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ANALYSIS OF INDIAN AND CANADIAN LAWS REGULATING THE BIOPESTICIDES: A COMPARISON

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ABSTRACT

An excessive use of toxic plant protection chemicals has irreversibly damaged the soil biology of agroecosystems, resulting in a substantial decline of productivity. Biocontrol agents, especially microbial biopesticides, are seen as one of the key solutions to overcome toxicity and pest resistance issues. Biopesticides are defined as mass-produced agents manufactured from living microorganisms or natural products used for the control of pests. Laws to regulate biopesticides both in India and Canada need to be analysed from the perspectives of trade facilitation, ease of business, proliferation of green technologies and products, and the sustainability and revitalization of soil biology. Registration of new biopesticides for its manufacturing, trade, import, storage, transport, disposal and safety is discussed from the point of view of the legal barriers imposed on the production process and trade. Having compared laws of both countries, authors offer recommendations for legal reform.

Keywords: Biopesticides; Microbial Products; Agrarian Laws; Legal Analysis; Legal Reform

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1. INTRODUCTION

An excessive application of toxic plant protection chemicals has steadily degraded the soil biology of agroecosystems, causing irreversible toxicity. Over the last half century, agricultural systems have tended to shift to more sustainable ways of growing food without irreversibly damaging the soil's ability to support crops. Green microbial products, such as biopesticides, have the potential to reduce the use of toxic pesticides or insecticides and increase farmers' current agricultural productivity, while at the same time contributing to the soil's ability to produce more in the future. Biopesticides are defined as mass-produced agents manufactured from living microorganisms or natural products used for the control of pests.[1] The OECD guidance for microbial biopesticides[2] states that, "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". While plenty of literature exists on the microbiological and biotechnological aspects of biopesticide production, there has been no critical analysis of the laws and regulations governing the manufacture, trade, use and transport of biopesticides, especially in India.

The challenges for most countries pertain to inadequate legislation, inadequate capacity and weak implementation of policies related to biopesticides.[3] Recently, a number of countries have changed their legal frameworks and policies to minimize the use of chemical pesticides and promote the use of biopesticides; however, biopesticides are still mainly regulated by the system originally designed for managing chemical pesticides. As a result, market entry barriers hinder the full development of biopesticides and impose burdensome costs on the biopesticide industry.[4] Immature policy apparatus, limited resources and capabilities, and lack of trust between regulators and producers are some of the serious issues observed. Multiple challenges exist in India and Canada for manufacturers and importers of biopesticides, especially at the registration and import stages. At the time of registration of a new biopesticide, the manufacturer/trader/importer must generate data that, while easily attainable for chemical-based products, are not easy to obtain for biopesticides. The organic, non-toxic and ecologically benign biopesticides

[1] Organization for Economic Co-operation and Development, 'Report of Workshop on the Regulation of Biopesticides: Registration And Communication Issues.' (OECD 2009) <https://www.oecd.org/env/ehs/pesticides-biocides/ENV-JM-MONO(2009)19-ENG.pdf> accessed 30 April 2021.

[2] ibid.

[3] Aruna Urs, 'The Sorry Tale of Biopesticides' (*Business-standard.com*, 2015) <https://www.business-standard.com/article/punditry/the-sorry-tale-of-biopesticides-115092100014_1.html> accessed 30 April 2021.

[4] Suresh Kumar and Archana Singh, 'Biopesticides For Integrated Crop Management: Environmental and Regulatory Aspects' (2014) 05 Journal of Biofertilizers & Biopesticides.

are required to pass a series of tests that were originally designed for conventional chemical pesticides, both in India and Canada. Another important issue concerns the technical or administrative personnel who deal with the registration, testing, monitoring, surveillance, inspection, and authorization tasks. Their understanding, capacities, and orientation limited to toxic chemical products, and they have little or no experience with microbial products. This creates many difficulties and grey areas in the compliance and implementation of the regulations both in India and Canada.

This article analyses the legal frameworks regulating biopesticides in India and Canada, and its comparative characteristics in relation to statutory effectiveness.

