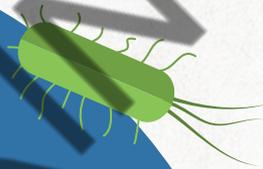
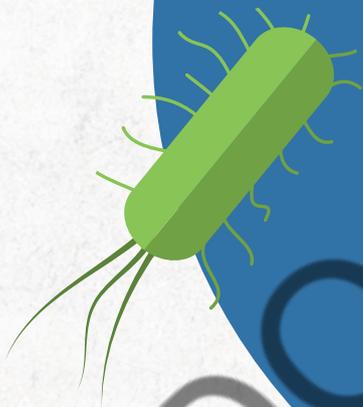




GUIDANCE  
DOCUMENT FOR

**Producers,  
Registration  
Holders, and  
Users for Bt-  
based Products  
in India**



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GUIDANCE DOCUMENT FOR

# Producers, Registration Holders, and Users for Bt-based Products in India

Prepared by:  
Toxics Link, New Delhi



Toxics Link  
for a toxics-free world

### **Disclaimer**

The information provided in the guidance document is collated from relevant acts, rules, orders and guidelines issued by the Government of India and respective State Governments from time to time. This document was drafted during the period 2021–2022. This document is intended to be used as an informal reference, and as such, does not replace or supplant the requirements of any regulations referred in these guidance documents. Also, as indicated by the use of non-mandatory language such as “guidance,” “may,” “should,” and “can,” these guidance documents identify policies and provide suggestions and do not create any new legal obligations or limit or expand obligations under any international, national, regional, state, territory, or local law.

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# Overview

The Government of India signed the Stockholm Convention on Persistent Organic Pollutants (POPs) in May 2002 and ratified it on 13<sup>th</sup> January 2006. Since the Stockholm Convention came into force in 2004, dichlorodiphenyltrichloroethane (DDT) has been designated as one of the POPs in the Stockholm Convention. However, India and a few other countries have sought exemption for DDT use in vector control. India has been the largest producer of DDT, and its production continues in the country. The state-owned enterprise HIL (India) is the only registered producer for DDT in the world. In fulfillment of its obligation under the Stockholm Convention, the Government of India submitted the National Implementation Plan (NIP) in 2011. The NIP has outlined a gradual phase-out of DDT along with the development and promotion of non-persistent organic pollutants (non-POPs) alternatives to DDT as one of the top priorities for a post-NIP programme that requires immediate attention and action.

In India, the National Vector Borne Disease Control Programme (NVBDCP) of the National Center for Vector-Borne Disease Control (NCVBDC) under the Ministry of Health and Family Welfare (MoHFW), Government of India has been using DDT for malaria vector control based on epidemiological impact and insecticides resistance. However, as India has committed to phase-out DDT, the Government of India through the NVBDCP is enhancing its alternative vector control strategy based on Integrated Vector Pest Management (IVPM), including the following interventions: biological control, chemical control, and environmental management, or all in combination with legislative measures and alternative approaches.

The Government of India is currently implementing a Global Environment Facility (GEF) project titled “Development and promotion of non-POPs alternatives to DDT” to phase out DDT with suitable environmentally friendly alternatives considering India’s commitment to phase out DDT in Stockholm Convention. In this context, these guidance documents have been developed for producers, registration holders and users to help them in meeting the legal requirements for DDT alternatives and thus facilitate a smooth transition from DDT to environmentally friendly alternatives. The objective of this guidance document is to ease the introduction of bio- and botanical pesticides and other locally appropriate, cost-effective and sustainable alternatives to DDT, such as Long-Lasting Insecticidal Nets (LLINs), Bt-based products, and neem-based products as the first step for reduction and eventual elimination of dependency on DDT, ensuring food safety, enhancing livelihood and protecting human health and the environment.

The information provided in the guidance document is collated from relevant acts, regulations, other government sources and the valuable inputs received from the relevant stakeholders including the government institutions such as Ministry of Environment, Forests and Climate Change (MoEFCC), National Center for Vector Borne Disease Control (NCVBDC), Central Insecticides Board and Registration Committee (CIB&RC) under the Ministry of Agriculture & Farmers Welfare, Ministry of Ayush, State Vector Borne Disease Control officials from Chhattisgarh, Punjab, Odisha, West Bengal; UNIDO; and producers such as HIL (India) Limited, Ajay Bio-Tech (India) Ltd. and Vestergaard.

# Acknowledgements

Toxics Link expresses sincere thanks to the United Nations Environment Programme (UNEP) for assigning the task of preparing this guidance document for producers, registration holders, and users on alternative products for vector control in the context of DDT being phased out. This document is an important component of the Global Environment Facility (GEF) project titled “Development and promotion of non-POPs alternative to DDT.”

We would like to extend our gratitude to the Ministry of Environment, Forests and Climate Change (MoEFCC) and National Center for Vector Borne Disease Control (NCVBDC) of Directorate General of Health Services, Ministry of Health & Family Welfare (MoHFW), Government of India, for their support in executing this project since its inception. Our special thanks to Dr. Kalpana Baruah, Vector Control Expert, NVBDCP for her technical support and also for facilitating our visits to the states. We are also grateful to the representatives from the Central Insecticides Board and Registration Committee (CIB & RC), Bureau of Indian Standards (BIS) and Ministry of Ayush, Government of India for their inputs and comments on the guidance document.

