POLICY PAPER

62

Biopesticides – Quality Assurance

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CONVENER : Dr A.N. Mukhopadhyay, Former Vice-Chancellor, Assam Agricultural University, Jorhat.

CO-CONVENER : Dr. C.S. Nautiyal, Director, CSIR-NBRI, Lucknow.

EDITORS : Dr C. Devakumar
: Dr P.K. Chhonkar

REVIEWERS : Dr Opender Koul, Dr B.S. Parmar, Dr A.C. Gaur and Dr N. Ramakrishnan

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NASC, Dev Prakash Shastry Marg, New Delhi - 110 012
Tel: (011) 25846051-52; Fax: (011) 25846054
Email: naas@vsnl.com; Web site: http://www.naasindia.org

Preface

Crop protection has immensely contributed to the success of Green Revolution and sustained production of food, fibre, fodder and feed. Due to intensification of agriculture, loss of biodiversity and reliance on monocropping, etc. biotic stresses due to pests and pathogens have increased. Last four decades of chemicalisation in agriculture, helped managing many pests and diseases but their application led to several problems like pesticide residues in food stuff, environmental pollution, imbalance of ecological equilibrium, and resurgence of minor pests and pathogens. Management of pests will continue to play a pivotal role in sustaining production and productivity in Indian agriculture.

The overwhelming advantages of bio-pesticides are their high selectivity to target pests and safety to non-target and beneficial organisms. In the sustainable intensification of agriculture through green economy, the bio-pesticides have an immense role. They are amenable to bio-intensive pest management and ideally suited for organic niche products including export-oriented commodities. They can also be tailored to IPM programmes for increased efficacy, higher yield and lower chemical load. These are also effective as pesticide resistance management tools in order to prolong the life span of precious green chemical pesticides. The biopesticide development must also be targeted for integrated cropping systems. They are renewable, sustainable, offer an improved impact profile, and reduce pesticide residues.

It is now widely recognised that biopesticides can be successfully exploited in modern agriculture especially within the framework of integrated pest management system without affecting our precious ecosystem. This technology is consistent with the goal of sustainable and conservation agriculture.

Quality management in biopesticides is a major issue for providing real benefit to the farmers from this novel technology. G.B. Pant University of Agriculture and Technology and Tamil Nadu Agriculture University did pioneering work on biopesticides and therefore, it is befitting that Prof. A.N. Mukhopadhyay who initiated this research three decades back in Pantnagar convened this brainstorming session on *Biopesticides – Quality Assurance*. I am sure, the recommendations will go a long way to serve the cause of ecofriendly crop protection. I understand that Dr. C. Devakumar has contributed in redrafting this policy paper. I am grateful to the Convener, all the participants, resource persons and the editors for shaping this document.

(R.B. Singh)
President, NAAS

Biopesticides – Quality Assurance

1.0 PREAMBLE

Crop protection has immensely contributed to the success of Green Revolution and sustained production of food, fibre, fodder and feed. Due to intensification of agriculture, loss of biodiversity and reliance on monocropping, etc. biotic stresses due to pests and pathogens have increased. Last four decades of chemicalisation in agriculture, helped managing many pests and diseases but their application led to several problems like pesticide residues in food stuff, environmental pollution, imbalance of ecological equilibrium, and resurgence of minor pests and pathogens. Management of pests, a term which includes insects, pathogens, weeds and rodents, etc. will continue to play a pivotal role in sustaining production and productivity in Indian agriculture.

Keeping in view the enormous potential of biopesticides, it was felt necessary to have a brainstorming among the scientists, regulatory authorities and industry personnels to discuss practical ways to ensure quality assurance of biopesticides produced in our country. A brainstorming session (BSS) was therefore convened by Dr. A.N. Mukhopadhyay, Former Vice-chancellor, Assam Agricultural University, Jorhat (Co-convener: Dr. C.S. Nautiyal, Director, CSIR-NBRI, Lucknow) on June 24, 2011 at the NAAS premises under the chairmanship of Prof. R.B. Singh, President, NAAS. Dr. Mukhopadhyay gave a brief historical account of biopesticides and underlined the criticality of their quality assurance. The following papers were also presented:

Biopesticides for Insect Pest Management by Dr. R.J. Rabindra, Director, NBAII, Bengaluru and *Bio-pesticides for Plant Disease Management* by Prof. H.B. Singh, BHU, Varanasi.

Prof. R.B. Singh explained the topical importance of the BSS. He enumerated the following advantages of biopesticides:

The overwhelming advantages of bio-pesticides are their high selectivity to target pests and safety to non-target and beneficial organisms. In the sustainable intensification of agriculture through green economy, the bio-pesticides have an immense role. They are amenable to bio-intensive pest management and ideally suited for organic niche products including export-oriented commodities. They can also be tailored to IPM programmes for increased efficacy, higher yield and lower chemical load. These are also effective as pesticide resistance management tools in order to prolong the life span of precious green chemical pesticides. The biopesticide development must also be targeted for integrated cropping systems. They are renewable, sustainable, offer an improved impact profile, and reduce pesticide residues. Market opportunities for microbial pesticides range widely from agricultural applications in cereals, cotton, tobacco, potatoes, vegetables, soft fruits, orchards, glasshouse crops and forestry, household insect control and infestation/ plague control for mosquitoes and locusts.

