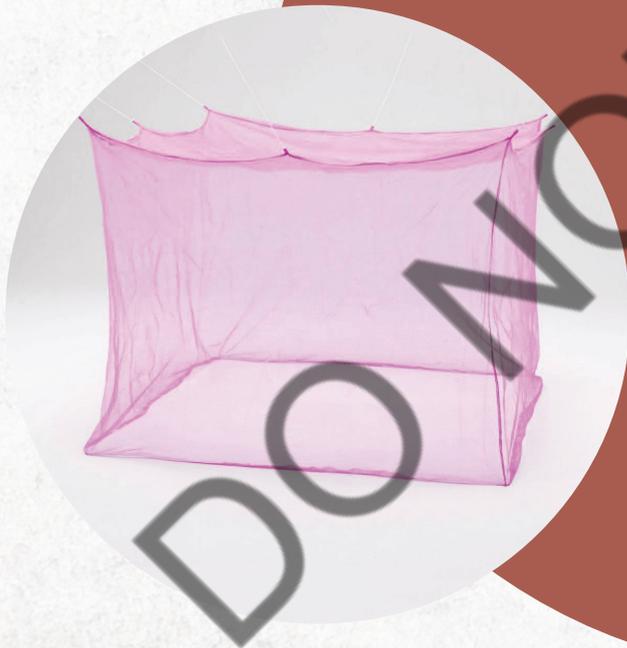




GUIDANCE  
DOCUMENT FOR

**Producers,  
Registration  
Holders, and  
Users for  
Long- Lasting  
Insecticidal  
Nets (LLINs) in  
India**



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**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 Insecticide 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 Insecticide 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.

We also acknowledge the support of colleagues at Toxics Link who provided administrative and technical support in finalization of these documents.

# Abbreviations

<b>BIS</b>	Bureau of Indian Standards
<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>ICMR</b>	Indian Council for Medical Research
<b>IEC</b>	Information, Education and Communication
<b>IS</b>	Indian Standard
<b>LLIN</b>	Long-lasting Insecticidal Net
<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>	World Health Organization Pesticide Evaluation Scheme

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# Guidance Document For Producers, Registration Holders, and Users of Long-Lasting Insecticidal Nets (LLINs) in India

The LLINs are impregnated with chemical pesticides and can have adverse impacts on human health and environment. Therefore, in India, adequate safeguard measures have been outlined in the **Insecticides Act, 1968** and **the Insecticides Rules, 1971** for the producers and registration holders to comply with the various stages of production and registration of LLINs. Some of the key provisions of the Act and Rules are briefly discussed in various sections of this guidance document.

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*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 LLIN
- 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

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*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** includes, inter alia, 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.

LLIN is itself composed of plastic materials such as polyethylene, and LLIN is packed in plastic packaging. Therefore, LLIN producers, registration holders, and users have to comply with various provisions of the **Plastic Waste Management Rules, 2016**. Some of the key provisions are given below:

- Section 6** lays down the Responsibility of urban local body (such as Municipal Corporation, Municipal Council, etc.)
- Section 7** lays down the Responsibility of Gram Panchayat (rural bodies)
- Section 9** lays down Responsibility of Producers, Importers and Brand Owners. This section provides details on the waste collection system based on the Extended Producers Responsibility.

# 1. Guidance for Producers of LLINs (including Exporters and Importers)

In India, LLIN use is already recommended under the National Vector Borne Disease Control Programme (NVBDCP) as a potential eco-friendly alternative to DDT for malaria control. At present, there are only a few producers of LLINs in India. However, there is an emerging opportunity for new LLIN producers as well as importers and exporters, 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, importers and exporters to know and understand the necessary regulatory requirements in the country for carrying out the business of LLIN in India.

The producers can set up the LLIN manufacturing unit for indigenous production and use of their LLINs in India. The LLINs can also be procured (imported) from other countries for use in India. Both the producers of LLIN in India and the importers of LLIN need to register their products with the Central Insecticides Board & the Registration Committee (CIB&RC) of the Directorate of Plant Protection, Quarantine & Storage (PPOS), Ministry of Agriculture & Farmers Welfare, Government of India under the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**. Moreover, if the LLIN is meant for the export purpose only, then also the exporters need to register their LLIN with the CIB&RC.