We sincerely thank the Health Department of Government of Chhattisgarh and Government of Punjab for providing logistic support during the field visits. We also want to acknowledge the inputs provided by State VBDCP officials of Chhattisgarh and Punjab and district program officials of Bastar, Chhattisgarh and Mayurbhanj, Odisha during the initial stakeholder consultations.

We also acknowledge the valuable inputs received from HIL (India) Ltd., Ajay Biotech and Vestergaard in finalizing the documents. We are also grateful to Central Pollution Control Board, UNIDO, CSIR-NEERI, Nagpur and the State VBDCP officials, State Pollution Control Board officers, State Agriculture Department officers, NGOs and other vector control experts from Odisha and West Bengal for their inputs and suggestions during the stakeholder consultation meetings. We would also like to acknowledge the technical knowledge and support provided by Dr. Pradeep K. Srivastava (Former Joint Director, NVBDCP), that helped shape and finalize the documents.

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# Abbreviations

<b>BIS</b>	Bureau of Indian Standards
<b>Bt</b>	<i>Bacillus thuringiensis</i>
<b>CIB&amp;RC</b>	Central Insecticides Board & Registration Committee
<b>CMSS</b>	Central Medical Services Society
<b>DDT</b>	Dichlorodiphenyltrichloroethane
<b>DPIIT</b>	Department for Promotion of Industry and Internal Trade
<b>GMO</b>	Genetically Modified Organism
<b>ICMR</b>	Indian Council for Medical Research
<b>IEC</b>	Information, Education and Communication
<b>IS</b>	Indian Standard
<b>MOHFW</b>	Ministry of Health and Family Welfare
<b>NCDC</b>	National Centre for Disease Control
<b>NCVBDC</b>	National Center for Vector Borne Diseases Control
<b>NVBDCP</b>	National Vector Borne Disease Control Programme
<b>PPQS</b>	Directorate of Plant Protection, Quarantine & Storage
<b>WHO</b>	World Health Organization
<b>WHOPES</b>	WHO Pesticide Evaluation Scheme

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# Guidance Document for Producers, Registration Holders, and Users of Bt-Based Products in India

All the biopesticides, including Bt-bioinsecticides, are regulated by the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**. The producers and registration holders of Bt-bioinsecticides have to comply with the provisions of the Act and the Rules during various stages of production and registration. Some of the key provisions of the Act and Rules are briefly discussed in various sections of this guidance document.

*The **Insecticides Act, 1968** aims to regulate the import, manufacture, sale, transport, distribution, and use of insecticides with a view to prevent risk to human beings on animals and for matters connected therewith.*

**Section 9** of the Act has detailed provisions on the registration of all insecticides, including Bt-bioinsecticides

**Section 10** of the Act has the provisions for the producers to appeal against non-registration of insecticides or cancellation of insecticides registration

**Section 13** provides details regarding licenses required for insecticides manufacturing and sale of the insecticides

**Section 14** lays down provisions on the Revocation, suspension, and amendment of manufacturing licenses issued under Section 13

**Section 17** Prohibition of import, and manufacture of certain insecticides

*The relevant provisions of the **Insecticides Rules, 1971** for the producers and registration holders are;*

**Chapter III** on the registration of insecticides (Manner of registration and Appeal against decision of Registration Committee)

**Chapter IV** on the grant of licenses for the manufacture of insecticides, sale of insecticides, conditions of licenses, etc.

**Chapter V** on the packaging and labeling of insecticides

**Chapter VII** on the transport and storage of insecticides in transit by rail, road, or water

**Chapter IX** has miscellaneous provisions, general forms for application and certificate for registration of insecticides, appeal under Section of the **Insecticides Act, 1968**, application for manufacture for the grant of license of manufacture of insecticides, application for the grant of license to sell, or exhibit for sale or distribute insecticides, etc.

## 1. Guidance for Producers of Bt-based products (Bt-bioinsecticides), including Exporters

Globally, *Bacillus thuringiensis* (Bt)-based biopesticides have been found to be effective in the vector control programme, including malaria. In India, Bt-bioinsecticides are already recommended for use under National Vector Borne Disease Control Programme (NVBDCP) as potential larvicides to control malaria. These bioinsecticides are eco-friendly and can be extensively used as alternatives to DDT for malaria control mostly in the urban setup. However, there is an emerging opportunity for new producers as well as exporters for Bt-bioinsecticides, considering the potential demand of India's vector control programme with the country looking forward to phasing out DDT. Therefore, it is essential for the producers and exporters to know and understand the necessary regulatory requirements in the country for carrying out the business of Bt-based products in India.

The producers setting up the Bt-bioinsecticides manufacturing unit for indigenous production and use in India or export or both need to register their Bt-bioinsecticides with the Central Insecticides Board & the Registration Committee (CIB&RC) of the Directorate of Plant Protection, Quarantine & Storage (PPQS), Ministry of Agriculture & Farmers Welfare, Government of India under the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**.

Apart from the mandatory CIB&RC registration of Bt-bioinsecticides, the producers need to fulfill the regulatory requirements before and after the commissioning of the production facility. The producers can simultaneously apply for registration of Bt-bioinsecticides and the necessary clearances required for setting up a new production unit. The exporters need to also comply with the regulations necessary for export purposes. At present, the imported Bt-bioinsecticides are not allowed to be registered with the CIB&RC and therefore, cannot be sold in India.