He also recalled that the National Farmers Commission (2007) (*http://agricoop.nic.in/imagedefault/policy/NCF3.pdf*) has strongly recommended the promotion of biopesticides for increasing agricultural production, sustaining the health of farmers and environment. It also included the clause that biopesticides would be treated at par with chemical pesticides in terms of support and promotion. Further research and development of biological pest control methods must be given priority and people in general and agriculturists in particular must be educated about the handling and use of such control measures.

No wonder that the topic has received world-wide attention (Ansari *et al.*, 2012; Copping, 2009).

The definition and types of biopesticides are listed in Box. 1.

Box 1. Definition and types of biopesticides

In the European Union, a biopesticide has been defined as "a form of pesticide based on micro-organisms or natural products". *http://ec.europa.eu/environment/integration/ research/newsalert/pdf/134na5.pdf*. According to the US Environmental Protection Agency (EPA), they "include naturally occurring substances that control pests (biochemical pesticides), microorganisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants) or PIPs". *http://www.epa.gov/opp00001/biopesticides/*

Biopesticides belong to three categories: (1) living organisms (i.e. natural enemies), which include invertebrates (e.g. predatory insects), nematodes and micro-organisms; (2) naturally occurring substances which include plant extracts and semiochemicals e.g. insect pheromones); and (3) genetically modified plants that express introduced genes that confer protection against pests or diseases (so called plant incorporated products).

2.0 A BRIEF HISTORICAL ACCOUNT

In the 19th century Professor Illya Metchnikoff (Professor of Microbiology at the University of Odessa) in the Ukraine demonstrated the use of the fungus *Metarhizium anisopliae* to control wheat cockchafer (grain beetle). The first recorded registration of a microbial pesticide was in the USA in 1948.

In India, interest on bio-pesticides begun sporadically with entomopathogenic fungi in 1910s. The development of wide-spread insecticide resistance in cotton in 1980s led to revival of interest on baculoviruses. Increased thrust augmented through IPM programmes by the Central and State Governments spurred the growth of bio-pesticides. Extensive efforts were made at G.B. Pant University of Agriculture and Technology, Pantnagar; IARI, New Delhi and Tamil Nadu Agricultural University, Coimbatore to develop biopesticides for management of pests and diseases (Mukhopadhyay, 1987). This was followed by setting up the Project Directorate of Biological Control at Bangalore now known as National Bureau of Agriculturally Important Insects (NBAII). Department of Biotechnology (DBT), New Delhi, Government of India established the National Biocontrol Network Programme (NBNP) in 1989 to study the management of key insect pests, diseases and weed of economically important crops viz. cotton, sugarcane, oilseeds, pulses, vegetables and fruit crops. The DBT has had a substantial funding programme for the research and development of microbial pesticides since 1989, with over 200 projects funded encouraging the development of new technologies and products through academic industrial links. The DBT also provides financial support for the generation of toxicological data to promote registration of microbials. During last three decades, some noteworthy advancements have been made for effective management of pest and diseases using biopesticides (Mukhopadhyay, 1996). The DBT has dedicated a website for Bio-control strategies for eco-friendly pest management (*www.dbtbiopesticides.nic.in*).

The National Agricultural Research System (NARS) plays a leading role in promoting biopesticides. The NBAII is involved in testing the quality of biopesticides and training the officers of the state departments of agriculture in quality control protocols. The National Centre for IPM routinely incorporates the use of biopesticides in its IPM validation programmes and demonstrations. Similarly, commodity research boards play a role in R&D of biopestcides for use in crops such as cotton, coffee, tea, and cardamom. The state governments play the main role in implementing IPM. Their IPM programmes for purchasing and distributing biopesticides to farmers have been vital to creating a market for and encouraging private commercial production of microbial pesticides. States such as Tamil Nadu, Gujarat, Andhra Pradesh, and Maharashtra have been particularly active in promoting microbial pesticide use.

The State Agricultural Universities are also producing biopesticides themselves and are advising companies in production. The Krishi Vigyan Kendras are also engaged in the promotion of local production of microbial pesticides. Indian companies have formed a biopesticide supplier's association, the All India Biotech Association, to co-ordinate the commercial sector's voice in developing government policy. Some non-governmental organizations (NGOs) and the CGIAR centres based in India are also contributing in this field.

3.0 CURRENT SCENARIO

Globally, there are about 1400 biopesticide products being sold. It is estimated that the biopesticides sector is poised to have a 5 year compound annual growth rate of 16 per cent (compared with 3% for synthetic pesticides), which is expected to produce a global market of $3.2 billion by 2014. Region-wise, the United States of America consumes maximum biopesticides (40%) of the global production followed by Europe and Oceanic Countries (20% each).