Apart from the mandatory CIB&RC registration of LLIN, 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 LLIN and the necessary clearances required for setting up a new production unit. The exporters and the importers need to comply with the regulations, especially for export and import purposes.

## 1.1 Regulatory Requirements for Production of LLIN in India

- The producers need to obtain a Certificate of Registration from CIB&RC as per the provisions of the **Insecticides Act, 1968**, necessary clearances and comply with regulatory requirements both at the central and state government levels for setting up the production (or manufacturing unit) of LLIN.
- The Producers must know that setting up a business in India involves 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 below.



**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 list of various approvals and clearances from the Department for Promotion of Industry and Internal Trade (DPIIT) for [setting up a new project](#). 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 producers/importers/exporters must register their LLINs with the Central Insecticides Board & the Registration Committee (CIB&RC) of Directorate of Plant Protection, Quarantine & Storage (PPQS), the Ministry of Agriculture & Farmers Welfare, Government of India, as per various provisions under **Section 9 of the Insecticides Act, 1968**.
- Once LLIN is approved and registered by CIB&RC, the producers need to take the approval from the respective state governments (i.e., manufacturing license) where the production unit of LLINs will be set up. The producers need to approach the Directorate of Agriculture of the respective states or in some cases, the local district agriculture office where the production unit shall be set up to get the LLIN manufacturing license. 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 websites. The producers should refer to the guidelines for the [minimum infrastructure](#) to be created by the producers of pesticides and their formulations to meet the requirements for the issue of manufacturing license by licensing authority of the respective states. As an example, in order to set up a manufacturing unit in the State of Maharashtra, the producers can visit [Maharashtra Industry, Trade and Investment Facilitation Cell](#) website to get information regarding the regulatory requirements for the State of Maharashtra. The producers can also refer to the guidelines on PPQS website if they need to set up an [additional unit for manufacturing](#) the same insecticides.
- All the importers of LLIN importing for the purpose of sale in the country need to obtain the Certificate of Registration from the CIB&RC. Similarly, the exporters of LLIN indigenously manufactured also need to obtain the Certificate of Registration from CIB&RC as per the provisions of the **Insecticides Act, 1968**. Currently, LLINs have been exempted from the excise duty as specified in the Schedule to the **Central Excise Tariff Act, 1985**. However, the producers have to prove through an authorized certificate at the time of clearance, that the goods are required for the Intensified Malaria Control Project (IMCP)-II under the National Vector Borne Disease Control Programme (NVBDCP), funded by Global Fund to fight AIDS, TB and Malaria (GFATM).<sup>1</sup>

### 1.1.1 Registration of LLIN with the CIB&RC

The LLINs are impregnated with chemical insecticides, which can be harmful to human health and environment; therefore, it is mandatory to register the LLIN with the CIB&RC as per the **Insecticides Act, 1968**. The Central Insecticides Board & Registration Committee (CIB&RC) of Directorate of Plant Protection, Quarantine & Storage (PPQS) under the Ministry of Agriculture & Farmers Welfare, the Government of India is responsible for the registration and advice to the Central and State governments on technical matters related to registration of insecticides. [The general guidelines for the registration of insecticides](#) under the **Insecticides Act, 1968** are given on the PPQS website. The contact address of the CIB&RC is provided in **Appendix-II**.

<sup>1</sup> [General Exemption under the Central Excise Act, 1944](https://www.cbic.gov.in/resources/htdocs-cbec/excise/cxt-2016-17-new/cx-gen-exem-61A-75.pdf;jsessionid=49CD7E26F43AC33C39F4210D61C99E80) (https://www.cbic.gov.in/resources/htdocs-cbec/excise/cxt-2016-17-new/cx-gen-exem-61A-75.pdf;jsessionid=49CD7E26F43AC33C39F4210D61C99E80)