### 1.1 Regulatory Requirements for Production of Bt-bioinsecticides in India

- ❶ The producers need to obtain a Certificate of Registration, necessary clearances and comply with regulatory requirements both at the central and state government levels for setting up the production unit (or manufacturing unit) of Bt-bioinsecticides.
- ❷ The Producers must know that setting up a business in India involves the following steps; namely, registering the manufacturing unit with its name and fulfilling the regulatory requirements at the pre-commissioning phase (approvals for setting up a manufacturing unit), and at the post-commissioning phase (approvals at pre-production stage). The regulatory requirements involved in the pre-commissioning and post-commissioning phases are schematically shown in Figure 1.



**Figure 1. Regulatory processes to be followed to start a new business/manufacturing facility in India**

[The above schematic has been drawn by Toxics Link based on the resources available on Department for Promotion of Industry and Internal Trade (DPIIT) and National Investment Promotion and Facilitation Agency (Invest India) websites]



- The producers can obtain the lists of various approvals and clearances required for [setting up a new project](#) in India on the Department for Promotion of Industry and Internal Trade (DPIIT) website. This list is also provided in **Appendix-I**. Further, the details of steps involved in the regulatory processes for establishing a production unit in India are available on the [Invest India](#) and [DPIIT](#) websites.
- All the Bt-bioinsecticides must be registered with CIB&RC of the PPOS under Ministry of Agriculture & Farmers Welfare, Government of India, as per various provisions under **Section 9 of the Insecticides Act, 1968** before they can be manufactured for sale and distribution in India and/or for export.
- Once Bt-bioinsecticide is approved and registered by the CIB&RC, the producers need to take the approval from the respective state governments (i.e., manufacturing license) where the production unit of Bt-bioinsecticide will be set up with the necessary papers and fees. The manufacturers can refer to the guidelines for [minimum infrastructure](#) facilities to be created by the manufacturers of microbial biopesticides (Antagonistic fungi, Entomopathogenic fungi, Antagonistic bacteria, Entomotoxic bacteria) to meet the requirements for the issue of manufacturing license by licensing authority of the respective state governments. However, the requirement of manpower, space, and equipment/instrument may differ for specific microbial biopesticides formulation(s) and their quantum of production. The producers can also refer to the guidelines on PPOS website if they need to set up an [additional unit for manufacturing](#) the same insecticides.
- The producers should check the regulatory requirements of the respective states before applying for a license to produce pesticides. The information regarding regulatory requirements can be obtained from the office of licensing authority of the concerned state either by visiting physically or by visiting their respective websites. For example, the regulatory requirements for the Indian state of Maharashtra can be obtained by visiting [Maharashtra Industry, Trade and Investment Facilitation Cell](#) website
- After the issue of manufacturing license, it is necessary to obtain a license to sell, stock, or exhibit for sale or distribute bioinsecticides, and applications for the same shall also be made to the licensing officer.

- ☑ In the case biolarvicides to be sold or stocked for sale at more than one place, separate applications shall be made, and separate shall be issued in respect of every such place.
- ☑ The producers need to keep in mind that genetically modified strains are not allowed in biolarvicides. The producer is liable for criminal prosecution for using the genetically modified strain in Bt-biolarvicides. The genetic sequence of the organism used for biopesticides has to be submitted while applying for registration.
- ☑ All the exporters of indigenously manufactured Bt-biolarvicides also need to obtain the Certificate of Registration from CIB&RC as per the provisions of the **Insecticides Act, 1968**.

### 1.1.1 Registration of Bt-biolarvicides with the CIB&RC

The Central Insecticide Board & Registration Committee (CIB&RC) of Directorate of Plant Protection, Quarantine & Storage (PPQS) under Ministry of Agriculture & Farmers Welfare, Government of India is responsible for the registration and advice to the Central and State governments on technical matters related to Bt-biolarvicides. The [general guidelines for registration of pesticides](#) under the **Insecticides Act, 1968** are given on the PPQS website. The contact address of the CIB&RC is provided in **Appendix-II**.

- ☑ All the Bt-biolarvicides must be registered by the producers with CIB&RC under **Section 9 of the Insecticides Act, 1968** before they can be produced for export or sale and distribution in India.
- ☑ The producers need to check the provisions for the registration of all insecticides, including Bt-biolarvicides as mentioned in **Section 9 of the Insecticides Act, 1968**.
- ☑ If the Bt-biolarvicides are introduced for the first time in India, the Registration Committee, pending any enquiry, may grant provisional registration for a period of two years under **Section 9(3B)**. Once provisional registration expires, the producers have to apply for permanent registration under **Section 9(3)** with CIB&RC. A [typical application form for insecticides registration](#) is available on the PPQS website.
- ☑ The producers may also be granted provisional registration under **Section 9(3B)** if the data submitted by the applicant is insufficient to be granted regular registration under **Section 9(3)**. The provisional registration is granted for two years for the generation of necessary data and may be extended by a year.
- ☑ For the registration of Bt-biolarvicides with CIB&RC, the producers must provide data on chemistry, bioefficacy, toxicity and packaging & labeling as per the requirement of guidelines framed by the CIB&RC. The [guidelines for registration under Sections 9\(3B\) and 9\(3\)](#), as the case may be, are provided on the PPQS website.