Despite the promising impacts of biopesticides, the Indian biopesticide industry is growing at a very slow pace. The biopesticides accounted for approximately 0.2% during 2000 of the total global pesticides market and it increased to 4.5% by 2010. The market value is estimated to be around US$ 1 billion. In India, biopesticide production is currently dominated by antagonistic fungi and bacteria such as *Trichoderma* spp. and *Pseudomonas fluorescens*, but the production of nucleopolyhedrosis viruses (NPV), granuloviruses (GV), and entomopathogenic fungi are also established and expanding (Rabindra, 2005; Singh *et al.*, 2012). A major goal has been to develop local sourcing of biopesticides as a means of ensuring availability at a low cost to benefit poorer farmers, and as a base for expanding an Indian biotechnology industry.

Data on the current production of biopesticides is difficult to assess accurately. In 2008, three larger private companies reported the following total production values: 187 metric tonnes (MT) of *Trichoderma harzianum,* 23 MT of *Trichoderma viride,* 15 MT of *Sendomonas lecanii,* 28 MT of *Beauveria bassiana,* 30 MT of *Verticillium lecanii*, and 25 MT of *Metarhizium anisopliae*.

As of early 2013, there were approximately 400 registered biopesticide active ingredients and over 1250 actively registered biopesticide products. It has been estimated that there are at least 32 commercial companies active in biopesticide production, with an additional 32 IPM centres under the Ministry of Agriculture also producing selected biocontrol agents. The state departments of agriculture and horticulture in the states of Tamil Nadu, Kerala, Karnataka, Andhra Pradesh, Uttar Pradesh and Gujarat have established biocontrol laboratories for producing selected microbial biocontrol agents. A few state agricultural universities and Indian Council of Agricultural Research (ICAR) institutions also produce small quantities of microbial pesticides (Rabindra, 2005). In total, at least 410 biopesticide production units have been established in India, 130 in the private sector (Singhal, 2004).

Botanicals

In India, products based on four plants are registered under the Insecticides Act, 1968. These include pyrethrum (*Chrysanthemum* sp. ex. *cinerariaefolium*, *coccinium* etc.), neem (*Azadirachta indica* A.Juss), nicotine (*Nicotiana* sp., for export only) and citronella oil (*Cymbopogon nardus*). Among these, neem pesticides are of maximum current interest, being in maximum demand all over the world. The remaining three plants have to be cultivated in favorable environments to obtain raw material. Product specifications and test methods for the technical materials and their formulations have been prescribed by the Bureau of Indian Standards and are available for reference and use.

Macrobials and Microbials

Pesticidal organisms are applied by inundative or inoculative means. Macrobials include parasitoids and predators which are mass released and the microbials such as bacteria, fungi, nematodes, protozoa, viruses, etc. are applied directly or as formulated products. Key macrobials in use are exemplified by parasites such as *Trichogramma* and predators such as Coccinellids. The other potential parasitoids include *Leptomastix dactylopii*, *Copidosoma koehleri*, *Teleromus remus*, etc. and the predators *Chrysoperla carnea*, *Scymnus coccivora*, *Pharoscymnus horni*, *Curinus coeruleus*, *Coccinella septempunctata*, *Cheilomenes sexmaculata*, *Chilocorus nigrita*, *Brumoides suturalis*, *Cardiastethus exiguous*, etc. Several parasitoids and predators are commercially available (*Bracon brevicornis*, *Goniozus nephantidis*, *Trichogramma chilonis* and *T. japonicum*, *Chrysoperla camea*, *Cryptolaemus montrouzieri*). Thirteen products based on bacteria (*Bacillus thuringiensis* var. *israelsensis* and *kurstaki*, *Pseudomonas fluorescens*), fungi (*Ampelomyces quisqualis*, *Beuveria bassiana*, *Metarhizium anisopliae*, *Paecilomyces lilacinus*, *Trichoderma harzianum* and *T. viride*, *Verticillium chlamydosporium* and *V. lecanii*) and virus (NPV of *Helicoverpa armigera* and *Spodoptera litura*) are registered for use in India. Sex pheromones are available commercially for cotton bollworms, sugarcane borers, brinjal fruit / shoot borer, diamond back moth, rice yellow stem borer, rhinoceros beetle and red palm weevil.

Trichoderma, a multifunctional fungal plant symbiont

Out of total biopesticides used in our country, the genus *Trichoderma* alone occupies 60% of their market share. Recent reports on *Trichoderma* and its genome from different parts of the world including India have clearly demonstrated its role as "multi-functional fungal plant symbiont" to enhance plant growth, productivity and plant disease management (Harman, 2011; Mukherjee *et al.*, 2013). This area has tremendous potential and following advantages are conferred due to appropriate use of this technology:

- Increased seed vigour and plant growth, especially of roots and shoots; and
- Induction of systemic resistance against diseases and stress factors to host plants.

Use of appropriate species/ strains of *Trichoderma* having the above attributes in addition to disease management could help formulating quality biopesticides of *Trichoderma* origin.

4.0 CONSTRAINTS IN COMMERCIAL VENTURE

Despite the progress in establishing a microbial insecticide supply, the scale of biopesticide use in India still remains relatively small in comparison to chemical pesticides. Awareness of microbial products amongst farmers is poor, despite active IPM promotion and training. Much of the current production is sold to government agencies for distribution to farmers in IPM programmes, but distribution system for biopesticides is underdeveloped in many areas. Market studies have suggested that, apart from the entomopathogen *M. anisopliae,* current production of microbial pesticides meets less than 10% of the identified need (Rabindra, 2005).