2. CONTEXT AND METHODOLOGY

This article is derived from a previous study[5] conducted between 2017 and 2020 at the Faculté de droit, Université de Montréal in partnership with Earth Alive Clean Technologies, in order to understand the various legal provisions in Indian and Canadian laws regulating biopesticides and biofertilizers. It aims not only to identify the policy and legal gaps existing in the Indian and Canadian legal frameworks governing biopesticides, but also to suggest ways forward in order to avoid bottlenecks impeding the entry and free trade of green products that can contribute to the achievement of the sustainable development goals (SDGs). The present study consists of an analysis of the pertinent clauses and sections of laws regulating pesticides and biopesticides in India and Canada with references to European Union regulations. Research methods included dialectical, qualitative and comparative legal research,[6] as well as gap analysis. The premise of this research is the belief that unless the practical impact of the laws or rules is known, there is little chance of reforming the legal framework in India and Canada.

3. INDIA'S LAW ON PESTICIDES

Before discussing legal aspects of biopesticides, it is important to understand the scientific overview of biopesticides. There are three broad categories of biopesticides: (1) microbial biopesticides, (2) botanical biopesticides, and (3) semiochemicals. The scope of this article is restricted to microbial biopesticides and biocontrol agents. Microbial biopesticides are derived from fungi, bacteria, algae, viruses, nematodes and protozoa, and

[5] Study of Indian and Ukrainian Legal Frameworks Regulating Biofertilizers and Biocontrol Agents in Reference to Canadian Microbial Products

[6] Dialectical research or dialectical inquiry or dialectical investigation is a form of qualitative research which utilizes the method of dialectic, aiming to discover fact through examining and interrogating competing ideas, perspectives or arguments. Dialectical research may also be thought of as the opposite of empirical research, in that the researcher is working with arguments and ideas, rather than data (Bertell Ollman, *Dialectical Investigations* (Routledge 1993)).

other compounds produced directly from these microbes such as metabolites.[7] The names of some microbial biopesticides are shown in Appendix 1. More than 3,000 types of microbes that cause diseases in insects have been recorded. Amongst these microbial biopesticides, over 100 bacteria have been identified as insect pathogens.[8] In addition to bacteria, more than 1000 viruses that act as insect pathogens have been isolated. Various nuclear polyhedrosis viruses (NPVs) have been found infesting 525 insect species worldwide.[9] Over 800 species of entomopathogenic fungi and 1,000 species of protozoa pathogens have also been described and identified, along with two major groups of entomopathogenic nematodes – *Steinernema* (55 species) and *Heterorhabditis* (12 species).[10]

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 consistently and reliably characterize the quality of biopesticide products. 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.[11] 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 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.

3.1 Inappropriate Treatment to Biopesticides

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, 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 problem is the intent of

[7] Joop C. van Lenteren, 'The State of Commercial Augmentative Biological Control: Plenty of Natural Enemies, But A Frustrating Lack of Uptake' (2011) 57 BioControl.

[8] Muhammad Nawaz, Juma Ibrahim Mabubu and Hongxia Hua, 'Current Status and Advancement of Biopesticides: Microbial and Botanical Pesticides.' (2016) 4 Journal of Entomology and Zoology Studies.

[9] Opender Koul, 'Microbial Biopesticides: Opportunities and Challenges.' (2011) 6 CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources.

[10] ibid.

[11] David Chandler and others, 'The Development, Regulation and Use Of Biopesticides for Integrated Pest Management' (2011) 366 Philosophical Transactions of the Royal Society B: Biological Sciences.

the law. Because they were designed to address chemical pesticides, the fundamental principles underlying the *Act* and the *Rules* treat biologicals (products of biological origin) on par with chemicals. 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, via a few circulars from 1994, 1996, 1999, 2000, 2001, 2007, 2008, 2009 and 2011, a policy framework under the *Insecticides Rules, 1971* has been developed governing the manufacture, sale, storage, distribution and transportation of a range of microbial biopesticides (based on baculoviruses: NPV 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 pisciculture, and eucalyptus extract), and semiochemicals (insect pheromones). To correct the course, it is necessary that biologically-produced microbial, botanical and pheromonic biopesticides be treated separately through a dedicated law or policy. On the other hand, biofertilizers, which are similar in origin to microbial technology, 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.[12] 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, unfairly inflating the price. And while chemical pesticides may be cheaper, farmers and consumers are bound to pay a hefty price for the consumption of toxic chemicals residues.