The above registration guidelines also provide the Indian standard for the requirements and the method of sampling and test for Entomotoxic bacteria technical and formulation. At present, Bt-based products are not allowed to be registered under **Section 9(4)**. The producers need to refer to Rules under **Chapter III of the Insecticides Rules, 1971** for further guidance on registration of their insecticides

- ➊ After submission of the application for any insecticides registration, it undergoes preliminary scrutiny for application and data completeness. The producers should refer to the [checklist](#) displayed on the PPQS website for registration under **Section 9(3)** to strengthen their registration application.
- ➋ Generally, the registration process takes 12 to 18 months (depending on the data deficiency, if any) once the application has been submitted to CIB&RC. The details regarding timeline for the registration of insecticides as per **Section 9(3) of the Insecticides Act, 1968** are enclosed in **Appendix -III**.
- ➌ The manufacturers must provide an undertaking along with the application of registration that the product does not contain any genetically modified organism (GMO). If a new strain has to be registered or an already registered strain has not been previously submitted, two samples have to be submitted to the Secretariat of CIB&RC; one for pre-registration verification from Central Insecticides Laboratory as per product specification requirement and another sample to be used for pre-registration verification of Gene code sequencing/16S R-DNA/fingerprinting in National Bureau of Agriculturally Important Microorganisms.
- ➍ Once the CR is issued, the producers become registration holder and have to comply with the conditions subject to which the Bt-bioinsecticide registration was granted. The CR includes composition, active ingredient, shelf life, label, doses, and their use, and safety precautions.

### 1.1.2 Labelling and packaging

Labelling and packaging are very important, and the producers need to follow the label claims approved by CIB&RC and issued with the Certificate of Registration of the product. The label and leaflets need to be printed in different languages as per guidelines of CIB&RC and affixed or attached to the package containing final products before it is sold or distributed.

The producers who are interested in participating in international bidding and export the Bt-bioinsecticides to other countries may need to follow World Health Organization (WHO) guidelines and can refer to the WHO recommendations for good labeling on the [publications page of the WHO website](#).



**Specific Resources:**

[Guidelines on Good Labelling Practice for Pesticides. International code of conduct on pesticide management](#)

### 1.1.3 Guidelines for quality of Bt-bioinsecticides

The producers must ensure the same quality of products and their constituents during the production of bioinsecticides as submitted to CIB&RC for registration of their products. The producers must comply with the safety, quality and efficacy requirements in accordance to the conditions specified in the respective Certificate of Registration issued by CIB&RC.

The producers who intend to export and sell their Bt-bioinsecticides in the international market can refer to WHO guidelines for quality control.



#### [Guidelines for quality control of pesticides. International code of conduct on the distribution and use of pesticides](#)

The vector control products, including Bt-bioinsecticides, those meet WHO prequalification requirements are added to the WHO List of Vector Control Products. These vector control products are known as WHO prequalified (previously known as WHO Pesticide Evaluation Scheme (WHOPES) recommended)

- The producers can refer to the vector control product prequalification page on the WHO website
- The list of WHO prequalified vector control products and their current status are available on the WHO website

## 1.2 Compliance to Technical Specification of Bt-bioinsecticides

The product and packaging should conform to the specifications submitted by the producer to CIB&RC for approval and to the Indian Standard (IS) specifications and amendments thereof as and when the same are formulated and published. The producers must approach the Bureau of Indian Standard (BIS) for obtaining IS certification for their products. The specification includes composition, active ingredient, dose, and strength, etc. These parameters are important to ensure the quality of the product as specified in Certificate of Registration. The producers can get the details from the [BIS website](#). The address and the contact details of BIS are in **Appendix-IV**.

## 1.3 Procedures to be followed for treatment, transport and storage

The producers need to follow the guidelines for the storage and transport of insecticides in line with the **Insecticides Rules, 1971**.<sup>1</sup> As the insecticides are generally transported by railways, the packages containing insecticides need to be packed in accordance with the conditions specified in the [Red Tariff](#), issued by the Ministry of Railways

All the insecticides should be transported or stored in such a way that it does not come into direct contact with foodstuffs or animal feeds. The package containing insecticides should be stored in separate rooms or premises away from the space used for storing other articles. For details, the producers can refer to **Chapter VII of Insecticides Rules, 1971**.

<sup>1</sup> [Insecticides Rules, 1971](http://ppqs.gov.in/sites/default/files/insecticides_rules_1971.pdf) (http://ppqs.gov.in/sites/default/files/insecticides\_rules\_1971.pdf)

## 2. Guidance for Registration Holders of Bt-based products (Bt-Bioinsecticides)

All Bt-bioinsecticides to be sold/used in India must be registered with the CIB&RC as per the provisions of the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**. This mandatory registration is applicable for the producers of Bt-bioinsecticides in India as well as exporters of Bt-bioinsecticides. The producers manufacturing Bt-bioinsecticides for use in India or for export or both need to apply by separate application for separate products to obtain the Certificate of Registration. After the producers receive the Certificate of Registration, they will be considered registration holders of Bt-bioinsecticides and will be able to participate in the commercial bidding process to sell Bt-bioinsecticides in India and outside India as specified in their respective Certificate of Registration.