Constraints that limit commercial investment in developing new biopesticides are listed below:

(i) Many biopesticides have high levels of selectivity. Although, it is of great benefit in terms of not harming other natural enemies and wildlife, but it implies low profit potential. The features that make most of them so attractive from the standpoint of environmental and human safety also act to limit the number of markets in which they are effective.

(ii) Unlike conventional chemical pesticides which have a large cost-cutting market, the drive to adopt biopesticides by farmers will need higher initial investment.

(iii) For fruit and vegetable crops, consumers' acceptance is as important as yield when it comes to making a profit. Due to long period of use, farmers have achieved scale economies in pesticide use as a result of 'learning by doing' but with the limited practical experience with biopesticides, they are averse taking risk leading to low level of adoption. Risk aversion is the highest if farmers' expectations are more focused on instant results.

5.0 REGISTRATION AND THE REGULATORY SYSTEM

World over, regulation of pesticides in general and biopesticides in particular has engaged the attention of OECD, FAO and European Union. (FAO, 2012; Chandler *et al.*, 2011; Grieves and Grant, 2011).

The OECD guidelines

The Organization for Economic Cooperation and Development (OECD) Project on Biopesticides was initiated in 1999 to help OECD member countries harmonise the methods and approaches used to assess biological pesticides. This was to help governments work together to assess pesticide risks to man and the environment. By working together, governments can evaluate the risks more quickly and thoroughly. The OECD agreed guidelines (*http://www.oecd.org/chemicalsafety/pesticides-biocides/biologicalpesticideregistration.htm*) contain two formats:

1. For industry to use when making data submission (dossiers) for microbials and pheromones/semiochemicals, and

2. For governments to use when writing their evaluation reports .

The formats do not require OECD countries to make the same regulatory decisions but to facilitate registration by minimising duplication of effort for both industry and governments. The Guidance for Industry Data Submissions and Guidance for Government Data Reviews, are designed to promote quality and consistency in the "dossiers" of data submitted by biopesticide producers when applying for a new registration, and the government "monographs" that review the data. Both sets of guidance specify the format to follow and level of information to include. The OECD guidance helps to ensure that dossiers and monographs are clear and complete, and that information is easy to find. This makes it easier for governments to use each other's pesticide risk evaluations. And it enables pesticide registrants (usually producers) to submit the same dossiers to different governments.

The Central Insecticide Board (CIB)

In India, biopesticides fall under the Insecticide Act (1968) under which any microbial organism manufactured or sold for pest and disease control should be registered with the Central Insecticides Board (CIB) of the Ministry of Agriculture. To promote registration, biopesticide products benefit from priority processing of registration, simplified registration procedures, and the acceptance of generic registration data for new products containing strains already registered. Manufacturers can register their products under either 9(3B) (provisional registration) or 9(3) (regular registration). This system treats biopesticides as generally regarded as safe (GRAS) to become eligible for provisional registration. Data on product characterization, efficacy, safety, toxicology, and labeling must be submitted while applying for registration.

Based on the OECD guidelines, the CIB has streamlined the guidelines and data requirements for registration as well as minimum infrastructure facilities in the manufacture of bio-pesticides (Table 1). The bio-pesticides including metabolites registered by CIB as on 2011 in listed in the Table 2. The major target pests of microbial pesticides are listed in Table 3. The CIB's established quality standards must be met, with reference to content, virulence of the organism in terms of LC_{50}, moisture content, shelf-life, and secondary non-pathogenic microbial load. Protocols for assessing these quality parameters have been prescribed.

Table 1. CIB Guidelines/Data Requirements for Registration of Biopesticides for Minimum Infrastructure Facilities to be created by the Manufacturers of Biopesticides.

Sl. No.	Particulars
1.	Guidelines/ data requirements for registration of Baculoviruses- Nuclear Polyhedrosis Viruses (NPV) and Granulosis Viruses (GV) u/s 9(3B) and 9(3) of the Insecticide Act, 1968.
1.1	Indian Standards - Baculoviruses-Nuclear Polyhedrosis Viruses (NPV) and Granulosis Viruses (GV) Specifications
2.	Guidelines/ data requirements for registration of Antagonistic fungi u/s 9(3B) and 9(3) of the Insecticide Act, 1968.
2.1	Indian Standards - Antagonistic fungi specifications
3.	Guidelines/ data requirements for registration of Entomogenous fungi u/s 9(3B) and 9(3) of the Insecticide Act, 1968.
3.1	Indian Standards - Entomopathogenic fungi - Specifications.
4.	Guidelines/ data requirements for registration of Antagonistic Bacteria u/s 9(3B) and 9(3) of the Insecticide Act, 1968.
4.1	Indian Standards - Antagonistic Bacteria- Specifications.
5.	Guidelines/ data requirements for registration of Entomotoxic Bacteria technical and formulation u/s 9(3B) and 9(3) of the Insecticide Act, 1968
5.1	Indian Standards - Entomotoxic Bacteria - Specifications
6.	Guidelines for minimum infrastructural facilities to be created by the manufacturers of microbial biopesticides (Antagonistic fungi, Entomopathogenic fungi, Antagonistic bacteria and Entomotoxic bacteria).
7.	Guidelines for minimum infrastructural facilities to be created by the manufacturers for Baculoviruses (NPV, GV).
8.	Guidelines for minimum infrastructural facilities to be created by the manufacturers of botanical biopesticides (Pyrethrum, Azadirachtin, Cymbopogon, etc.).