- All the insecticides, including LLINs, must be registered by the producer with CIB&RC under **Section 9 of the Insecticides Act, 1968** before they can be produced/imported for sale and distribution in India or produced for export only.
- Therefore, the producers need to check the provisions for the registration of LLINs as mentioned in **Section 9 of the Insecticides Act, 1968**
- If the insecticides 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) of the Insecticides Act, 1968** with the 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. The latest [guidelines on the registration of LLINs under Section 9\(3\)](#) can be referred on the PPQS website
- At present, LLINs are not allowed to be registered under Section 9(4), i.e. "Me too" registration
- The producers need to first apply for inclusion of the chemical in the Schedule to the **Insecticides Act, 1968** for new insecticides to be used for LLINs. The guidelines for [inclusion of new chemicals](#) in the schedule to the **Insecticides Act, 1968** can be referred on the PPQS
- The producers/importers need to refer to Rules under **Chapter III of the Insecticides Rules, 1971** for further guidance on registration of the LLIN
- 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)**, as the case may be to strengthen their registration application
- 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**.
- Once the Certificate of Registration is issued to the producers, the producer becomes the registration holder and has to comply with the stipulated conditions to which the LLIN registration was granted. The Certificate of Registration issued by the CIB&RC specifies the conditions of registration, composition, shelf life, label, doses, uses, safety precautions, etc.

### 1.1.2 Labelling and packaging

The producers must refer to **Chapter V of Insecticides Rules, 1971** for complying with the labelling and packaging requirements of their product. Labelling and packaging are very important, and the producer needs to follow the label and leaflet approved by the CIB&RC and enclosed with the product Certificate of Registration. The labels and leaflets need to be printed in different languages as per guidelines of the 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 the international bidding and export the LLIN may need to follow World Health Organization (WHO) guidelines and can refer to the WHO recommendations for good labeling and packaging practices on the [publications page of the WHO website](#)



Specific Resources:

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

[Recommendations on the Sound Management of Packaging for Long Lasting Insecticidal Nets \(LLINs\)](#)

### 1.1.3 Guidelines for quality of raw materials and LLIN products

The producers must ensure the same quality of raw materials and products during the production of LLINs 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 LLINs 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 LLINs, 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 is available on the WHO website

## 1.2 Responsibility of the producers to comply the Plastic Waste Management Rules, 2016

The LLIN producers are currently using plastic materials in the products as well as in the packaging of LLIN. Therefore, LLIN producers have to comply with various provisions of **Section 9 of the Plastic Waste Management Rules, 2016** issued by the Ministry of Environment, Forests and Climate Change, Government of India as amended from time to time, as their products and packaging materials generate

plastic waste. They need to establish a system for collecting back the plastic waste generated due to their products as per the provisions of **Plastic Waste Management Rules, 2016**.<sup>2</sup>

### 1.3 Compliance of Technical specification of LLIN

The LLIN product should conform to the specifications submitted by the producers to CIB&RC and also to the Indian Standard (IS) specifications and amendments thereof as and when the same are formulated and published. The producers have to approach the Bureau of Indian Standard (BIS) for obtaining IS certification for their product. The specification includes chemical composition, insecticidal dose and strength, the weight of fabric, denier, size, and dimension of the net, etc. These parameters are important in order to ensure the quality of LLIN as specified in the Certificate of Registration. The producers can get the details from the [BIS website](#). The address and the contact details of BIS are provided in **Appendix-IV**.

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

- The producers need to know about the established procedure of LLIN production, which involves insecticides treatment at the production level by a process that binds or incorporates insecticides into the fibers so as to maintain its biological efficacy against vector mosquitoes for at least 3 years under recommended conditions of use in the field. The producers need to follow the conditions for storage and transport of insecticides or insecticidal products in line with **Insecticides Rules, 1971**.<sup>3</sup>
- LLINs are transported by both road and railways. Safe transportation of insecticides requires trained drivers, well-labelled vehicles, checking of quality of packaging and pesticide load during transit and at point of delivery. A systematic tracking system from factory to point of delivery needs to be established by the manufacturers, along with a system for reporting spills and leakages during transit.
- The guidelines for transportation of LLINs are provided in the Operation Manual for Malaria Elimination in India 2016.<sup>4</sup> Further, when the LLINs are 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>2</sup> [Plastic Waste Management Rules, 2016](https://www.egazette.nic.in/WriteReadData/2016/168620.pdf) (https://www.egazette.nic.in/WriteReadData/2016/168620.pdf)

<sup>3</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)

<sup>4</sup> [Operation Manual for Malaria Elimination in India 2016](https://nvbdcp.gov.in/WriteReadData/1892s/5232542721532941542.pdf) (https://nvbdcp.gov.in/WriteReadData/1892s/5232542721532941542.pdf)

## 2. Guidance for Registration Holders of LLINs

All the LLINs 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 applied to all the producers for indigenous sale and/or export as well importers of LLINs into India. For each different LLIN, the producers/importers/exporters need to apply through a separate application for each LLIN product to obtain the Certificate of Registration. After the producers/importers/exporters receive the Certificate of Registration, they will be considered as registration holders of LLINs.