In India, at present Bt-bioinsecticides are only allowed to be used through the public health programmes and not allowed for sale in the retail market. Therefore, the registration holders of Bt-bioinsecticides after obtaining the Certificate of Registration from the CIB&RC need to approach the Directorate of National Vector Borne Disease Control Programme (NVBDCP), of the National Center for Vector Borne Diseases Control (NCVBDC), for inclusion of their Bt-bioinsecticides for public health use. Only after the registration holders of Bt-bioinsecticides are able to get their products approved for use in the national programme, they can participate in the commercial bidding process.

The public health programmes are flagship initiatives of the Ministry of Health and Family Welfare, Government of India and are called National Public Health Programmes in ordinary parlance. The Directorate General of Health Services, Ministry of Health and Family Welfare is instrumental and responsible for the implementation of various programmes at a national level in the areas of Family Welfare, Prevention, and Control of Communicable and Non-communicable diseases. The National Vector Borne Disease Control Programme (NVBDCP) is one of the most comprehensive and multi-faceted public health activities in the country and is concerned with the prevention and control of malaria and other vector-borne diseases such as filariasis, kala-azar, dengue and Japanese encephalitis. The Directorate of NVBDCP, of the National Center for Vector Borne Diseases Control (NCVBDC) is the nodal agency for programme implementation in respect of prevention and control of these vector-borne diseases.

The NVBDCP has the ultimate responsibility to introduce new Bt-bioinsecticides for use in the country under public health programmes based on the results of scientific evaluation of the product. Bt-bioinsecticides are procured by different States/Union Territories and urban local bodies for public health programmes and the registration holders need to follow the procurement procedure of the respective government bodies for the supply of Bt-bioinsecticides to them.

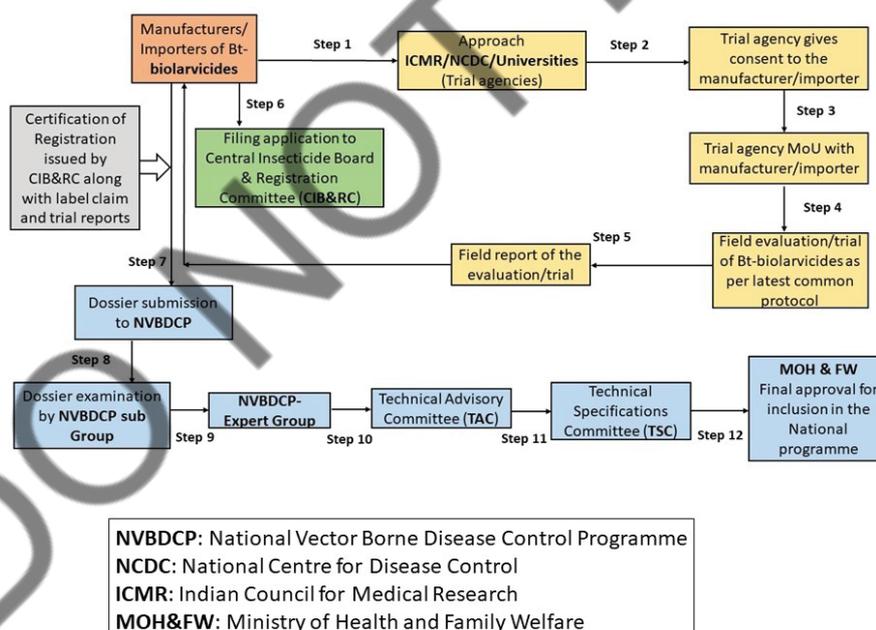
The contact details and address of the NCVBDC are provided in **Appendix-V**.

## 2.1 Inclusion of the registered Bt-bioinsecticides in public health programmes by NVBDCP

The NVBDCP considers the introduction of new Bt-bioinsecticides and/or deletion of Bt-bioinsecticides for use under the public health programme on the basis of registration/de-registration of the product by CIB&RC.

To include any new registered Bt-bioinsecticide under NVBDCP, it needs to be evaluated as per Revised Common Protocol for uniform evaluation for public health pesticides for use in vector control developed by ICMR, NVBDCP and NCDC.<sup>2</sup> Even the WHO prequalified insecticides, including Bt-bioinsecticides are approved by NVBDCP for use in national programmes only after large-scale and multi-centric field testing/evaluation for efficacy and suitability to Indian conditions.

The registration holders of Bt-bioinsecticides need to submit the complete dossier including Certificate of Registration issued by CIB&RC along with the approved label claim and the Phase-I, Phase-II and Phase-III trial reports to the NVBDCP for consideration of the inclusion of their Bt-bioinsecticides into the public health programmes. The steps involved in the process of Bt-bioinsecticide approval for their use in the national programme are given in the latest Standard Operating Procedure on the NVBDCP website. The Ministry of Health and Family Welfare (MOH&FW) is the final authority to give approval for the inclusion of new Bt-bioinsecticides into the programme.