3.2 The *Insecticides Act, 1968* – Scope of the Law

The *Insecticides Act, 1968* (the *Act*) is "an act to regulate the import manufacture, sale, transport, distribution and use of pesticides with a view to prevent risk to human beings or animals, and for matters connected herewith". It was brought into effect on the recommendation of the inquiry commission as a measure to check food poisoning. The 1968 Act was amended in 1972, 1977 and 2000. Section 3 of the Act deals with definitions, section 4 with the Central Insecticides Board, section 9 with registration of insecticides, section 16 with the Central Insecticides Laboratory, section 19 with insecticide analysis, and sections 20-22 with the inspectors. Provisions of this Act are in addition to and not in derogation of any other law for the time being in force. The other relevant enactments are: (1) Prevention of *Food*

[12] Hasrat Arjjumend, Konstantia Koutouki and Anatolii Getman, 'Ukrainian Legislation For Safeguarding The Agroecosystems And Environmental Health: The Challenges Ahead', *Kharkiv International Legal Forum: Law and Problems of Sustainable Development in Globalized World*, (Pravo Publishing House 2017) <http://dspace.nlu.edu.ua/bitstream/123456789/15286/1/Arjjumend_Koiutouki_Getman_3-17.pdf.> accessed 30 April 2021.

Adulteration Act, 1954, (2) *Drugs (Control) Act, 1950*, (3) *Drugs and Cosmetics Act, 1940*, (4) *Dangerous Drugs Act, 1930*, (5) *Poisons Act, 1919*, and the (6) *Destructive Insects and Pests Act, 1914*. The *Insecticides Act, 1968* has registered 739 chemical pesticides in India and banned/denotified a number of toxic pesticides. Noticeably, 970 companies have registered biopesticides as of 9 April 2021.[13] Through its Gazette Notification no. 147 dated 26 March 1999, the Government of India included the following categories of biopesticides:

Antagonistic Fungi and Bacteria
(a) Bacillus subtilis
(b) Gliocladium species
(c) Pseudomonas species
(d) Trichoderma species
Entomogenous Fungi
(a) Beauveria bassiana
(b) Metarrhizium anisopliae
(c) Nomuraea rileyi
(d) Verticilium lecanii
Grannulosis Viruses (GV)
Nuclear Polyhedrosis Viruses (NPV)

Further, the *Bacillus* species was also added in the schedule with the variants:

Bacillus thuringiensis var. *israelensis*,
Bacillus thuringiensis var. *kurstaki*,
Bacillus thuringiensis var. *galleriae*, and
Bacillus sphaericus.

Recently, the following 25 genera, species, or strains have also been added into the Schedule:

1. *Nomurea rileyi*
2. *Hirsutella* spp.
3. *Verticillium chlamydosporium*
4. *Streptomyces griseoviridis*
5. *Streptomyces lydicus*
6. *Ampelomyces quisqualis*
7. *Candida oleophila*
8. *Fusarium oxysporum* (non-pathogenic)
9. *Burkholderia cepacia*
10. *Coniotyrium minitans*
11. *Agrobactarium radiobacter* strain 84
12. *Agrobactarium tumefaciens*
13. *Pythium oligandrum*
14. *Erwinia amylovora* (hairpin protein)

[13] 'Bio-Pesticide Registrant | Directorate of Plant Protection, Quarantine & Storage | GOI' (*Ppqs.gov.in*, 2021) <http://ppqs.gov.in/divisions/cib-rc/bio-pesticide-registrant> accessed 30 April 2021.

15. *Phlebia gigantean*
16. *Paecilomyces lilacinus*
17. *Penicilliuim islanidicum* (for groundnut)
18. *Alcaligenes* spp.
19. *Chaetomium globosum*
20. *Aspergillus niger* strain AN27
21. VAM (fungus)
22. *Myrothecium verrucaria*
23. *Photorhabdus luminescences* akhurustii strain K-1
24. *Serratia marcescens* GPS 5
25. *Piriformospora indica*

In addition to above microbial biopesticides, the following 'plant origin biopesticides' are also the part of Schedule:

1. Pyrethrins (Pyrethrum)
2. Neem products
3. Karanjin
4. Extracts of *Cymbopogan* spp.
5. Oxymatrine
6. Reduced Azadirachtin(s)
7. Triptericium of wilfordii Hook GTW (Plant extract)
8. Bitterbarkomycin
9. Squamocin
10. Eucalyptus leaf extract

3.3 Central Insecticides Board and Registration Committee (CIBRC)

Constituted under sections 4 and 5, the Central Insecticides Board and Registration Committee (CIBRC) regulates pesticides in India along with 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.[14] The functions of CIBRC are twofold, as specified in the *Act*: (a) advising on the risk to human beings or animals involved in the use of insecticides and the safety measures to prevent such risks (section 2(2a)); and (b) advising on the manufacture, sale, storage, transport and distribution of insecticides with a view to ensure safety to human beings or animals (section 2(2b)). These functions of CIB are further expanded under rule 3 of the *Insecticide Rules, 1971*, and include:

(a) advising the Central Government on the manufacture of insecticides under the *Industries (Development and Regulation) Act, 1951*;
(b) specifying the uses of each class of insecticides based on their toxicity and whether or not they are suitable for aerial application;
(c) advising tolerance limits for insecticide residues and establishing minimum intervals between the application of insecticides and harvest in respect of various commodities;

[14] Rohid Bhide, 'Regulatory Perspective of Agrochemicals In India' (*Grainews*, 2013) <http://news.agropages.com/News/NewsDetail---10045.htm> accessed 30 April 2021.

