensis* Berliner (Bt) –an important microbial control agent (Nawaz, Mabubu and Hua 2016). *Bacillus thuringiensis* is known to produce a protein crystal (the Bt d-endotoxin) during bacterial spore formation. Bt d-endotoxin is capable of causing the lysis of gut cells when consumed by susceptible insects (Gill, Cowles and Pietrantonio 1992). It is host specific and can cause host death within 48 hours (Bond *et al.* 1971; Siegel 2001). Studies have also shown that it does not harm vertebrates and is safe for people,

Table 1: List of some important microbial biopesticides

Common name	Target insects	Reference
Entomopathogenic viruses		
Corn earworm NPV (HezeSNPV)	*Helicoverpa zea*: corn earworm, tomato fruitworm, tobacco budworm, *Helioth virescens*	Rowley, Popham and Harrison (2011)
Cotton bollworm NPV (HearNPV)	*Helicoverpa armigera*, cotton bollworm, pod borer	Rowley, Popham and Harrison (2011); Hauxwell *et al.* (2010); Rabindra and Grzywacz (2010); Yang *et al.* (2012)
Diamond back moth GV	*Plutella xylostella*	Yang *et al.* (2012)
Velvetbean caterpillar, NPV (AngeMNPV)	*Anticarsia gemmatal*is	Moscardi *et al.* (2012); Panazzi (2013)
Alfalfa looper NPV (AucaMNPV)	Noctuidae	Yang *et al.* (2012)
Tea moth (BuzuNPV)	*Buzura suppressaria*	Yang *et al.* (2012)
Entomopathogenic bacteria		
Bacillus thuringiensis subspecies kurstakia	Lepidoptera	Van Frankenhuyzen (2009); Jurat-Fuentes and Jackson (2012
B. thuringiensis sub-species aizawaia	Lepidoptera	Mashtoly *et al.* (2011)
B. thuringiensis sub-species japonensis	Coleoptera: Scarabaeidae	Mashtoly *et al.* (2010)
Paenibacillus popilliae	Coleoptera: Scarabaeidae, *Popillia japonica*	Koppenhofer, Jackson and Klein (2012)
Entomopathogenic fungi		
Aschersonia aleyrodis	Hemiptera	Lacey *et al.* (2011); McCoy *et al.* (2009)
Beauveria brongniartii	Coleoptera (Scarabaeidae)	Townsend, Nelson and Jackson (2010)
Conidiobolus thromboides Acari	Hemiptera, Thysanoptera	Hajek, Papierok and Eilenberg (2012)
Lecanicillium longisporum	Hemiptera	Down (2009); Kim, Goettel and Gillespie (2009)
Metarhizium anisopliae sensu lato	Coleoptera, Diptera, Hemiptera, Isoptera	Lacey *et al.* (2011); Jaronski and Jackson (2012)
Nomuraea rileyi	Lepidoptera	Thakre *et al.* (2011)

(Adapted from Nawaz, Mabubu and Hua 2016)

beneficial organisms, and the environment (Lacey and Siegel 2000). In addition to bacteria, more than 1000 viruses that act as insect pathogens have been isolated. Various nuclear polyhedrosis viruses (NPVs) have been found infested 525 insect species worldwide (Koul 2011, cited in Nawaz, Mabubu and Hua 2016). Over 800 species of entomopathogenic fungi and 1000 species of protozoa pathogens have also been described and identified (Koul 2011, cited in Nawaz, Mabubu and Hua 2016), along with two major groups of entomopathogenic nematodes – *Steinernema* (55 species) and *Heterorhabditis* (12 species) (Koul 2011).

Baculovirus biopesticides deserve special mention here due to their characteristics of being highly specific, having no adverse effects on vertebrates and plants, and the ease with which they may be genetically manipulated. However, like other biopesticides, the commercial use of baculoviruses presents difficulties, including short field stability, and high production costs (Mills and Kean 2010; Ravensberg 2011; Regnault-Roger 2012). Nawaz, Mabubu and Hua (2016) have also noted that the wild type baculoviruses have a slow killing rate, reducing their practical application. Alternative strategies are currently being developed through the use of recombinant DNA technology to enhance their killing action, including through the insertion of genes encoding insect hormones or enzymes, or insect specific toxins (Gramkow *et al.* 2010).