In India, at present LLINs 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 LLIN 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 LLIN for public health use. Only after the registration holders of LLIN are able to get their products approved for use in the national programme, they can participate in the commercial bidding process. The LLIN procurement process is centralized and managed by the Central Procurement Agency, i.e., Central Medical Services Society (CMSS) under the MOH&FW, Government of India through commercial bidding.

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.

Further LLINs are also procured by the defence sector, police departments, and various departments under the Ministry of Home Affairs, India and the registration holders need to follow the procurement procedure of the respective government bodies for the supply of the LLINs to them.

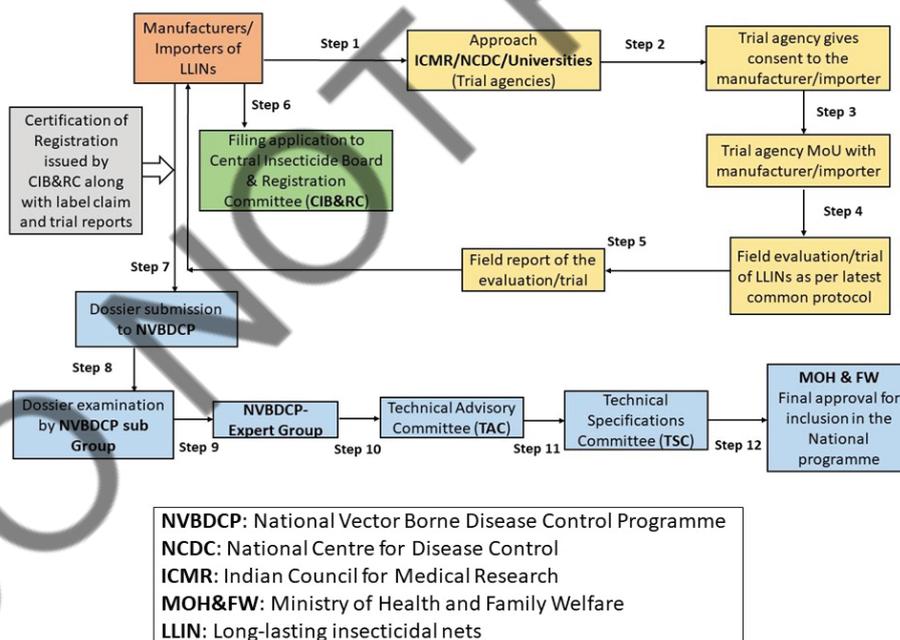
The contact details and addresses of CMSS and NCVBDC are provided in **Appendix-V**.

## 2.1 Inclusion of the registered LLIN in public health programmes by NVBDCP

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

To include any new registered LLIN under NVBDCP, the LLIN needs to be evaluated as per Revised Common Protocol for uniform evaluation of public health pesticides for use in vector control developed by ICMR, NVBDCP and NCDC.<sup>5</sup> Even the WHO prequalified insecticides, including LLINs, 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 LLIN need to submit the complete dossier including the 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 LLINs in the public health programme. The steps involved in the process of LLIN approval for their use in the national public health programme are given in the latest Standard Operating Procedure on the NVBDCP website and shown in the schematic below. The Ministry of Health and Family Welfare (MOH&FW) is the final authority to give approval for the inclusion of new LLINs into the programme.