(d) specifying the shelf-life of insecticides;
(e) suggesting colorization, including colouring matter which may be mixed with concentrates of insecticides, particularly those of highly toxic nature;
(f) carrying out such other functions as are supplemental, incidental or consequential to any of the functions conferred by the *Act* or these rules.

The Department of Biotechnology within the Indian Ministry of Science and Technology is the technical agency that evaluates effectiveness, quality and safety issues during the approval process. 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; that the microorganism does not produce a known genotoxin; and that all additives in the microbial manufacturing product and in the end-use formulations are of low toxicity and have little potential to harm human health or the environment.

Section 5a(i) of the *Insecticides Act, 1968* speaks about the constitution of the 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. The Registration Committee, under rule 4 of the *Insecticide Rules, 1971*, has been given the following tasks: (a) specify the precautions to be taken against poisoning through the use or handling of insecticides; (b) carry out such other incidental or consequential matters necessary for carrying out the functions assigned to it under the *Act* or *Rules*. 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 the economic viability of biocontrol agents (affecting manufacture, trade, supply, etc.).

3.4 Registration Process

Applications for registering the manufacture and import of a new pesticide or biopesticide can be made in prescribed Form I (rule 6) to the Secretary, Registration Committee, Directorate of Plant Protection, Quarantine & Storage, Ministry of Agriculture, NH-IV, Faridabad – 121001 Haryana. The application process requires a tremendous amount of data. Form I does not contain elaborate guidelines specifying the information that is required at the time of application submission. Several relevant parameters on which data are required for registration of biopesticides are mentioned in Appendix 2. The requisite tests and analysis of each

biopesticide to be registered are relatively exhaustive and specific. In addition, recently, highly technical tests such as DNA barcoding and fingerprinting are made mandatory for new registrations of microbial biopesticides.[15] Under section 16 of the *Act*, the Central Insecticide Laboratories are notified from time to time. Under rule 5 of the *Insecticide Rules, 1971*, the functions of the laboratory are described.

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 short shelf life, the sampled strain does not fit the standards set for that particular category of the biopesticide. Therefore, the length of time required for the registration of biopesticide must be shortened in accordance with the shelf life of the various biopesticide strains.

Section 9(3) of the *Insecticides Act, 1968* also requires the Registration Committee to investigate claimed safety precautions for humans 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 a serious biosafety issue involved, biopesticides should be treated different from chemical pesticides, with due care to the ecological and public health effects of biopesticides.

As per the provisions of section 9 of the *Act*, applications for licenses to manufacture registered pesticides (also under Rule 9) and to obtain licenses for sale, etc., of registered pesticides (Rule 12) are lodged. Sections 9 (application) and section 13 (license granting) of the *Insecticides Act, 1968* are somewhat inconsistent with each other. The registration of biopesticides is carried out at a federal level, whereas the license is granted by state governments after the registration is done by the central government, the state government issues a license for a particular biopesticide. Contrary to actual practice, there is no mention in Sections 9 and 13 that licenses would be issued for insecticides (or biopesticides for that matter) only after their registration by the central government.

[15] 'India CIBRC Issued New Regulation Decisions on Biopesticides' (*Grainews*, 2015) <http://news.agropages.com/News/NewsDetail---15797-e.htm> accessed 30 April 2021.

