

Review Article

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Regulatory Norms and Quality Control of Bio-Pesticides in India

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ABSTRACT

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Biopesticides have attracted attention in pest management in recent decades, and have long been promoted as prospective alternatives to synthetic pesticides. Biopesticides are natural and good alternative sources of synthetic pesticides. In India, all pesticides, including biopesticides, are regulated under the Insecticides Act, 1968, and the rules framed under it. The act regulates the import, manufacture, transport, sale, distribution, and use of pesticides with a view to prevent any risk to human beings and animals. Unlike synthetic pesticides, which can be produced in desired purity and yield, it is often difficult to produce biopesticides with constituent purity due to a wide variation in the active and associated ingredients. Due to lack of innovative advancements in research and policies in India, biopesticides production and consumption is limited when compared to synthetic chemical pesticides. This article suggests some regulatory norms and quality control parameters of biopesticides production in India.

Introduction

Pesticide use has certainly contributed towards improving agricultural production, in terms of both yield and quality, thus increasing agricultural income, particularly in developed countries.

However, careless use of pesticides without adhering to the safety norms and recommended practices has posed serious health risks to humans, other living organisms, and the environment, from on-farm workers' exposure and release of chemicals into the air and water, to commodities containing pesticide residues (Carvalho, 2017 and Damalas, 2009).

Currently, in India 287 pesticides are registered under section 9(3) of the Insecticide Act, 1968 as on 26/02/2018 for use and technical grade pesticides are manufactured indigenously. However, bio- pesticides may represent about 4.2% of the overall pesticides market in India (Das, 2014). Globally, biopesticides production is 4.5% and in USA it is 6%, whereas in India, it accounts only 3% of the total chemical pesticides production. Presently, only 12 types of biopesticides including neem based and microbial based formulations are registered under the Insecticide Act, 1968 in India. Therefore, there has been a growing demand for food safety and quality in recent decades, as reflected in the tight safety regulations on

imports of products and strict regulations on the amount of pesticide residues on commodities (Isman, 2015). Moreover, increasingly high standards regarding product quality are continuously being set. Public awareness about the adverse effects of pesticides on the safety of foods and on the environment has increased in recent years, and the search for alternatives to widely used chemical pesticides, including biopesticides, has become a priority (Palaez and Mizukawa, 2017).

Regulation of Biopesticides

Pesticides play an important role in Indian agriculture to meet increasing demands for food and fibre. India is the 12th largest producer of chemical pesticides in the world (EPA, 2017). Of the total pesticides produced, the utilization of synthetic pesticides in India is about 50% on cotton crop alone followed by 17% on rice (Gahukar, 1997). Presently, the average per hectare consumption of pesticides in India is about 280 g/ha and consumption of pesticides is increasing at the rate of 2 to 5% per year. It is noteworthy that the consumption of chemical pesticides in India is very low (381 grams per hectare) when compared to the global consumption (500 grams per hectare) at present (Vendan, 2016).

Bio-pesticides are potential alternatives to synthetic chemical pesticides. It was known that, biopesticides are living natural enemy organisms and/or their products including plant and microbial products and/or their byproducts and they could reduce pest populations (Kumar and Singh, 2015). In the present decade, biopesticides are widely acceptable and demanded for sustainable agriculture and for production of safer foods. It was significantly considered that, bio-pesticides are eco-friendly, target-specific, easily biodegradable and safer alternatives (Arora *et al.*, 2009).

In general, the organisms selected for pest control are specifically active against the target pest. Therefore, the risk of affecting non-target organisms, including humans, is presumed to be relatively low. However, it is necessary to carry out some standardized safety tests, supporting the presumption and proof of efficacy, before allowing large scale use of biopesticides. Accordingly, guidelines have been laid down by the Food and Agriculture Organization of The United Nations; various countries have also framed their own guidelines for registration of biopesticides (Kulshrestha, 2004).

Biopesticides have been registered under the guidelines of the Insecticides Act, 1968, which was approved by the pesticide Registration Committee in India given in Table 1. Several stakeholders, including scientists, regulators, marketers, and end-users, are involved in the development and commercialization chain of pest control products. Some participants in this chain are often involved from the earliest stages of the development process, but there are many issues still to be resolved; the marketers may often disagree with the regulators and scientists, such that end-users are often puzzled by perceived weaknesses in the final product (Damalas and Koutroubas, 2018).

Quality control of Biopesticides

Unlike synthetic pesticides, which can be produced in desired purity and yield, it is often difficult to produce botanical pesticides with constituent purity due to a wide variation in the active and associated ingredients content of the plants/ parts in different agro-climatic zones. This leads to variation in the physico-chemical, chemical, phyto-compatibility, toxicological and other related parameters of the products. The contamination of botanicals with various physical, chemical or microbial contaminants is another issue.