**Figure 2. Steps for inclusion of LLINs 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 biolarvicides in the National Vector Borne Disease Control Programme<sup>6</sup>)

<sup>5</sup> [Revised Common Protocol for Uniform Evaluation of Public Health Pesticides including Bio-larvicides for use in Vector Control](https://nvbdcp.gov.in/WriteReadData/1892s/Revised-Common-Protocol-2014.pdf) (https://nvbdcp.gov.in/WriteReadData/1892s/Revised-Common-Protocol-2014.pdf)

<sup>6</sup> [Standard Operating Procedure for Introduction of Public Health Pesticides Including Biolarvicides in the National Vector Borne Disease Control Programme](https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20for%20introduction%20of%20public%20health%20pesticides%20including%20biolarvicides%20in%20the%20NVBDCP.pdf) (https://nvbdcp.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20for%20introduction%20of%20public%20health%20pesticides%20including%20biolarvicides%20in%20the%20NVBDCP.pdf)

## 2.2 Commercialization of LLIN by the registration holders through public health programme

The procurement of LLIN in India is carried out through the Central Medical Services Society (CMSS) under MOH&FW, Government of India. The registration holders need to understand the bidding process required for LLIN procurement if their product has been included under the programme. They should carefully go through the bidding document issued by the procuring agency. The registration holders can participate in the bidding process after fulfilling the bidding requirements and conditions. A sample of LLIN bidding document can be referred on the [CMSS website](#).

The successful bidders need to sign the agreement and will abide by the **Indian Contract Act, 1872**.<sup>7</sup> The standard bidding document comprises of the 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 by the bidders. The suppliers must ensure that the manufacturing and expiry dates must be clearly mentioned on the LLINs before being supplied.

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<sup>7</sup> [Indian Contract Act, 1872](https://www.indiacode.nic.in/handle/123456789/2187?locale=en) (https://www.indiacode.nic.in/handle/123456789/2187?locale=en)

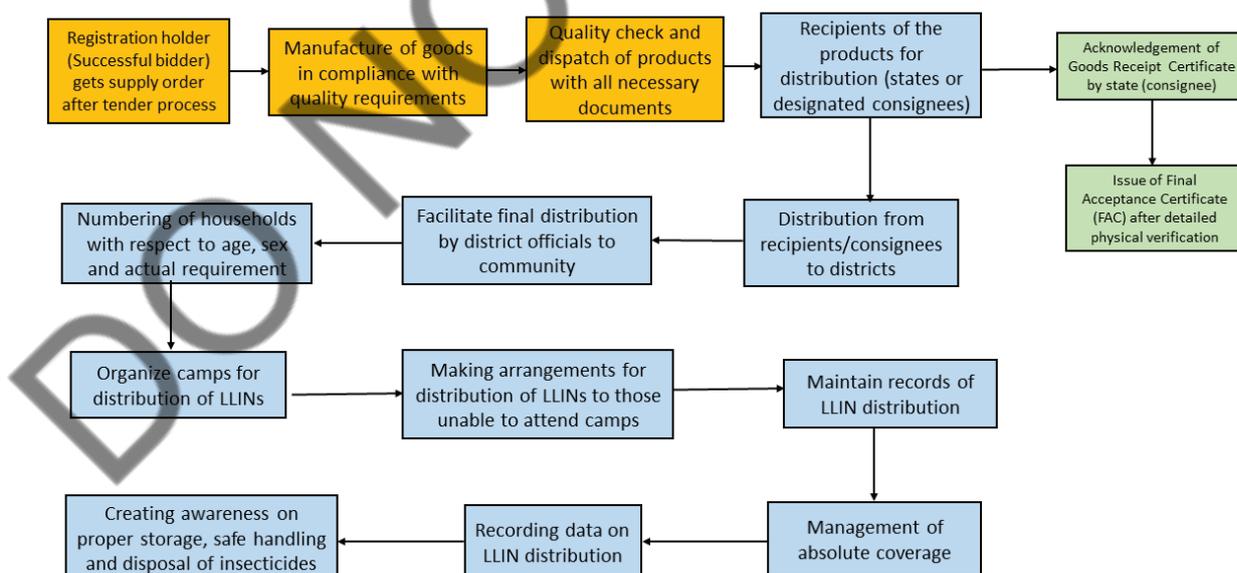
### 3. Guidance for Users of LLINs

In India, all the implementation guidelines for the vector control programme, including the guidelines for distribution and use of LLINs, are issued by the Government of India. However, as health being a state subject in India, the implementation of programme activities, including the distribution of LLINs to the target communities 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 including LLIN.