3.5 Packing and Labelling

Under rules 16 to 20 of the *Insecticides Rules, 1971*, the importance, manners, procedures and prohibitive actions are described for packing, packaging and labelling of pesticides or biopesticides. Without the prescribed proper packing and labelling, no pesticide or biopesticide is allowed to be exhibited or sold. According to rule 17(1), "every package containing the insecticide shall be of a type approved by the Registration Committee." Rule 17(2) makes it more explicit by stating, "before putting any insecticide into the primary package, every batch thereof shall be analyzed as per the relevant specifications of the manufacture thereof, in accordance with the approved methods of analysis and the result of such an analysis shall be recorded in the register maintained for the purpose…". Each package needs to contain a leaflet having necessary information about the pesticide or biopesticide. Important disclosure is to be made about the particulars regarding chemicals harmful to human beings, animals and wildlife. Warning and cautionary statements must be included regarding the symptoms of poisoning, suitable and adequate safety measures and emergency first aid treatment, and decontamination or safe disposal of used containers. Under Rule 19, the procedure of labelling is elaborately explained. Toxicity caused by the pesticide in case of leakage, spillage, usage or accidental contamination is addressed in all these instructions. However, there is no word mentioned about biopesticides in any section of the *Act* or any rule, despite the fact that various notifications and amendments are adopted both in the *Act* as well as *Rules*.

3.6 Inspection, Sampling and Analysis of Biopesticides

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. In the *Insecticides Act, 1968*, there is no specific instruction given to inspectors on how to sample or handle the biopesticides. Unlike the Fertilizer Control Order, the *Insecticides Act, 1968* has not prescribed any sampling method. Under section 21(1)(e) of the *Act* and Rule 24(2) of the *Insecticides Rules, 1971*, the procedure prescribed for the analysis of insecticides (or for biopesticides) is the same as that prescribed by the Indian Standards Institution[16] (ISI). Analysis of samples is conducted only by the Central Insecticides Laboratory constituted under the provisions of section 16 of the *Act*. In accordance with the Rule 21 of the *Insecticide Rules, 1971*, an analyst should be qualified in Agriculture, Science or Chemistry apart from training in analysing insecticides.

[16] *Deputy Director of Agriculture vs M/s Sandoz Ltd* [1991] Andhra High Court, CriLJ 1830 (Andhra High Court).

3.7 Disposal of Pesticides

Rule 44 of the *Insecticide Rules, 1971* emphasizes environmental and safety aspects. The manufacturers, formulators and operators must dispose of packages or surplus materials and employ safe washing methods in order to avoid environmental or water pollution. The packages must also be broken and buried away from human habitation.

4. CANADA REGULATION ON BIOPESTICIDES AND ITS COMPARISON WITH THE INDIAN FRAMEWORK

The Indian legal framework dealing with pesticides (and biopesticides) can be compared with Canadian law on pest control products, i.e., pesticides. By incorporating the word "organisms," the Canadian approach broadens the scope of the law on pesticides to include biological products. By comparison, India's law on pesticides has accommodated microbial biopesticides and plant-origin biopesticides through amendments and notifications.

4.1 Background of Canadian Regulation

In Canada, the *Constitution Act, 1867* addresses legislative control over the availability, use and disposal of pesticides at federal and provincial levels. Initially, pesticide control came under provincial control between the 1920s and 1930s. Currently, there are two prominent laws regulating pesticides and biopesticides: the *Pest Control Products Act*, from1939 and the *Foods and Drugs Act* enacted in 1970. The *Pest Control Products Act* was consolidated in 2002 and enacted as the *Pest Control Products Act, 2002* (last amended 12 July 2019). This law is "an Act to protect human health and safety and the environment by regulating products used for the control of pests". Compared to the Canadian laws, India's *Insecticides Act, 1968* has exhibited scarce references to environmental protection and public health and safety.

4.2 Scope of the Laws

The *Pest Control Products Act, 2002* of Canada describes pest control products under section 2 as: "*a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects*". The word 'an organism' here implies microorganisms like fungi, bacteria or viruses that are used to produce biopesticides (microbial products) through using biotechnology. The scope of the Canadian law is very broad in this sense; however, it is only the Indian law (i.e., *Insecticides Act, 1968*) that provides a comprehensive list of what is included and subject to registration under the law. Nearly 35 items of microbial biopesticides and 10 plant-origin biopesticides are included under the Indian law.

4.3 Registration of Pesticides or Biopesticides

Section 7 of the *Pest Control Products Act, 2002* provides for the registration of pest control products. If required, authorities may conduct evaluations of the product for health or environmental risks as per the powers under section 7(3a). Further, a scientific approach will be applied while evaluating the health and environmental risks (section 7(7b)). Certain technical aspects under evaluation include aggregate exposure to the pest control product, namely, dietary exposure and exposure from other non-occupational sources, including drinking water and use in and around homes and schools, and cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity. Additional data required include different sensitivities to pest control products of major identifiable subgroups, e.g., pregnant women, infants, children, women and seniors. Section 6(2) clarifies that no person shall manufacture, import, export or distribute a registered pest control product under section 53.3 or 54 of the *Pest Control Products Act, 2002*, unless it conforms to the conditions of registration respecting its composition and the person complies with the other conditions of registration. Accordingly, Canadian legislation is particularly concerned about human and environmental safety. Microbial biopesticides are not given any distinct treatment given their biological origin or as green products. In India, too, the registration process of pesticides and biopesticides is very exhaustive and intensive. For microbial biopesticides, complex analyses like DNA barcoding and fingerprinting are made mandatory.

