









Guidance for

Producers and Registration holders of Long-Lasting Insecticidal Nets

In the fight against malaria, the United Nations Industrial Development Organization (UNIDO) and United Nations Environment Programme (UNEP), supported by the Global Environment Facility (GEF), are working with India to develop and promote non-persistent organic pollutants (POPs) alternatives to dichlorodiphenyltrichloroethane (DDT). These include long-lasting insecticidal nets (LLINs): mosquito nets that have insecticide bind to or incorporated within the fibres.

As part of the Government of India's Ministry of Health, Family and Welfare (MoHFW), the National Center for Vector Borne Diseases Control (NCVBDC) recommends the use of LLINs as a core vector control intervention for prevention of malaria. These nets are safe, effective, environmentally friendly and sustainable alternative to DDT.

In light of India's commitment to phase out DDT production and the predicted rise in demand for DDT alternatives, specifically LLINs, under India's vector control programme, there is a significant opportunity for new LLINs producers and importers. Moreover, India can become a potential production hub for LLINs, considering the substantial opportunities for exporting these products to cater to the international market.

It is important for the producers, exporters and importers to know and comply with the necessary regulatory requirements established by the Government of India and the respective state governments.

Important Regulations

- Insecticides Act, 1968 and Rules, 1971
- Indian Contract Act, 1972
- Plastic Waste Management Rules, 2016
- Solid Waste Management Rules, 2016



GUIDANCE FOR PRODUCERS, IMPORTERS, AND EXPORTERS OF LLINS

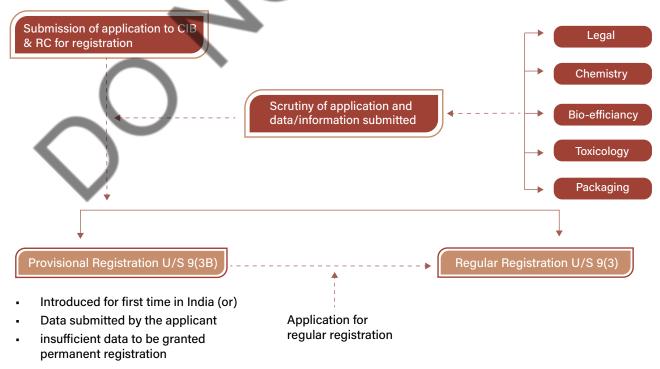
Regulatory processes to be followed for setting up a manufacturing unit for indigenous use as well as export

Regulatory processes to be followed to start a new business/manufacturing facility in India¹

Setting up a legal existence Starting/Registering a unit Obtain DIN, PAN, TAN Registering/Categorization **Digital Signature** of unit in State Certificate for proposed Approval for State directors Incentives (optional) Application for issue of IEM/ME certificate of Registration/Industrial Incorporation License/MSME Registration of GST, etc. Registration, etc **Starting** Manufacturing **Facility in India** Post-Commissioning phase Pre-Commissioning phase Consent to operation Acquisition of land **Building Completion Certificate** Environmental clearances Final Fire Approval Consent to Establish Water and Power Connection Factory Layout Plan Authorization for Hazardous Approval **Building Plan Approval** Professional and Central Tax Provisitional Fire Approval, Registration, etc.

Mandatory registration of LLIN by all domestic producers as well as importers

Registration process of LLIN



- Approval from the respective state governments, where the production unit is set up (Manufacturing license)
- Complying with Regulations
 - Compliance with stipulated conditions (for example, technical specifications, labelling and packaging, quality of raw materials, etc.) specified in the Certificate of Registration issued by CIB&RC
 - Fulfilling regulatory requirements before and after the commissioning of the production facility. (Simultaneous applications for LLIN registration and necessary clearances are possible)
 - Compliance with regulations for export and import purposes (only for exporters and importers)

Exporters who participate in international bidding may need to follow WHO guidelines



Guidelines for quality control of pesticides. International code of conduct on the distribution and use of pesticides²

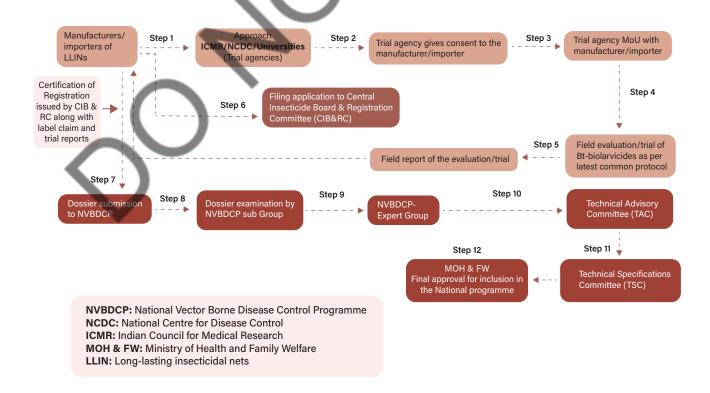


<u>Vector control product</u> prequalification page^{3,4}

GUIDANCE FOR REGISTRATION HOLDERS OF LLINS

All LLINs intended for sale, export, or import must be registered individually with CIB&RC. Once the Certificate of Registration is issued to the producers and importers, they become the registration holders.

- Inclusion of the registered LLIN in public health programmes by National Vector Borne Disease Control Programme (under NCVBDC)
 - Currently, LLINs only permitted for use in public health programs and not for retail sale
 - Registration holders need to approach the NCVBDC* for inclusion of their LLLIN in the national public health programmes.



Revised Common Protocol for Uniform Evaluation of Public Health Pesticides including Bio-larvicides for use in Vector Control 5

 $\underline{\textbf{Standard Operating Procedure for Introduction of Public Health Pesticides Including Biolarvicides in the National Vector Borne}\\ \\ \textbf{Disease Control Programme } \underline{\textbf{6}}$

- Ommercialization of LLIN through public health programmes
 - Centralized LLIN procurement process managed by the Central Medical Services Society (CMSS) under the Ministry
 of Health & Family Welfare, Government of India
 - · Also procured by defence sectors, police departments, and various departments under the Ministry of Home Affairs
 - · Complying with the procurement procedure and bidding conditions of the respective government bodies

IMPORTANT WEB LINKS

Central Insecticides Board & Registration	ppqs.gov.in/divisions/central-insecticides-board-registration-
Committee (CIB&RC)	committee
Bureau of Indian Standards (BIS)	www.bis.gov.in/
National Center for Vector Borne Disease	ncvbdc.mohfw.gov.in/
Control (NCVBDC)	
Central Medical Services Society (CMSS)	www.cmss.gov.in/

 $^{1. \}qquad \text{https://dipp.gov.in/sites/default/files/approval_clearances_required_for_new_projects.pdf} \\$

^{2.} https://www.who.int/publications/i/item/who-htm-ntd-whopes-2011.4

^{3.} https://extranet.who.int/pqweb/vector-control-products

^{4.} https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list

^{5.} https://ncvbdc.mohfw.gov.in/Doc/Revised-Common-Protocol-2014.pdf

^{6.} https://ncvbdc.mohfw.gov.in/Doc/Final%20Interim%20Standard%20Operating%20Procedure%20(SOP)%20%20for%20introduction%20 of%20public%20health%20pesticides%20including%20biolarvicides%20in%20the%20NVBDCP.pdf