The second category of biopesticides, botanical biopesticides, are derived from plants that have the ability to kill or sterilize insects, to control weeds, or to regulate plant growth. Worldwide, nearly 6000 plant species have been identified with insecticidal properties (Nawaz, Mabubu and Hua 2016). In India, the application of botanical biopesticides is a very old tradition. Products derived from plants such as neem, custard apple, tobacco, and pyrethrum have been used as safer insecticides (Koul 2012). Farmers apply botanicals to protect crops and stored products from insect pests. Studies have shown that botanical biopesticides have ecologically-benign characteristics, such as a volatile nature and low environmental risks compared to current synthetic pesticides (Nawaz, Mabubu and Hua 2016). Indeed, the minimal residual activity of botanical biopesticides does not affect predation, parasitism, or pollination by insects (Xu 2011). For example, Azadirachtin compounds derived from the neem tree can be used on several food crops and ornamental plants for controlling whitefly, thrips, scale and other pests (Sarwar *et al.* 2012; Sarwar *et al.* 2013). Table 2 has a list of some important botanical biopesticides.

In spite of their advantages, botanic biopesticides have faced a number of challenges concerning commercialization, quality control, and product standardization. For example, as with synthetic pesticides, the improper and excessive use of botanical biopesticides may result in pest resistance (Nawaz, Mabubu and Hua 2016). Phytotoxicity is another a negative feature of botanical biopesticides. For instance, neem oil can be phytotoxic to tomato, eggplant, and ornamental plants if applied in high doses. Botanicals produced from some plant species such as *Aconitum* spp. and *Ricinus communis* are also considered to be highly toxic to humans and fish (Stevenson *et al.* 2012).

The third broad category of biopesticides is semiochemicals, which are chemical signals produced by one organism that cause behavioural changes in an individual of the same or a different species (Chandler *et al.* 2011). Commonly used semiochemicals for crop protection are insect sex pheromones, some of which can now be synthesized and are used for lure-and-kill systems (El-Sayed *et al.* 2009) and mating disruption (Chandler *et al.* 2011). Worldwide, mating disruption is used on over 660,000 hectares of land and has been particularly useful on orchard crops (Witzgall *et al.* 2008). According to Nawaz, Mabubu and Hua (2016), about 1000 kinds of insect pheromones have been identified so far and more than 30 target species have been controlled successfully by sex pheromones. Other types of semiochemicals are deployed to attract insect pests and kill them (Witzgall, Kirsh and Cock 2010; Dhaliwal *et al.* 2012). For example, the application of compounds such as jasmonic acid to plants can induce the production of herbivore induced plant volatiles (HIPVs). Sodium alginate is an example of an HIPV that triggers biological control by attracting natural enemy insects and aphids (Heuskin *et al.* 2012; Gurr *et al.* 2012).

Table 2: Some plant products used as biopesticides

Plant product used as biopesticide	Target pests
Limonene and Linalool	Fleas, aphids and mites, also kill fire ants, several types of flies, paper wasps and house crickets
Neem	A variety of sucking and chewing insects
Pyrethrum / Pyrethrins	Ants, aphids, roaches, fleas, flies, and ticks
Rotenone	Leaf-feeding insects, such as aphids, certain beetles (asparagus beetle, bean leaf beetle, Colorado potato beetle, cucumber beetle, flea beetle, strawberry leaf beetle, and others) and caterpillars, as well as fleas and lice on animals
Ryania	Caterpillars (European corn borer, corn earworm, and others) and thrips
Sabadilla	Squash bugs, harlequin bugs, thrips, caterpillars, leaf hoppers, and stink bugs

(Adapted from Salma, Ratul and Jogen 2011)

Overall, biopesticides face significant challenges and competition *vis-à-vis* synthetic pesticides for a variety of reasons. In some cases, biopesticides are highly specific, targeting particular pests, while the market prefers products with broad-spectrum activity (Glare *et al.* 2012). In other cases, biopesticides are only effective at specific stages of a pest's life-cycle (Singh *et al.* 2010), further narrowing the biopesticide's usage and applicability. If not used in a specified dose, at a specified time, and on specified crop, the biopesticide will be ineffective, but farmers may lack education or motivation, preferring broad range chemical pesticides instead. As a result, the development of biological pesticides must overcome the problems of improper preparation or formulations, short shelf life, delayed action, high market costs, and legal/ registration issues (Chandler *et al.* 2011).