4.4 Packaging and Labelling

Norms for the packing, packaging and labelling are equally stringent in Canadian and Indian legislation. These norms have equal force as they do not allow products to be sold, transferred, transported, distributed or stored without compliance of the given instructions of packing and labelling. Section 6(3) of Canada's *Pest Control Products Act, 2002* instructs that under section 53, 53.3 or 54, no person shall store, import, export or distribute a pest control product that is not packaged and labelled in accordance with the regulations and, if it is registered, the conditions of registration. Biopesticides are treated in the same manner as other pesticides.

4.5 Inspection, Analysis and Disposal of Biopesticides

Like India's *Insecticide Act, 1968* and *Rules 1971*, sections 45 and 46 of the *Pest Control Products Act, 2002* in Canada has laid down an appointment procedure for inspectors. Section 48 deals with the powers of inspectors, whereas subsequent sections (49 to 57) address procedures of inspecting, sampling, testing and seizing the pest control products. Section 58 talks about the disposal of pest control products. In continuation, section 59 empowers the inspectors to advise owners or possessors of the pest control products to dispose appropriately of the material if it is discovered to pose serious risks to human health or the environment. Under section 59(3), an

inspector can issue a notice in this regard to the holder of a toxic or hazardous pest control product for adequate disposal. In case of offence, an inspector can, under section 59(4), punish in the following manner:

(a) on summary conviction, to a fine of not more than $200,000 or to imprisonment for a term of not more than six months, or to both; or

(b) on conviction on indictment, to a fine of not more than $500,000 or to imprisonment for a term of not more than three years, or to both.

Indian legislation does not give strict advice to the holders of pesticides or biopesticides for their disposal, although public and environmental health and safety are emphasized.

5. CONCLUSION AND RECOMMENDATIONS

Around 67,000 different crop pest species – including plant pathogens, weeds, invertebrates and some vertebrate species – are responsible for an estimated 40% reduction in the world's crop yield.[17] One way to increase food availability is to improve the management of pests. Yet, the unsustainable application of chemical fertilizers and plant protection chemicals has caused a steady decline in soil and crop productivity the world over. Agricultural practices must evolve to sustainably meet growing local and global demand for food without irreversibly damaging the world's agroecosystems and natural resources (especially soil). Critically, this must occur while also maintaining food security, even in the context of climatic change. 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) on poverty and hunger, nutrition and health, education, economic and social growth, peace and security, and environmental preservation.

5.1 Indian Law Regulating the Biopesticides

All three broad categories of biopesticides – microbial biopesticides, botanical biopesticides, and semiochemicals – are adopted by India's *Insecticides Act, 1968* through amendments and notifications. Through its Gazette Notification no. 147 dated 26 March 1999, the Government of India included the following categories of biopesticides: Antagonistic Fungi and Bacteria (4 species), Entomogenous Fungi (4 species), Grannulosis Viruses (GV), Nuclear Polyhedrosis Viruses (NPV), 3 variants of *Bacillus thuringiensis*, and *Bacillus sphaericus.* Later, 25 additional genus, species, or strains were added into the Schedule. In addition to the above microbial biopesticides, 10 "plant origin biopesticides" also became the part of Schedule.

[17] E.C. Oerke and others, *Crop Production and Crop Protection* (Elsevier Science 2014).

The *Insecticides Act, 1968* and the *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 or animals and for all connected matters. The Central Insecticides Board and Registration Committee (CIBRC) is responsible for advising central and state governments on technical issues related to manufacture, use and safety issues of pesticides. The Department of Biotechnology of the Ministry of Science & Technology is the technical agency that evaluates effectiveness, quality and safety issues during the approval process. Apart from these regulations, the organic food producers in India are supposed to comply with the National Program for Organic Production (NPOP) standards with mandatory organic certification by authorized certification agencies. Before the authorization and registration of a biopesticide, it is ensured that 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; that the microorganism does not produce a known genotoxin; that all additives in the microbial manufacturing product and in end-use formulations are of low toxicity, and that they pose little threat to human health or the environmental.