The state governments need to submit their LLIN requirements to the Government of India annually. Based on the requirements, the Government of India authorized procurement agency (i.e. CMSS) procures and supplies LLINs to the states or their designated consignees through commercial bidding. The LLINs received are further distributed by the designated consignees to the target communities who are the ultimate beneficiaries.

Therefore, the key users may be divided into two categories:

1. Recipient of the products for distribution i.e., service providers including technical, administrative, logistics officials at the state, district, and block/primary health centres (consignees) and
2. Communities who are the ultimate beneficiaries of the control measures under NVBDCP (end users or ultimate beneficiaries)



**Figure 3. LLIN supply and distribution to end-users under NVBDCP**

(This figure is drawn by Toxics Link based on the guidelines provided in the Operation Manual for Malaria Elimination in India 2016<sup>8</sup>)

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

## 3.1 Recipients of the LLINs for distribution

### 3.1.1 Guidance for Recipients of LLIN procured by NVBDCP for distribution i.e., service providers including technical, administrative, logistics officials at the state and district levels (consignees)

- The designated state government officials need to assess the population at risk and work out their LLIN requirements based on the NVBDCP guidelines and advisories issued from time to time. Currently, the set norm is 1 LLIN for 1.8 person as per NVBDCP guidelines. The state officials should sensitize the designated districts officials for working out the requirements of different sizes of LLINs, as approved in the vector control programme, in their respective districts. The demand thus generated need to be projected in the state's annual action plan with due justification which is submitted through NVBDCP every year for approval to the Government of India
- Generally, LLINs are centrally procured through central procurement agency and supplied to the states. Therefore, the states should prepare a list of the consignee(s) within the states with full address and contact details and send to the central procurement agency both by email and post. After the central procurement agency's notification of supply order to the successful bidders (suppliers), the States should inform all their respective consignees to arrange adequate storage space to store the LLINs received from the supplier. The states can also refer to the Operational Manual for Malaria Elimination in India 2016 for guidelines on LLIN distribution
- Adequate storage of LLINs is very crucial. Therefore, the State needs to put a system in place to regularly monitor LLIN storage conditions and provide necessary guidance and instructions to the concerned officials to ensure proper storage within the available resources. The storage place needs to have proper security and surveillance to avoid any sort of mishap. A dedicated nodal person has to be assigned exclusively for managing the storage. Special care should be taken to avoid rodent nuisance where the LLINs are being stored.
- A copy of the order placed to the successful bidder (supplier) is marked to the consignees (State) to issue road permits and ensure the availability of space for storage before delivery. The supply is usually started by the supplier after completing the pre-dispatch formalities as per tender terms and conditions and on receipt of road permits
- The designated State officials (consignee) need to acknowledge the receipt of goods and issue the consignee acceptance certificate to the supplier as well as to the procurement agency in the standard format. The consignees should make all arrangements to avoid any demurrage charges of the goods and document discrepancy.
- The Final Acceptance Certificate needs to be issued by the consignee after detailed physical verification of the quantities, specifications, batch number, expiry date, delivery schedule, and certificate of quality control test results in conformity with the standards as provided in the technical specifications. The details of the goods received need to be entered in the stock register with the signature/verification report of the receiving authority within one month or stipulated time

The checklist for receiving commodities, checklist for physical verification, standard format for consignee acceptance certificate, final acceptance certificate, and guidelines for storage of commodities are given in Annex 23, Pages 230–236 of Operation Manual for Malaria Elimination in India 2016.<sup>9</sup>