Critical Analysis of Indian Legislation

When considering legislation governing biopesticides, two crucial concerns should be taken into account. First, regulations must be formulated to ensure human and environmental safety and to characterize consistent and reliable quality of biopesticide products. The EU ensures that the efficacy of a biopesticide product is quantified and proven in order to support claims made on its label (Chandler *et al.* 2011). However, as OECD guidance for microbial biopesticides (OECD 2009, p.11) puts it, "the microorganism and its metabolites pose no concerns of pathogenicity or toxicity to mammals and other non-target organisms which will likely be exposed to the microbial product; the microorganism does not produce a known genotoxin".

According to Chandler *et al.* (2011), only authorized biopesticide products can be used legally for crop protection in most of developed countries and many developing countries. Second, registration and regulatory agencies require a biopesticide data portfolio – a concept originating from the framework governing chemical pesticides. Such data includes information about the mode of action, toxicological and eco-toxicological evaluations, and host range testing (Chandler *et al.* 2011). Generating this scientific data is quite expensive for companies, and can therefore deter companies from commercializing biopesticides. Taking these two crucial concerns regarding biopesticide governance into consideration, the Indian government and regulatory agencies need to strike a balance between seeking data and allowing commercialization of the biopesticides. There is also a need to critically analyze the existing Indian legal framework to understand the gaps and weaknesses hindering the overall trade, manufacture and use of biopesticides in the country.

Pesticide regulations in India are governed by two different bodies: the Central Insecticides Board and Registration Committee (CIB&RC) and the Food Safety and Standards Authority of India (FSSAI). CIBRC is responsible for advising central and state governments on technical issues related to the manufacture, use and safety of pesticides (Bhide 2013). The Department of Biotechnology of the Ministry of Science and Technology serves as the technical agency in the approval process for effectiveness, quality and safety issues. Before authorization and registration, it must be determined that the microorganism and its metabolites pose no concerns relating to pathogenicity or toxicity to mammals and other non-target organisms that will likely be exposed to the microbial product; the microorganism does not produce a known genotoxin; and all additives in the microbial manufacturing product and in end-use formulations are of low toxicity and have little potential for human health or environmental hazard.

In India, biopesticides and biocontrol agents are still largely regulated by legal frameworks originally designed for chemical insecticides and pesticides. The Insecticides Act, 1968 and Insecticides Rules, 1971 regulate the import, registration process, manufacture, sale, transport, distribution and use of insecticides (pesticides) with a view to prevent risk to human beings and animals, as well as all connected matters. The basic tenet of problem is the intent of the law. Because they were designed to address chemical pesticides, the fundamental principles underlying the Act and the Rules treat biologicals like chemicals. But this treatment is grossly inappropriate; the science relating to the origin, production, application, physiology and functions of biopesticides is completely different from that of chemical pesticides. However, through few circulars of year 1994, 1996, 1999, 2000, 2001, 2007, 2008, 2009, 2011 a scope of manufacturing, selling, storing, distributing and transporting has been created in Rules of 1971 for range of microbial biopesticides (based on baculoviruses – nuclear polyhedrosis virus and granulosis virus, antagonistic fungi, entomopathogenic fungi, antagonistic bacteria, and entomotoxic bacteria), botanical biopesticides (neem products, herbal plant growth regulators, pyrethrum extract, cymbopogom plant extract, rotenone of piscicultire, and eucalyptus extract), and semiochemicals (insect pheromones). By Gazette of India no. 156 dated 26 March 1996 the biopesticides continued to be regulated under Insecticides Act, 1968 and Insecticides Rules, 1971. At present 34 strains of bacteria, fungi and viruses fall under biopesticides that need registration by CIB&RC before its commercialization.