Table 2. Biopesticides Registered under section 9(3) of the Insecticides Act, 1968 for use in the country (as on 15/10/2013).

S. No.	Name of the biopesticide
1.	Azadirachtin (Neem Products)
2.	*Ampelomyces quisqualis*
3.	*Bacillus sphaericus*
4.	*Bacillus thuringiensis* var. *israellensis*
5.	*Bacillus thuringiensis* var. *kurstaki*
6.	*Bacillus thuringiensis* var. *galleriae*
7.	*Metarhizium anisopliae*
8.	Nuclear polyhyderosis virus of *Helicoverpa armigera*
9.	Nuclear polyhyderosis virus of *Spodoptera litura*
10.	*Pseudomonas fluorescens*
11.	Pyrethrins (pyrethrum)
12.	*Trichoderma harzianum*
13.	*Trichoderma viride*
14.	*Verticillium lecanii*

Trichoderma viride, Trichoderma harzianum, Trichoderma virens, Pseudomonas, Beauvaria, Metarhizium and *Bacillus thuringiensis (Bt)* have carved a niche for themselves in India as important biopesticides for management of various pests and diseases.

Table 3. Major target pests of microbial pesticides used in India (Rabindra, 2005).

	Taxus	Targets
Fungicides		
Pseudomonas fluorescens	Bacterium	Soil borne diseases
Ampelomyces quisqualis	Fungus	Powdery mildew
Trichoderma harzianum	Fungus	Soil borne pathogens
Trichoderma viride	Fungus	Soil borne pathogens
Fungicides/bactericides		
Bacillus subtilis	Bacterium	Soil borne pathogens
Insecticides		
Bacillus thuringiensis subsp. *israelensis*	Bacterium	Lepidopteran pests
Beauveria bassiana	Fungus	Coffee berry borer, diamondback moth, thrips, grasshoppers, whiteflies, aphids, coding moth

Contd...

Table Contd...

	Taxus	Targets
Metarhizium anisopliae	Fungus	Coleoptera and Lepidoptera, termites, mosquitoes, leafhoppers, beetles, grubs
Paecilomyces fumosoroseus	Fungus	Whitefly
Paecilomyces lilacinus	Fungus	Whitefly
Verticillium lecanii	Fungus	Whitefly, coffee, green bug, homopteran pests
Helicoverpa armigera nucleopolyhedrosis virus	Virus	*Helicoverpa armigera*
Spodoptera litura nucleopolyhedrosis virus	Virus	*Spodoptera litura*
Nematicides		
Verticillium chlamydosporium	Fungus	Nematodes

6.0 INNOVATIVE APPROACHES FOR BIOPESTICIDE MARKET

It has been observed that development and regulatory model of bio-pesticide has largely been done according to a chemical pesticide model that has the unintended consequence of downplaying the beneficial biological properties of biopesticides such as persistence and reproduction or plant growth promotion. However, the pesticides model still has much to offer, for example, in improving the formulation, packaging and application of biopesticides.

A case in point is USA, where more institutional support in the form of a dedicated Biopesticides and Pollution Division within the EPA (Environmental Protection Agency). Complemented with more external policy support through the Interregional Research Project No 4 (IR-4 Project) programme, it has enhanced the bio-pesticide portfolio.

The Good Laboratory Practices (GLP) regulatory testing of microbial pesticides following publication of the US EPA Subdivision M guidelines in 1983, harmonization of these guidelines in 1996 was soon followed by publication of similar Japanese Ministry of Agriculture, Forestry, and Fisheries (JMAFF) guidelines. In the European Commission (EC), testing requirements for microbial pesticides used as plant protection products became subject to EC Directive 91/414/EEC and subsequent amendments 2001/36/EC and 2005/25/EC.

In 2010, the International Organisation for Biological Control of Noxious Animals and Plants (IOBC) (*http://www.iobc-wprs.org/pub/*) published an excellent review detailing the rapid expansion of microbial pesticide usage and advance of regulatory systems worldwide. Its emphasis is on the need to streamline and fast-forward product registration processes through harmonisation of data requirements and procedures for risk assessment.

It is generally agreed that one way to streamline and accelerate product registration processes is through international harmonization of a regulatory framework e.g. for data requirements, fees, timelines, criteria for approval, and risk assessments. Indeed, major steps have been taken to increase both the harmonization and transparency of data requirements and the procedures for risk assessment at OECD, North American, and European Union levels. As microbial agents have a wide range of mechanisms of action, and their properties are generally poorly understood, regulatory assessment frameworks must have a certain degree of flexibility and reliance on expert opinion in order to comply with the "intra- and inter-specific variation of microorganisms and their constituents" (Mensink and Scheepmaker, 2007).