**Figure 2. Steps for inclusion of Bt-bioinsecticides in the public health programme under NVBDCP**

(The above figure has been redrawn based on the original flow chart provided in the Standard Operating Procedure for introduction of public health pesticides including bioinsecticides in the National Vector Borne Disease Control Programme<sup>3</sup>)

- [Revised Common Protocol for Uniform Evaluation of Public Health Pesticides including Bio-insecticides for use in Vector Control](https://nvbdcp.gov.in/WriteReadData/l892s/Revised-Common-Protocol-2014.pdf) (https://nvbdcp.gov.in/WriteReadData/l892s/Revised-Common-Protocol-2014.pdf)
- [Standard Operating Procedure for Introduction of Public Health Pesticides Including Bioinsecticides in the National Vector Borne Disease Control Programme](https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20%20for%20introduction%20of%20public%20health%20pesticides%20including%20bioinsecticides%20in%20the%20NVBDCP.pdf) (https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20%20for%20introduction%20of%20public%20health%20pesticides%20including%20bioinsecticides%20in%20the%20NVBDCP.pdf)

## 2.2 Commercialization of Bt-bioinsecticides by the registration holders through public health programme

The registration holders need to understand the bidding process required for Bt-bioinsecticide procurement if their product has been included under the public health programme. They should carefully go through the tender or bidding document issued by the government procurement agency. The registration holders can participate in the bidding process after fulfilling the tender requirements and conditions. If the bid is awarded to any registration holder, the entity should ensure that they supply the required quantity on time.

The successful bidders need to sign the agreement and will abide by the **Indian Contract Act, 1872**.<sup>4</sup> The standard bidding document comprises General Condition of Contract (GCC) and Special Condition of Contract (SCC) in addition to other requisite forms. The technical parameters/specifications as given in the bidding document need to be strictly followed.

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<sup>4</sup> [Indian Contract Act, 1872](https://www.indiacode.nic.in/bitstream/123456789/2187/2/A187209.pdf) (https://www.indiacode.nic.in/bitstream/123456789/2187/2/A187209.pdf)

### 3. Guidance for users of Bt-based products (Bt-bio-larvicides)

In India, all the implementation guidelines for the vector control programme, including the guidelines for distribution and use of Bt-bio-larvicides are issued by the Government of India. However, as health being a state subject in India, the implementation of programme activities, including the distribution and use of Bt-bio-larvicides in target areas is the responsibility of various States and Union Territories. The guidelines include the implementation process for vector control, a list of approved products for use in vector control programme, their technical specifications, and norms for calculating the technical requirements of products.

Further as the Bt-larvicides are allowed for sale in the retail market, various housing societies, NGOs and other private parties are also using Bt-bio-larvicides. They also need to be aware of the specific guidelines for the users.

- ❶ The States and Union Territories are recipients of products for distribution and as per the present policy, have to procure the requisite Bt-bio-larvicides as decentralized items. The States and Union Territories need to align their respective malaria elimination programme in accordance with the NVBDCP guidelines<sup>5</sup> and advisories issued from time to time. The States/Union Territories should issue advisory guidelines to the districts (consignees) for smooth implementation of Bt-bio-larvicides distribution and use
- ❷ NVBDCP recommends the use of all larvicides as anti-larval measures in urban areas. NVBDCP has issued guidelines on the use, dose, and frequency of larvicides, which may be referred to in Operational Guidelines for Urban Vector-Borne Diseases Scheme<sup>6</sup>
- ❸ The consignees need to have designated in-charge of stores/warehouses where the goods will be received and stored before distribution to different end-points. The in-charges should know about the procedure to receive bio-larvicides and to tally the goods as per specifications, date of expiry, manufacturer detail, etc. The consignees should properly maintain the stock and distribute the goods before their expiry
- ❹ The concerned state agencies should check the quality of the sprayers including necessary safety measures to prevent any harm with the sprayers. Also, the state agencies need to ensure the availability of the safety devices like PPE to the spray workers.
- ❺ The spray workers are the key people involved in Larval Source Management. The spray workers receive the bio-larvicides from the assigned stock for spraying them in the breeding sites. A ready-to-use solution of bio-larvicides needs to be prepared by diluting the formulation as recommended by NVBDCP and covering the recommended area by spraying so that the recommended dose is obtained in the breeding sites.
- ❻ The spraying activity needs supervision by the local government officials to check whether it is being done correctly as per norms prescribed in the operating manual. These officials can also refer to the

5 [Operation Manual for Malaria Elimination in India 2016](https://nvbdcp.gov.in/WriteReadData/l892s/5232542721532941542.pdf) (https://nvbdcp.gov.in/WriteReadData/l892s/5232542721532941542.pdf)

6 [Operational Guidelines for Urban Vector-Borne Diseases Scheme, NVBDCP](https://nvbdcp.punjab.gov.in/Download/OPERATIONAL-GUIDE-LINES-FOR-URBAN-VBD-SCHEME-2016.pdf) (https://nvbdcp.punjab.gov.in/Download/OPERATIONAL-GUIDE-LINES-FOR-URBAN-VBD-SCHEME-2016.pdf)

Certificate of Registration of that product for correct information on the preparation of ready-to-spray formulation, dosage, frequency of application, equipment required, and the breeding sites where it is recommended for use. The local officials should also ensure that Bt-bio-larvicides are utilized before their expiry date. These bio-larvicides are not recommended for use in potable water collection.