On the other hand, biofertilizers are similar in origin to microbial technology and have received relatively better treatment under Indian law. The Fertilizer (Control) Order, 1985 has been modified to accommodate biofertilizers with amendments in 2006 and 2009, including special provisions addressing biofertilizers (Arjjumend, Koutouki and Getman 2017). In the absence of a separate law on biopesticides, the Insecticides Act, 1968 and the Insecticide Rules, 1971 require similar amendments. Indeed, the failure to introduce such amendments has caused the trade in biopesticides to suffer. Farmers and consumers are bound to pay heavy prices for chemical pesticides, while consuming pesticide residues. The following points illustrate the gravity of this issue:

Section 5a(i) of the Insecticides Act, 1968 speaks about the constitution of Registration Committee which is given the tasks of registering insecticides and pesticides (including biopesticides) after scrutinizing their formula and verifying claims made by the importer or the manufacturer regarding their efficacy and safety to human beings and animals. While the Registration Committee is expected to emphasize toxicological and ecosystem safety issues, the majority of these concerns apply to toxic organo-chemicals. Yet most biocontrol agents are ecologically safe and non-toxic. Thus, as far as biosafety is concerned, a separate legal framework is required to provide regulatory guidance for different categories of biopesticides in a systematic and comprehensive manner. Treating all categories of pesticides under one regulatory framework harms economic viability of biocontrol agents (affecting manufacture, trade, supply, etc.).

Under Section 9(3) of the Insecticides Act, 1968, the period for registration of an imported or manufactured biopesticide is 12 months from the date of application. This period may be further extended by 6 months if the Registration Committee is unable to arrive at a decision within said period on the basis of the materials before it. This lengthy registration period is impractical from a business perspective. It is also unsuitable for biopesticides, as the shelf life of biocontrol agents is very short. Often, laboratory tests take such a long time that the effective shelf life of the particular strain contained in the biopesticide expires before registration is granted. Due to delay in testing and expiry of shelf life, the sampled strain does not fit on standards set for that particular category of the biopesticide. Therefore, the length of time required for the registration of biopesticides must be shortened in accordance with the shelf life of various biopesticide strains.

Section 9(3) of the Insecticides Act, 1968 also requires the Registration Committee to investigate claimed safety precautions for human and animals, including wildlife. In cases where the precautions claimed are insufficient or, notwithstanding the observance of such precautions, the use of the insecticides involves serious risk to human beings or animals, the Committee may refuse the registration. Similarly, according to Sections 9(3B) and 9(3C), the Registration Committee must take precautionary measures when the insecticide is being introduced and registered for the first time in India. Such provisions are also applicable to biopesticides. However, unless there is serious biosafety issue is involved, biopesticides should be treated different from chemical pesticides, with due care to the ecological and public health effects of biopesticides.

Sections 9 (registration) and 13 (license granting) of the Insecticides Act, 1968 are somewhat inconsistent with each other. The registration is carried out at federal level, whereas the license is granted by state governments. After the registration is done by central government, the state government issues license to a particular biopesticide. Contrary to the practice, there is no mention in Sections 9 and 13 that license would be issued to insecticides (or biopesticides for that matter) only after the registration by central government.

Under Section 21 of the Act, inspectors are given powers to inspect and collect samples of pesticides. Their duties are also fixed under Section 22 of the Act. However, the training of these inspectors relates only to toxic chemicals; they lack the proper training and knowledge to handle biopesticides. This lack of training may have grave implications for the trade and free use of biopesticides.

CONCLUSION

An analysis of Indian law on pesticides reveals multiple challenges facing the manufacturers, importers, traders and users of biopesticides. Some of these challenges can be summarized as follows:

Existing Indian laws and regulations were conceived to regulate conventional chemical pesticides, but are currently being applied to biopesticides without accounting for the key differences between the two. At the time of registration of a new product, the manufacturer/trader/importer must generate data that are easily obtained for chemical products, but which may be difficult to obtain for biopesticides. Furthermore, there are questions as to the utility of some of this data when applied to biologicals. Under the old laws and rules, and organic non-toxic and ecologically-benign products such as biopesticides are required to pass the same tests as conventional chemicals.

Another major issue concerns the technical or administrative personnel who deal with the registration, testing, monitoring, surveillance, inspection and authorization of substances. Their level of knowledge and experience with biopesticides is limited, resulting in shortcomings concerning implementation and compliance with the regulations.

The Government of India has introduced a Pesticides Management Bill (now pending in parliament), which is intended to replace the existing Insecticides Act, 1968. However, this bill still fails to differentiate biopesticides from conventional chemical pesticides. The foregoing analysis of existing Indian legislation points to the need to create a separate and distinct legal framework for biopesticides. The regulatory options governing biopesticides should also be in line with novel microbial technologies. These changes would ultimately contribute to achieving the SDGs, and would support the flow of goods and services for organic agriculture and horticulture in India.

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