So far, nearly 500 biopesticides are available in the Indian market duly registered by CIB, but quality control is a major issue in most of the products. Extensive research on biopesticides in national laboratories and SAUs have clearly demonstrated the efficacy of biopesticides for management of pests and diseases. Relaxation in international Trade Barrier by WTO and GATT agreement has led to export of surplus food grains, vegetables, fruits and flowers from India provided they conform to the international standards especially with regard to MRL (maximum residue level) of chemical pesticides. Central and state governments are advocating liberal use of biopesticides in place of chemical pesticides. Consequently, therefore, demands for biopesticides at state and national levels have increased considerably. There are several schemes/ missions where biopesticides are subsidized to promote their usage and produce quality products free from chemical pesticides. Unfortunately, however, increase in demand has led to supply of spurious products in the market, pending the passage of the Pesticide Management Bill (PMB) 2008. The principal objective of the PMB is to monitor, regulate the manufacture, sale of pesticide which *inter alia* includes grant of registration, manufacturing, selling licenses, samplings and analysis by pesticide testing laboratories. Therefore, registration, issuance of license, sampling and enforcement of law at state level are very important functions. When we look into entire implementation, a few things become very prominent:

(a) Over a lakh of registration certificates are issued for pesticides (including biopesticides) but no mechanism exists to re-verify them.

(b) More than 1300 manufacturing licenses including 500 for biopesticides are issued but there is no mechanism to know whether they are actually in business.

(c) Market surveys conducted confirm the quality concerns, especially from new and inexperienced producers. A system of referral laboratories accredited by the DBT for quality testing has been established but enforcement of standards remains an issue.

An effective regulatory system must address the following issues:

- A system of data requirements to guide the assessment of human health and safety, value (including efficacy), and environmental safety;
- Mechanisms which afford opportunities for public and industry input into the decision-making process, including the right to appeal decisions;
- Policies which establish reasonable timelines for assessment of various classes of products;
- The flexibility to modify regulatory procedures in line with new scientific information;
- Regulatory fees which are affordable to registrants; and
- Enforcement of legislation and regulations related to product use, sale, distribution, and other regulatory requirements.

7.0 CONCERN ABOUT SPURIOUS BIOPESTICIDES

Spurious as the name suggests refers to counterfeit in common parlance. It does not cover a product with a sub-optimal active ingredient and altered composition. This should be covered by the definition of misbranded and substandard. Spurious biopesticides are mostly being manufactured by persons/ companies having legal manufacturing license. As per rules, the monitoring and inspection are the primary jobs but probably due to shortage manpower neither the stipulations fulfillment conditions of Registration Committee (RC) are adhered to nor the Licensing officer inspects the premises before issuing or renewing the license. The existing Insecticide Act 1968 is not being implemented by the Law Enforcing Machinery i.e., State Agriculture Functionaries in its true spirit (Mukhopadhyay, 1994). They lack will to improve the conditions of the farmers who are the ultimate users of the biopesticides and spurious biopesticides worth around Rs. 500 crores are being sold annually to the innocent poor farmers of the country.

The definition of spurious products needs to be widened to protect against deception on public and be specifically covered by the following:

(i) If it is manufactured, distributed and/ or sold under a name or mark, so as to pass of the goods of another or infringes on trademark of another manufacture, such acts of manufacturers shall be deemed to be spurious.

(ii) If it is imported under a false name of description or purporting to be another biopesticides.

(iii) Illicit trade on the products of doubtful origin must be curbed. Law must curb fraud including the deceit and adulteration. Penalties may be streamlined to serve as effective deterrents and

(iv) Unregistered and unregulated products must be weeded out through vigilance. Origin of products with fake assurance statements must be traced and dealt with a heavy hand.

8.0 QUALITY ASSURANCE (QA)

Definition

“The maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production”.

“A planned and systematic pattern of all the actions necessary to provide adequate confidence that a product will conform to established requirements”. *http://stats.oecd.org/glossary/detail.asp?ID=4954*. As per OECD, one must ensure “that there is a quality assurance programme with designated personnel and that quality assurance responsibility is being performed in compliance with principles of good laboratory practice”.