### 3.1.2 LLIN allotment by states/districts to blocks/PHCs/sub centres

- The States and Union Territories should develop and follow state-specific LLIN distribution plans in line with NVBDCP advisories issued from time to time. The States/ Union Territories should issue advisory guidelines to the districts for smooth implementation of LLIN distribution-related activities
- The state will make the allotment for the district as per their requirement and district action plan. The districts are divided into different blocks (sub districts), blocks into primary health centres (PHCs), PHCs into health sub centres (HSCs), and HSCs into villages for better planning and distribution of LLINs to the target communities. If there is one district covering for 3 to 4 clusters districts, financial planning and arrangement should be accordingly made for each district.
- Prior to the distribution process in the concerned district, a District Task Force meeting need to be conducted under competent authority (district collector and district magistrate) with the involvement of line departments especially law enforcement agencies.
- The designated officials will be responsible for receiving and storing LLINs supplied by state/district and ensuring timely supply of LLIN stock to different sub-centers/blocks selected for LLIN distribution
- The state should fill up the stock position statement by compiling the data received from the districts and submitting it to the Directorate of NVBDCP, every quarter. They should also issue the quarterly consumption certificate and finally the annual consumption certificate with details like consumption, stock in hand, further requirements, etc.
- The state/district authority if feels necessary may randomly check the quality of the items as per the state procedure by an independent, authorized testing laboratory and document the test reports.

The information on the [State Pesticides Testing Laboratories](#) and [Regional Pesticide Testing Laboratories](#) is given on the PPQS website. Further, a list of [GLP/NABL laboratories permitted for analysis](#) is also provided on the PPQS website. If any discrepancy is noticed, the state should inform NVBDCP immediately for further necessary action

- The designated consignees within the state/districts should know the arrival of the goods, batch number, specifications and make the arrangements for receipt of the goods
- The state should be aware and develop a plan on the safe disposal of LLINs and LLIN plastic packaging material in line with the provisions of the **Plastic Waste Rules, 2016**, as amended from time to time. The district/block level officials should take necessary steps for the disposal of LLIN and LLIN packaging materials as per the guidelines communicated by the state.

<sup>9</sup> [Operation Manual for Malaria Elimination in India 2016](https://nvbdcp.gov.in/WriteReadData/1892s/5232542721532941542.pdf) (https://nvbdcp.gov.in/WriteReadData/1892s/5232542721532941542.pdf)

### 3.1.3 LLIN distribution to the community

- Distribution of LLINs to the community needs to be planned meticulously with a detailed distribution plan and strategy. The distribution guidelines should be formulated by the state and communicated to the districts.
- The concerned block level officials need to list out the villages and conduct a rapid survey before LLIN distribution. Every household in a village should be numbered and listed with age and sex to estimate the LLIN requirements. It is desirable to keep buffer stock in case of a shortage. LLINs should be distributed to the community by the officials as early as possible after receipt of goods. Adequate funding should be made for transportation from the consignees to end users.
- LLINs are provided free of charge to all the members residing in the targeted villages. The distribution can be done through public health facilities or at community-level camps. During the distribution, the officials may seek the support from community-based organisations (CBOs), non-government organisations (NGOs), and faith-based organisations (FBOs). To have a smooth distribution of LLIN to the community, the local leaders, Gram Panchayat, Municipalities, or administrative authorities must be involved
- The date of distribution of LLINs can be informed to the community members and others at least 7 days prior to distribution. A respected person from the village may be invited to inaugurate the LLIN distribution process

The distribution of LLINs involves the following:

- Organize camps for distribution of LLINs
  - Keep records of LLIN distribution using the prescribed formats
  - Plan for distribution to those who are unable to attend the camps
- 
- The state government should plan an effective communication strategy, both pre- and post-distribution to reach out to the community for acceptance and use of LLINs in a proper way. The state government should develop proper Information, Education and Communication (IEC) materials in vernacular language depicting the correct use of LLINs. Special focus should be on reaching out to vulnerable groups such as the tribal population
  - LLINs are also being distributed to residential schools. The district-level officials should sensitize the concerned school officials on proper storage and use of LLIN so that they can create awareness among the children about it
  - Those involved in LLIN distribution to the community members should take the following measures:
    - They should demonstrate the method of the correct hanging of LLINs as well as how to use them for sleeping outdoors by tying them to four sticks during distribution
    - They should use local language to ensure effective use of LLINs
    - They should carry out periodic visits to check the effective use of LLINs by the community members and avoiding their use for other purposes (such as misuse of LLIN for fishing)

- They should provide proper instructions regarding washing of LLINs and precautions to be taken while using LLINs