- ④ The spray workers should be repeatedly trained to use the bio-larvicides in a correct manner. The local government officials should ensure that the Bt-bio-larvicide is used in strict conformity with the precautions mentioned on the label and leaflet provided by the producers along with the product.
- ④ The monthly report of larval spraying carried out and stock position of bio-larvicides should be recorded in proper proforma which may be referred to in Operational Guidelines for Urban Vector-Borne Diseases Scheme.
- ④ The state should be aware and develop a plan for the safe disposal of expired Bt-bio-larvicides and plastic packaging materials as per the provisions of the **Solid Waste Management Rules, 2016**<sup>7</sup> and **Plastic Waste Management Rules, 2016**<sup>8</sup>, as amended from time to time. The district-level officials should take necessary steps for the disposal of expired bio-larvicides and their packaging materials as per the guidelines communicated by the state.
- ④ These users should also follow the specific guidelines issued by the NVBDCP on the use of Bt-bio-larvicides and the necessary safety precautions that are required.
- ④ The Government may promote effective behavior change communication activities and intersectoral convergence meetings to help the users to use the bio-larvicides effectively

7 [Solid Waste Management Rules, 2016](https://cpcb.nic.in/uploads/MSW/SWM_2016.pdf) (https://cpcb.nic.in/uploads/MSW/SWM\_2016.pdf)

8 [Plastic Waste Management Rules, 2016](https://www.egazette.nic.in/WriteReadData/2016/168620.pdf) (https://www.egazette.nic.in/WriteReadData/2016/168620.pdf)

# Appendices

## Appendix-I: List of important approvals/clearances required for new projects in India

This list has been provided at the below link: [https://dipp.gov.in/sites/default/files/approval\\_clearances\\_required\\_for\\_new\\_projects.pdf](https://dipp.gov.in/sites/default/files/approval_clearances_required_for_new_projects.pdf)

[Last Accessed: 10 May 2022]

Approvals/Clearances Required	Department to be Approached and Consulted
<b>Business registration</b>	
Incorporation of the Company	Registrar of Companies
<b>Starting/Registering a unit in state</b>	
Registration/IEM/Industrial license	District Industry Center for Small Scale Industries (SSI) /Secretariat of Industrial Assistance (SIA) for large and medium industries
Finance	i. State Financial Corporation/State Industrial Development Corporation for term loans ii. For loans higher than Rs. 15 million, all India financial institutions like Industrial Development Bank of India (IDBI), Industrial Credit and Investment Corporation of India (ICICI), Industrial Finance Corporation of India (IFCI) etc.
<b>Pre-Commissioning Phase</b>	
Land acquisition	State Directorate of Industries (DI)/ State Industrial Development Corporation (SIDC)/ Infrastructure Corporation/ Small Scale Industrial Development Corporation (SSIDC)
Permission for land use (in case industry is located outside an industrial area)	State DI/Local authority/District Collector
Approvals for lifts & escalators	State local authority
Building Plan Approval	State Industrial development authority/local body
Environmental, Forest and Wildlife Clearance	State Environmental Impact Assessment Authority (SEIAA) or MoEF&CC, GoI depending on the project category
Consent to Establish (NOC) under Water and Air Act	State Pollution Control Board
Factory Layout Plan Approval	State labour department or competent state authority
Provisional Fire Approval	State Fire and Safety Department
Registration of Boilers	State Boiler Department
Registration under Building and other <b>Construction Workers Act (BOCW), 1996</b>	State labour department or competent state authority
Registration under <b>Contract Labour Act, 1970</b>	State labour department or competent state authority

Approvals/Clearances Required	Department to be Approached and Consulted
<b>Post-Commissioning Phase</b>	
Authorization for hazardous waste	Application to State Pollution Control Boards for Collection/ Reception/ Treatment/ Transport/ Storage and Disposal of Hazardous waste
Building Completion Certificate	State Industrial development authority/local nodal authority
Final Fire Approval	State Fire and Safety Department
Central Excise Registration and Customs	Central Board of Indirect Taxes and Customs
Power	State Electricity Distribution Company
Shops & Establishment Act	State Labour Department
Water Connection	SIDC/State Industrial Promotion Boards/Irrigation Department/ Central Groundwater Commission
Employee Registration	Employees' State Insurance Corporation (ESIC) and Employees' Provident Fund Organization (EPFO)
GST Registration	GST Online Portal or at GST Seva Kendra set up by the Central Government
Importer Exporter Code	Directorate General of Foreign Trade (DGFT), Ministry of Commerce and Industries
Professional Tax Registration	State Taxes Department
Trademark/Brand Registration	Office of the Controller General of Patents, Designs & Trade Marks
Consent to Operate	State Pollution Control Board

## Appendix-II: Contact details of Central Insecticides Board & Registration Committee (CIB&RC)

### Central Insecticides Board & Registration Committee

Directorate of Plant Protection Quarantine & Storage

Department of Agriculture, Cooperation & Farmers Welfare

Ministry of Agriculture & Farmers Welfare

Government of India

Old CGO Complex, NH-IV, Faridabad, Haryana-121001

Website: <http://ppqs.gov.in/contactus/central-insecticides-board-and-registration-committee-cibrc>

### Contact person

Secretary, CIB&RC

Tel: +91-1292413002/1292476210

E-mail: [cibsecy@nic.in](mailto:cibsecy@nic.in)

## Appendix-III:

Timeline for registration of insecticides after submission of registration application (According to **Section 9 of Insecticides Act, 1968**)

Generally, the registration process takes 12 to 18 months (depending on the data deficiency, if any) once the application has been submitted.