QA issues of biopesticides

Most of the biochemical pesticides products suffer from photo-, thermo-, hydro- and (or) bio-lability resulting in their poor shelf and (or) field lives. Similarly, the organisms which are inundatively released in the fields need to acclimatize to environmental conditions. The purity of their nuclear cultures has to be ensured to minimize consumer risk. The purity and viability of BCAs must be assured irrespective of the method of rearing and multiplication either on their natural or substitute hosts or other artificial diets. Assurance on the adoption of the parent culture in any given environmental condition must be guaranteed for building consumer confidence on their use. QA system must be robust in increasing variability in the rearing of natural enemies such as long term storage of the host, sex ratio, culture maintenance during summer and winter, cannibalism, crises of contamination, high prey density, behavioral changes, loss of vigor, etc. and these criteria must find due accounting in the quality certification. Microbial consortia-based products are claimed for their multi-functional benefits (Jain *et al*., 2013). Such QA for such consortia needs careful calibration in terms of cultural methods and their microbial composition in the product cycle. In formulated forms, suppression of metabolism and provision of survival factors are important approaches for improving shelf life. QA information on the survival and multiplication of these organisms in favorable environments must be stated. Pheromones are highly sensitive and sophisticated dependent as they are on their stereoisomeric purity. Quality and quality assurance statements must factor them in the product cycle, including their kinetics of release. Quality assurance statement on botanicals must ensure that the formulations are standard and stable products that comply with the shelflife requirement. Unlike a chemical pesticide mostly with a single active ingredient, botanical pesticides harbour a host of active ingredients making their analysis cumbersome and tedious more so in formulations. While making the QA certification, one must ensure that non-interference of auxiliaries in the analysis has been taken care of. A quality product to the maximum satisfaction of the consumers has to be watchword of any production system. Quality must, therefore, be ensured at all costs (Parmar, 2010).

An illustrative checklist of QA of biopesticides is shown in Box. 2.

9.0 AWARENESS CREATION

- Most of the farmers in the country do not have sufficient and clear knowledge on the use of biopesticides. In order to educate farmers, educating and training extension workers is most important. This can be done through demonstration trials on the farmers' fields, as seeing is believing. An intensive publicity programme can be done through media like TV/ Radio, seminars, exhibitions and write ups in local newspapers.

- A critical appraisal of the slow adoption of biopesticides by consumers may be undertaken and the constraints addressed.

- Education/ training programmes may be organized by the Central and State Governments wherein package of practices, prepared strictly in conformity with the uses approved by the Registration Committee, should be circulated among the farmers and Farmer's Field Schools. Proactive role needs to be played by the

Box 2. An illustrative checklist of QA of biopesticides

The quality parameters and their limits need to be prescribed in such a manner that they are enforceable by law and in harmony with international standards;

- ✦ Network of duly accredited laboratories/ certification units should be created to address the needs and requirements of the certification. Establish pesticide investigational laboratory in certain States to analyze adulterants/ contaminants in bio-pesticides.
- ✦ Quality assurance for each product should be in conformity with the prescribed national standards and guidelines. QA must also include standards of manufacture, formulation, package, storage and delivery at end user level. Good practices in the product cycle will ensure conformity to quality standards. Samples for evaluation must be handled based on secret codes.
- ✦ QA should be based on the results reported by laboratories/ test units following Good Laboratory Practices as per OECD guidelines. Quality assurance statement should be based on recommendation of the duly designated responsible person(s). Reliability of the quality assurance statement on the product label may be ensured. Record of the approved study plans, standard operating parameters, data generated, observations recorded, etc. must be preserved for the prescribed period of time.
- ✦ Random inspections may be executed at different stages of handling and processing to ensure compliance to the prescribed format.
- ✦ Final reports may be inspected to ensure that the methods, procedures and observations are accurately and completely described. Ensure that the results based on which the quality assurance statement is being made, are accurate and precise and reflect accurately and completely the raw data of the results. The statement should have approval of the top management.

pesticides industry in popularizing the use, strictly as approved by the Registration Committee among farmers not only at the time of market development but also at the time of label expansion.

- ✦ Consumer awareness on the various aspects of biopesticides such as product quality, use, active ingredients, etc. through various government, non-government and private agencies needs to be created.

- Symbolic labels for this green technology may be designed and prescribed for the masses.
- Website of the Registration Committee displaying registered pesticides and their approved uses may be updated regularly (within 30 days of the issue of the Certificate of Registration or letter of endorsement). Every State Department of Agriculture may display their recommendations in conformity with approved uses of registered pesticides on its website, preferably in regional languages for the convenience of users.

10.0 RECOMMENDATIONS

1. The Government and the industry may have a mission to improve the popular perception and demand of biopesticides considering their renewable nature, safety and environment and eco-friendliness. The mission must facilitate the successful development, commercialization, and adoption of biopesticides in public-private partnership (PPP) mode.
2. The industry must promote standards for biopesticides, communicate their value in agriculture, forestry and public health to the consumers and other target markets. A strong academic-industry alliance is necessary for scaling up the commercialization of biopesticides. A roadmap may be developed for putting this agenda into implementation.
3. In PPP mode, we must ensure proper product stewardship at all levels of the value chain: (a) processes for maintaining product quality, integrity and resolving product complaints; (b) scientifically valid efficacy tests supporting claims and promotions and (c) commercially acceptable product efficacy levels in target geography with minimal field trial variability.
4. There is a need to bring out manuals for helping in the development of high quality bio-pesticides. Harmonization of international regulations is required. Limiting factors should be overcome. We need to be proactive and innovative in bringing down costs and time.
5. The regulatory procedures prevalent in North America and European Union are in the public domain but such documents from India may also be developed and uploaded in the website.
6. We need to develop safety indices for biopesticidal formulations including acceptable levels of microbial contaminants.

7. At global level, considerable progress has been made in production efficiency, formulation, quality, field efficacy, application strategies and marketing. The Government may prepare status report to map the strategies for the promotion of the use of biopesticides and provide a systematic approach with a strong focus on economics, safety and marketing of the products.