### Management of absolute coverage

Universal coverage is to cover 100% population at risk, which may not be achieved sometimes due to procurement and supply issues. In such a scenario, the concerned state government authorities should ensure that the balance of available stock should also be used. The concerned state government agencies should sensitize the community for 100% use, i.e., all the residents in that area should use LLINs without fail. This should be monitored by the local authorities using indicators such as the percentage of households with at least one LLIN, percentage of population with access to a LLIN within the household, percentage of population sleeping under LLIN and separately percentage of children under five years sleeping under LLIN. For best effectiveness in the community, coverage of the population at risk with LLINs must be as close to 100% as possible with a high utilization rate (>80%). The users can refer to the WHO recommendations for achieving universal coverage with long-lasting insecticidal nets in malaria control.<sup>10</sup>

### 3.2 End users/beneficiaries i.e., community

- The community users need to carefully go through the leaflets (depicting directions for use and precautions taken during use) and IEC material provided if any while using LLINs
- The users should follow the instructions given to them during distribution if they encounter any health issues, especially while using LLINs for the first time. The users need to bring to the notice of the concerned village level or block level officials if they face persistent health issues because of LLIN usage
- The users should follow the instructions for proper storage and washing of LLIN, which should be communicated to them by the concerned officials during distribution. The users need to keep the LLIN safely after completing its lifespan of three years and can use it as plain nets because the insecticides content would have been washed off.

Various activities which can be supported and/or monitored by the community in the malaria control programme, specific to the use of LLINs are:

- Ensuring equitable bed net distribution, as per norms
- Preventing sale of bed nets by recipients for ensuring their use
- Alerting appropriate authorities regarding any malpractices

<sup>10</sup> [WHO recommendations for achieving universal coverage with long-lasting insecticidal nets in malaria control, September 2013 \(revised March 2014 and 2017\)](https://www.who.int/docs/default-source/malaria/mpac-documentation/mpac-oct2017-draft-updated-recommendations-universal-lin-coverage-session9.pdf?sfvrsn=5af603e8_2) (https://www.who.int/docs/default-source/malaria/mpac-documentation/mpac-oct2017-draft-updated-recommendations-universal-lin-coverage-session9.pdf?sfvrsn=5af603e8\_2)

## 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

<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: Section 9(3) of the Insecticides Act, 1968 states that:**

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 Central Medical Services Society (CMSS)**

#### **Central Medical Services Society**

(An Autonomous Body under Ministry of Health and Family Welfare, Govt. of India)

2<sup>nd</sup> Floor, Vishwa Yuvak Kendra

Pt. Uma Shankar Dikshit Marg,

Teen Murti Road,

Opp. Police Station, Chanakyapuri,

New Delhi-110021

Website: [www.cmss.gov.in](http://www.cmss.gov.in)

Tel: +91-11-21410905/6

## Appendix-VI: 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)

Phone: +91-11-23967745, 23967780

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

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

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## 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 to be created by the producers of pesticides and their formulations to meet the requirements for the issue of manufacturing license by licensing authority of the respective states.  
<http://ppqs.gov.in/sites/default/files/c12011.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 LLINs under **Section 9(3)**.  
<http://ppqs.gov.in/sites/default/files/1.142011.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. Recommendations on the Sound Management of Packaging for Long Lasting Insecticidal Nets (LLINs).  
<https://apps.who.int/iris/bitstream/handle/10665/338356/WHO-HTM-GMP-MPAC-2014.1-eng.pdf?sequence=1&isAllowed=y> [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]  
Prerequisites for prequalification vector control on the WHO website. <https://extranet.who.int/pqweb/vector-control-products> [Last Accessed: 10 May 2022]
11. **Plastic Waste Rules, 2016.**  
<https://www.egazette.nic.in/WriteReadData/2016/168620.pdf>  
[Last Accessed: 05 Jan 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. Packages containing insecticides shall 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]
14. 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]
15. Sample CMSS bidding document.  
<http://cmss.gov.in/sites/default/files/Tender%20LLIN-1.pdf> [Last Accessed: 10 May 2022]
16. **Indian Contract Act, 1872.**  
<https://www.indiacode.nic.in/handle/123456789/2187?locale=en> [Last Accessed: 10 May 2022]
17. Operation Manual for Malaria Elimination in India 2016.  
<https://nvbdcp.gov.in/WriteReadData/l892s/5232542721532941542.pdf> [Last Accessed: 10 May 2022]

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