### **Section 9(3) of the Insecticides Act, 1968 states,**

On receipt of any application for the registration of an insecticides, the Committee may, after such enquiry as it deems fit and after satisfying itself that the insecticides to which the application relates conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the insecticides and its safety to human beings and animals, register<sup>3</sup> [on such conditions as may be specified by it] and on payment of such fee as may be prescribed, the insecticides, allot a registration number thereto and issue a certificate of registration in token thereof within a period of twelve months from the date of receipt of the application:

Provided that the Committee may, if it is unable within the said period to arrive at a decision on the basis of the materials placed before it, extend the period by a further period not exceeding six months

## Appendix-IV: Contact details of Bureau of Indian Standards (BIS)

### **Bureau of Indian Standards**

Room No. 560, Manakalaya

9, Bahadur Shah Zafar Marg,

New Delhi - 110002

Website: <https://www.bis.gov.in/>

Ph: +91-11-23230131

Email: [info@bis.gov.in](mailto:info@bis.gov.in)

## Appendix-V: Contact details of National Center for Vector Borne Disease Control (NCVBDC)

### **National Center for Vector Borne Disease Control**

Directorate General of Health Services

Ministry of Health and Family Welfare

Government of India

22, Sham Nath Marg, Delhi-110054

(Landmark: I.P. College, Near Civil Lines Metro Station)

Website: <https://nvbdcp.gov.in/>

Phone: +91-11-23967745, 23967780

Email: [nvbdcp-mohfw@nic.in](mailto:nvbdcp-mohfw@nic.in)

## Information Resources

1. List of approvals and clearances required for new projects in India provided by the Department for Promotion of Industry and Internal Trade (DPIIT).  
[https://dipp.gov.in/sites/default/files/approval\\_clearances\\_required\\_for\\_new\\_projects.pdf](https://dipp.gov.in/sites/default/files/approval_clearances_required_for_new_projects.pdf)  
[Last accessed: 10 May 2022]
2. Steps involved in the regulatory process for establishing a production unit in India are available on the following websites.  
<https://www.investindia.gov.in/> [Last accessed: 10 May 2022]  
<https://dipp.gov.in/> [Last accessed: 10 May 2022]
3. Guidelines for minimum infrastructure facilities to be created by the manufacturers of microbial biopesticides (Antagonistic fungi, Entomopathogenic fungi, Antagonistic bacteria, Entomotoxic bacteria) to meet the requirements for the issue of manufacturing license by licensing authority of the respective state governments.  
<http://ppqs.gov.in/sites/default/files/c2.12011.doc> [Last accessed: 10 May 2022]
4. (Example) Regulatory requirements for establishing a pesticide manufacturing facility in the State of Maharashtra.  
<https://maitri.mahaonline.gov.in/> [Last accessed: 10 May 2022]
5. General guidelines for registration of insecticides under the **Insecticides Act, 1968** are given on the website.  
<http://ppqs.gov.in/divisions/central-insecticides-board-registration-ommittee/registration-procedure> [Last accessed: 10 May 2022]
6. Guidelines on registration of Entomotoxic bacteria technical and formulation (Bt-bioinsecticides) under Section 9(3B) and 9(3) of the **Insecticides Act, 1968**.  
<http://www.ppqs.gov.in/sites/default/files/2.1.52011.doc> [Last accessed: 10 May 2022]
7. Checklist for registration under Sections 9(3)  
<http://ppqs.gov.in/divisions/cib-rc/checklist> [Last accessed: 10 May 2022]
8. Good labelling practices for pesticides recommended by World Health Organization (WHO).  
<https://www.who.int/publications/i/item/9789241509688> [Last accessed: 10 May 2022]
9. Prerequisites for prequalification vector control on the WHO website.  
<https://extranet.who.int/pqweb/vector-control-products> [Last accessed: 10 May 2022]
10. WHO prequalified vector control products.  
<https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list>  
[Last accessed: 10 May 2022]
11. Packages containing insecticides need to be packed in accordance with the conditions specified in the Red Tariff, issued by the Ministry of Railways.  
<https://indianrailways.gov.in/railwayboard/uploads/Download%20File.pdf>  
[Last Accessed: 10 May 2022]
12. **Insecticides Rules, 1971.**  
[http://ppqs.gov.in/sites/default/files/insecticides\\_rules\\_1971.pdf](http://ppqs.gov.in/sites/default/files/insecticides_rules_1971.pdf) [Last accessed: 10 May 2022]

13. Latest Standard Operating Procedure for introduction of public health pesticides under NVBDCP.  
[https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20\(SOP\)%20%20for%20introduction%20of%20public%20health%20pesticides%20including%20biolarvicides%20in%20the%20NVBDCP.pdf](https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20%20for%20introduction%20of%20public%20health%20pesticides%20including%20biolarvicides%20in%20the%20NVBDCP.pdf) [Last accessed: 10 May 2022]
14. **Indian Contract Act, 1872.**  
<https://www.indiacode.nic.in/bitstream/123456789/2187/2/A187209.pdf>  
[Last accessed: 10 May 2022]
15. Operation Manual for Malaria Elimination in India 2016.  
<https://nvbdcp.gov.in/WriteReadData/l892s/5232542721532941542.pdf>  
[Last accessed: 10 May 2022]
16. Operational Guidelines for Urban Vector-Borne Diseases Scheme 2016, NVBDCP.  
<https://nvbdcp.punjab.gov.in/Download/OPERATIONAL-GUIDELINES-FOR-URBAN-VBD-SCHEME-2016.pdf> [Last accessed: 10 May 2022]
17. **Plastic Waste Rules, 2016.**  
<https://www.egazette.nic.in/WriteReadData/2016/168620.pdf>  
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