8. Highlight the fact that biopesticides is a knowledge intensive input. The issues of data protection and IPR must be addressed.

9. Substandard spurious biopesticide is one of the most important factors resulting in failure at the field and lack of farmers' confidence in the product. There should be more testing laboratories with adequate infrastructure and manpower to check the quality of biopesticides at various stages of production, marketing, procurement and applications. For bioefficacy testing, more ICAR institutes, SAUs and some traditional universities having good infrastructural facilities may be notified by CIB. There should be a strict and transparent monitoring of production units to ensure a quality product.

10. CIB should form a technical expert committee comprising of scientists to oversee the infrastructural facilities of biopesticide production units before granting registration under section 9(3B) or 9(3). The existing production units should be subjected to accreditation. For effective implementation and monitoring of biopesticides usage, cluster mode approach is recommended.

11. For microbial mediated bioeconomy, socio-economists may be involved to assess the impact of biocontrol agents.

12. Lack of supply of quality material from State Governments and retailers is a major limiting factor. Procurement of the biopesticide at state and national levels should be made more transparent and directly from the manufacturer to curb spurious products.

13. Registration requirement for biopesticides could be relaxed and rationalized. Since some of these agents have the ability to increase plant growth, they should be considered as plant growth promoting agents for relaxing registration requirements like toxicological data. In many countries, they are marketed as plant growth promoters.

14. Biological seed/plantation material treatment is a novel low cost technology (Mukhopadhyay *et al.*, 1992) for the poorest of the poor and must be promoted by the Ministry of Agriculture and State Governments for increasing agricultural production and productivity. Possibility of seed/planting material treatment

and biopriming of nurseries with biopesticides should be investigated. Seed industries must be sensitized in the area of biological seed treatment using biopesticides.

15. There is an urgent need to develop bar coding of microbes used in commercial production of biopesticides. There is also a need to develop microbial consortia for better results. Accordingly, CIB may amend the existing rules for biopesticide registration. Selection of proper strain/species of biocontrol agents is the key factor for success of biopesticides.

16. More focus may be given to develop low-cost technologies for mass production of biocontrol agents. Attention may be given to develop post-harvest disease management practices.

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List of Participants

1. Prof. R.B. Singh, President, NAAS, New Delhi.
2. Prof. Anwar Alam, Secretary, NAAS, New Delhi.
3. Dr. A.N. Mukhopadhyay, Convener, Former Vice-Chancellor, AAU, Jorhat.
4. Dr. C.S. Nautiyal, Co-Convener, Director, CSIR-NBRI, Lucknow.
5. Dr. C. Devakumar, Editor, NAAS, New Delhi
6. Dr. M. Anandaraj, Project Coordinator, AICRP on Spices, Indian Institute of Spices Research, Post Bag No. 1701, Marikumnu, Calicut.
7. Dr. Joseph Bagyaraj, Former Prof. & Head Microbiology, UAS, 41, RBI Colony, Ananad Nagar, Bangalore.
8. Dr. B.N. Charkraborty, North Bengal University, Siliguri, W.B.
9. Dr. P. Chowdappa, Principal Scientist, Indian Institute of Horticultural Research, Hessaraghatta Lake Post, Bangalore.
10. Dr. S.K. Datta, Dy. Director General (CS), ICAR, New Delhi.
11. Dr. Prem Dureja, Emeritus Scientist, Division of Agricultural Chemicals, IARI, New Delhi.
12. Dr. H.S. Gupta, Director, IARI, New Delhi.
13. Dr. J. Janardan, Principal Scientist & Head (Agri. Entomology), ICAR-RCER, Patna.
14. Dr. C.D. Mayee, Chairman, ASRB, New Delhi.
15. Dr. K. Muralidharan, Director (Technical) Sowbhagya Biotech, (P) Ltd., Hyderabad.
16. Dr. S.R. Niranjana, Professor, Applied Botany and Biotechnology, University of Mysore, Mysore.
17. Dr. A.R. Podile, Professor, Department of Plant Science, University of Hyderabad.
18. Dr. R.J. Rabindra, Director, National Bureau of Agriculturally Important Insects, Bangalore.
19. Mr. R.L. Narayana Rao, Managing Director, Sowbhagya Group, Hyderabad.
20. Dr. S.N. Puri, Vice-Chancellor, Central Agricultural University, Imphal.
21. Dr. M.R. Roy, Director, Super Agro India Ltd. Kolkata.
22. Dr. Indu S. Sawant, Principal Scientist, NRC on Grapes, Pune.
23. Dr. A.K. Saxena, Head, Division of Microbiology, IARI, New Delhi
24. Dr. Pratibha Sharma, Professor, Division of Plant Pathology, IARI, New Delhi.
25. Dr. Gurbachan Singh, Agriculture Commissioner, Govt. of India, MoA, New Delhi.
26. Dr. H.B. Singh, Professor, Department of Mycology and Plant Pathology, BHU, Varanasi.
27. Mr. Saurabh Singhal, Managing Director, Biotech International Limited, New Delhi.

Note: The designations and affiliations of the participants are as on the date of BSS.

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