An analysis of Indian law on pesticides reveals multiple challenges facing the manufacturers, importers, traders and users of biopesticides. 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 biopesticides. Under the current laws and rules, 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.

One of the major obstacles in promoting biopesticides as an alternative to chemical pesticides is the lack of appropriate recognition of biopesticides, reflecting the weakness of the underlying policy framework in India.[18] 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 biopesticides on farmers' fields, and farmers' confidence in the quality and performance of

[18] Suresh Kumar and Archana Singh, 'Biopesticides: Present Status and the Future Prospects' (2015) 06 Journal of Biofertilizers & Biopesticides.

the products, continue to be debated in India.[19] The Government of India introduced a Pesticides Management Bill (pending in parliament for many years), which is intended to replace the existing *Insecticides Act, 1968*. However, this bill still fails to differentiate biopesticides from conventional chemical pesticides. The analysis of 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.

5.2 Recommendation for India's Law on Biopesticides

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, 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 problem is the intent of the law. First, regulations must be formulated to ensure human and environmental safety and to consistently and reliably characterize the quality of biopesticide products. 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.[20] 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 biopesticides.

Because India's regulations were designed to address chemical pesticides, the fundamental principles underlying the *Act* and the *Rules* treat biologicals on par with chemicals. 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. To correct the course, biologically-produced microbial, botanical and pheromonic biopesticides must be treated differently. In the absence of a separate law on biopesticides, the *Insecticides Act, 1968* and the *Insecticide Rules, 1971* require appropriate amendments. Indeed, the failure to introduce such amendments has caused the trade in biopesticides to suffer. Farmers and consumers are bound to pay hefty prices for chemical pesticides – and end up consuming chemical residues.

[19] Rohid Bhide, 'Regulatory Perspective of Agrochemicals in India' (*Grainews*, 2013) <http://news.agropages.com/News/NewsDetail---10045.htm> accessed 30 April 2021.
[20] Chandler and others (n 13)

5.3 Canadian Law Regulating Biopesticides

The *Pest Control Products Act, 2002* is the Canadian law regulating biopesticides in the country. This law is "an Act to protect human health and safety and the environment by regulating products used for the control of pests". The law is progressive in the context of protecting the environment and human health. Additionally, section 2 of the *Act* includes in the definition the word "an organism," which implies microorganisms like fungi, bacteria or viruses that are used to produce biopesticides through using biotechnology. Before granting registrations to the companies, government authorities conduct evaluations of the proposed product. Notably, human health concerns, environmental risks, and threats to animal health are the central aspects of the pre-registration scientific assessments. Thus, the Canadian legislation is particularly concerned about human and environmental safety. Yet, microbial biopesticides are not given any distinct treatment due to their biological origin and non-toxic properties. Given the potential negative effects of pesticides on human and environmental health and safety, the Canadian law contains very strict penal provisions for non-compliance of the norms set for the disposal of toxic or hazardous pest control products. This is in contrast to the Indian legislation which does not give strict advice to the holders of pesticides or biopesticides for its disposal.

5.4 Recommendation for Canadian Law on Biopesticides

The Canadian law provides for strict regulation of pesticides and biopesticides to ensure environmental and human safety. In addition, the inclusion of microbial products right in the definition gives adequate space for biopesticides in the regulation process. However, like India, a separate regulation dealing with biopesticides and biocontrol agents should be promulgated in order to differentiate biological products from toxic chemical pesticides and pest control products.

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APPENDIX.1

List of some important microbial biopesticides[21]

Common name	*Target insects*
Entomopathogenic viruses	
Corn earworm NPV (HezeSNPV)	*Helicoverpa zea*: corn earworm, tomato fruitworm, tobacco budworm, *Helioth virescens*
Cotton bollworm NPV (HearNPV)	*Helicoverpa armigera*, cotton bollworm, pod borer
Diamond back moth GV	*Plutella xylostella*
Velvetbean caterpillar, NPV (AngeMNPV)	*Anticarsia gemmatal*is
Alfalfa looper NPV (AucaMNPV)	Noctuidae
Tea moth (Buzu NPV)	*Buzura suppressaria*
Entomopathogenic bacteria	
Bacillus thuringiensis subspecies kurstakia	Lepidoptera
B. thuringiensis sub-species aizawaia	Lepidoptera
B. thuringiensis sub-species japonensis	Coleoptera: Scarabaeidae
Paenibacillus popilliae	Coleoptera: Scarabaeidae, *Popillia japonica*
Entomopathogenic fungi	
Aschersonia aleyrodis	Hemiptera
Beauveria brongniartii	Coleoptera (Scarabaeidae)
Conidiobolus thromboides Acari	Hemiptera, Thysanoptera
Lecanicillium longisporum	Hemiptera
Metarhizium anisopliae sensu lato	Coleoptera, Diptera, Hemiptera, Isoptera
Nomuraea rileyi	Lepidoptera