Table.1 Registered biopesticides based on bacteria, fungi, and viruses

Antagonistic fungi and Bacteria	
<i>Bacillus thuringiensis/ Bacillus subtilis</i>	
i.	<i>Bt var. israelensis</i> 164, serotype H-14 WP Formulation
ii.	<i>Bt var. kurstaki</i> strain A-97, Serotype H3a, 35 WP
iii.	<i>Bt var. israelensis</i> Serotype H-14, Strain VCRC B-17, Slow release granules
iv.	<i>Bt var. israelensis</i> Serotype H-14, Strain VCRC B-17 WP formulation
v.	<i>Bt var. israelensis</i> (WS)
vi.	<i>Bt var. israelensis</i> Serotype H-14 12 (AS)
<i>Trichoderma spp.</i>	
i.	<i>Trichoderma viride</i> WP
ii.	<i>Trichoderma viride</i> 1% WP
iii.	<i>Trichoderma viride</i> 0.50% WS
iv.	<i>Trichoderma herzianum</i> 0.50% WS
v.	<i>Trichoderma</i> 1.15% WP
<i>Pseudomonas spp.</i>	
i.	<i>Pseudomonas fluorescens</i> 1.25% WP
Entomogenous fungi	
i.	<i>Beauveria bassiana</i> (WP)
Granulosis viruses	
i.	NPV of <i>Helicoverpa armigera</i> (AS)
ii.	NPV of <i>Helicoverpa armigera</i> 0.43% (AS)
iii.	NPV of <i>Spodoptera litura</i> 0.50% (AS)

AS- Aqueous suspension; NPV- Nuclear polyhedrosis virus; WP- Wettable powder; WS- Water suspension
 Source: Directorate of Plant Protection, Quarantine, and Storage, Govt. of India, Faridabad

Table.2 Annual Availability of Biopesticides in India

Biopesticides	Quality/ Annum (Approx)
Bt	50,000 kg
NPV (Liquid)	500,000 LE
Beauveria	Meager
Neem 300 ppm	1,000,000 L
Neem 1500 ppm	250,000 L
Pheromone traps	500,000 no's
Lures	2 million
Trichogramma	10 lakh cards
Trichoderma	Over 500 T

Source: Kalra and Khanuja, 2007.

A lack of proper standards and analytical procedures, poor shelf life of the accepted standards, etc. are the serious impediments in quality control of botanicals (Isman, 2006 and

Parmar and Walia, 2001). Quality control needs to be ensured at all levels of mass production of natural enemies, viz. host/prey insects, natural enemy and plants or their

products. Maintaining a high quality natural enemy of nucleus culture is necessary as these are subjected to abiotic stresses. Quality control is needed in all the sectors, i.e. rearing, culturing, preserving, storage methods, containers, transportation and releasing techniques. Recently, quality control standards and data requirements for registration have been finalized by the Government of India for various biopesticides. The registration data must include its composition and description, biological properties and quality control standards at different stages, specificity of containers/packaging, delivery system, label information for market products, tolerance limits, residues, safety to non-target organisms, taxonomic identification, detail production technology, efficacy and biological impact, contamination, and shelf-life under storage and regular use (Dubey *et al.*, 2003).

Biopesticides in India

In India, the annual growth rate of biopesticides is estimated to be 2.5 per cent. The production and availability of microbial in India is low due to several limitations both at the industry and policy levels coupled with low adoption by farmer community.

The niche market for biopesticides, botanicals is only 12 per cent worldwide and less than 1 per cent in India. For that the Insecticide Act of 1968 has been amended accordingly to simplify the process of registration to allow speedier development and production of biopesticides. The National Farmer Policy 2007 has strongly recommended the promotion of biopesticides for increasing agricultural production, sustaining the health of farmers and environment (Shahnawaz *et al.*, 2004). The annual availability of biopesticides in India is given in Table 2 (Kalra and Khanuja, 2007).

Future prospects

Biopesticides have long been attracting global attention as a safer strategy than chemical pest control, with potentially less risk to humans and the environment. To this end, co-operation between the public and private sectors is required to facilitate the development, manufacturing, and sale of this environmentally friendly alternative. In this context, discovery of new substances and research on formulation and delivery would boost commercialization and use of biopesticides (Pavela, 2014). Additional research on integrating biological agents into common production systems is necessary. Moreover, regulations that promote registration of low-risk compounds with provision of incentives could also facilitate commercialization and availability of biopesticides in the market. While new substances could serve as a promising option for use in pest control, more field research is required to assess the efficacy on specific pest problems in various cropping systems. Microencapsulation based on nanotechnology could improve the residual action of biopesticides, and this could increase their field use (Damalas and Koutroubas, 2018).

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