APPENDIX.2

Technical data required for registering a biopesticide in India

- Strain specifications
  - Genus and species
  - Rhizosphere competence
  - Biological control capability
  - Growth promotion capability

[21] Hasrat Arjjumend and Konstantia Koutouki, 'Science of Biopesticides and Critical Analysis of Indian Legal Frameworks Regulating Biocontrol Agents' (2018) 11 International Journal of Agriculture, Environment and Biotechnology <http://ndpublisher.in/countpdfdownload.php?id=3051&pdf=IJAEBv11n3t.pdf> accessed 30 April 2021.

- Wide range of growth parameters like pH and temperature
- CFU count
  - The data required for claiming 1 year shelf-life of the product is for 15 months for talc-based formulation, i.e., the microbe should remain viable for 15 months with a colony forming units (CFU) count not less than 2 x 10^6 spores/ml or g on selective media (SM).
  - Pathogenic contaminants such as *Salmonella, Shigella* and *Vibrio* should not be present. Other microbial contaminants not to exceed 1 x 10^4 counts per ml or g.
- Target fungi
- Moisture content
  - Maximum moisture content of the product should not exceed more than 8 per cent for dry formulation of fungi and 12 per cent for bacteria.
- Chemistry
  - Systematic name: Genus and species
  - Common name, if any
  - Natural occurrence: morphological description
  - Manufacturing process: solid or liquid state fermentation
  - Qualitative analysis
  - CFU on selective medium
  - Absence of Gram$^-$ bacterial contaminants (*Salmonella, Shigella* and *Vibrio*)
  - Moisture content
  - Shelf-life claim: two different locations along with meteorological data
- Technical bulletin/Product profile

Bioefficiency

  - Lab bioefficacy test: The product should be tested against target pathogen/pest at one of the laboratories of ICAR/SAUs/CSIR/ICMR system
  - Field bioefficacy test: The intended product should be tested for field bioefficacy under Indian conditions.
  - Field bioefficacy guidelines have been recently revised/enhanced w.e.f. 01.01.2011

Field Bioefficiency

  - 9 (3B): Provisional Registration
  - One crop: 2 seasons (rabi and kharif)/year, 2 agro-climatic conditions (4 bioefficacy trial reports)
  - 9 (3): Permanent Registration
  - One crop: 2 seasons (rabi and kharif)/year, 3 agro-climatic conditions (6 bioefficacy trial reports)
  - Safety data on non-target organisms

Toxicity

- Toxicological studies may be conducted by recognized institutes viz. IITR Lucknow, IIBAT Chennai, JR Foundation Vapi, INTOX, Pune
  a) (For formulated products to be directly manufactured)
     Single dose oral- Rat (21 days) (Toxicity/Infectivity/Pathogenicity)
     Single dose oral- Mouse (21 days) (Toxicity/Infectivity/Pathogenicity)
     Single dose Pulmonary- Rat (14 days) (Toxicity/Infectivity/Pathogenicity)
     Single dose Dermal- Rabbit (21 days) (Toxicity/Infectivity/Pathogenicity)
     Single dose Dermal- Intraperitoneal (21 days) (Toxicity/Infectivity/Pathogenicity)
     Primary skin irritation
     Eye irritation
  b) Human Safety Records
- Environmental Toxicological Studies (For formulation only) On Non-Target Vertebrates
  - Toxicity to chicken, pigeon, freshwater fish
- Dossier preparation for 9(3b) & 9(3) registration

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Authors' Declarations and Essential Ethical Compliances

Authors' Contributions (in accordance with ICMJE criteria for authorship)

Contribution	Author 1	Author 2
Conceived and designed the research or analysis	Yes	Yes
Collected the data	Yes	No
Contributed to data analysis & interpretation	Yes	Yes
Wrote the article/paper	Yes	Yes
Critical revision of the article/paper	No	Yes
Editing of the article/paper	Yes	No
Supervision	No	Yes
Project Administration	No	Yes
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Overall Contribution Proportion (%)	60	40

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