



GUIDANCE
DOCUMENT FOR

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



DO NOT PRINT

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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 13th 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

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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.

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Abbreviations

ASU	Ayurvedic, Siddha and Unani
BIS	Bureau of Indian Standards
CDSCO	Central Drugs Standard Control Organization
CIB&RC	Central Insecticides Board & Registration Committee
DDT	Dichlorodiphenyltrichloroethane
DPIIT	Department for Promotion of Industry and Internal Trade
FAO	Food and Agriculture Organization
IS	Indian Standard
IEC	Information, Education and Communication
MOHFW	Ministry of Health and Family Welfare
NVBDCP	National Vector Borne Disease Control Programme
PPQS	Directorate of Plant Protection, Quarantine & Storage
WHO	World Health Organization

Guidance Document For Producers, Registration Holders, and Users of Neem-Based Products

In India, neem-based products are being used as mosquito repellents only through the retail market and no neem product is being approved for use in the public health program. Depending on the composition of the product, the neem-based products meant for vector control are regulated under the **Insecticides Act, 1968** or the **Drugs and Cosmetics Act, 1940**.

The neem-based products (containing neem extracts) to be used as mosquito repellents are considered as Ayurveda medicines/drugs and are regulated under the **Drugs and Cosmetics Act, 1940** and **Drugs and Cosmetics Rules 1945** (now known as **Drugs Rules, 1945**) as amended from time to time. In addition to creams, products having neem extracts with other herbs or oils such as liquid vaporizers, room spray, incense sticks to be used as mosquito repellents are regulated under the **Drugs and Cosmetics Act, 1940** and licensed as Ayurvedic medicinal products.

*The **Drugs and Cosmetics Act, 1940** regulates the import, manufacture, and distribution of drugs and cosmetics in India*

Chapter IV provides details on the manufacture, sale, and distribution of drugs (standards of quality, prohibition of manufacture and sale of certain drugs, etc.)

Chapter IVA lays down provisions relating to Ayurvedic drugs

*Some of the important provisions of the **Drugs Rules, 1945** important for the producers of neem-based products are given below:*

Part XVI on the Manufacture for Sale of Ayurvedic, Siddha or Unani Drugs

Part XVII on the Labelling, Packing and Limit of Alcohol in Ayurvedic (including Siddha) or Unani Drugs

Part XIX on the Standards of Ayurvedic, Siddha and Unani Drugs

However, the neem-based products containing "**Azadirachtin**" as primary ingredient for use as household insecticides for vector control (hereafter referred to as neem-based insecticides), are regulated by the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**. The producers and registration holders of neem-based insecticides have to comply with the provisions of the said Act and 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 neem-based products for vector control
- 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 Neem-based products (including importers and exporters)

Plant-based pesticides are increasingly gaining popularity, as they exhibit a multitude of components that minimize the chance of resistance to synthetic chemical pesticides in mosquitoes. Neem (*Azadirachta indica*) has emerged as one of the highly potent bio-pesticide and its derived products have shown a variety of insecticidal properties against a wide range of insect species, including malaria. Moreover, neem-based products are eco-friendly and act as potential alternatives to DDT for malaria control.

At present, neem-based products for mosquito control can either be registered as insecticides or as drugs, depending on the composition of the product.

Neem-based products as Insecticides

In India, neem-based products containing **Azadirachtin (an active principle in neem) as primary ingredient for use as household insecticides** have to be registered only with the Central Insecticides Board & the Registration Committee (CIB&RC) and the producers of such neem-based insecticides have to apply for manufacturing license to the state insecticides licensing authorities. Further 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 neem-based products and the necessary clearances required for setting up a new production unit. The importers and exporters need to comply with the regulations, especially for export and import purposes.

The producers can set up the manufacturing unit for indigenous production and use of neem-based insecticides in India or for production and export to other countries or for both. The importers and producers of neem-based insecticides in India, including for export purposes need to register their products 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**.

Neem -based products as Ayurvedic Drugs

In India, any formulation containing any part(s) of the neem plant as a wholesome ingredient qualifying under section 3(a) or 3(h)(i) of the **Drugs and Cosmetics Act, 1940** and **Drugs Rules, 1945**¹ are considered as Ayurvedic drugs and are regulated under the **Drugs and Cosmetics Act, 1940** and **Drug Rules 1945**.

However, formulation containing phytochemicals isolated from neem (fractions), the produces need to take license as per the provisions of Phytopharmaceuticals as defined under Rule 2(eb) of the **Drugs Rules, 1945** from the Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health and Family Welfare (MoHFW).

1.1 Regulatory Requirements for Production of neem-based insecticides

- The producers need to obtain the Certificate of Registration, necessary clearances and comply with regulatory requirements both at the central and state government levels for setting up the production (or manufacturing unit) of neem-based insecticides
- The Producers must know that setting up a business in India involves the following steps; 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.

¹ **The Drugs and Cosmetics Act, 1940 and Rules, 1945** (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf)

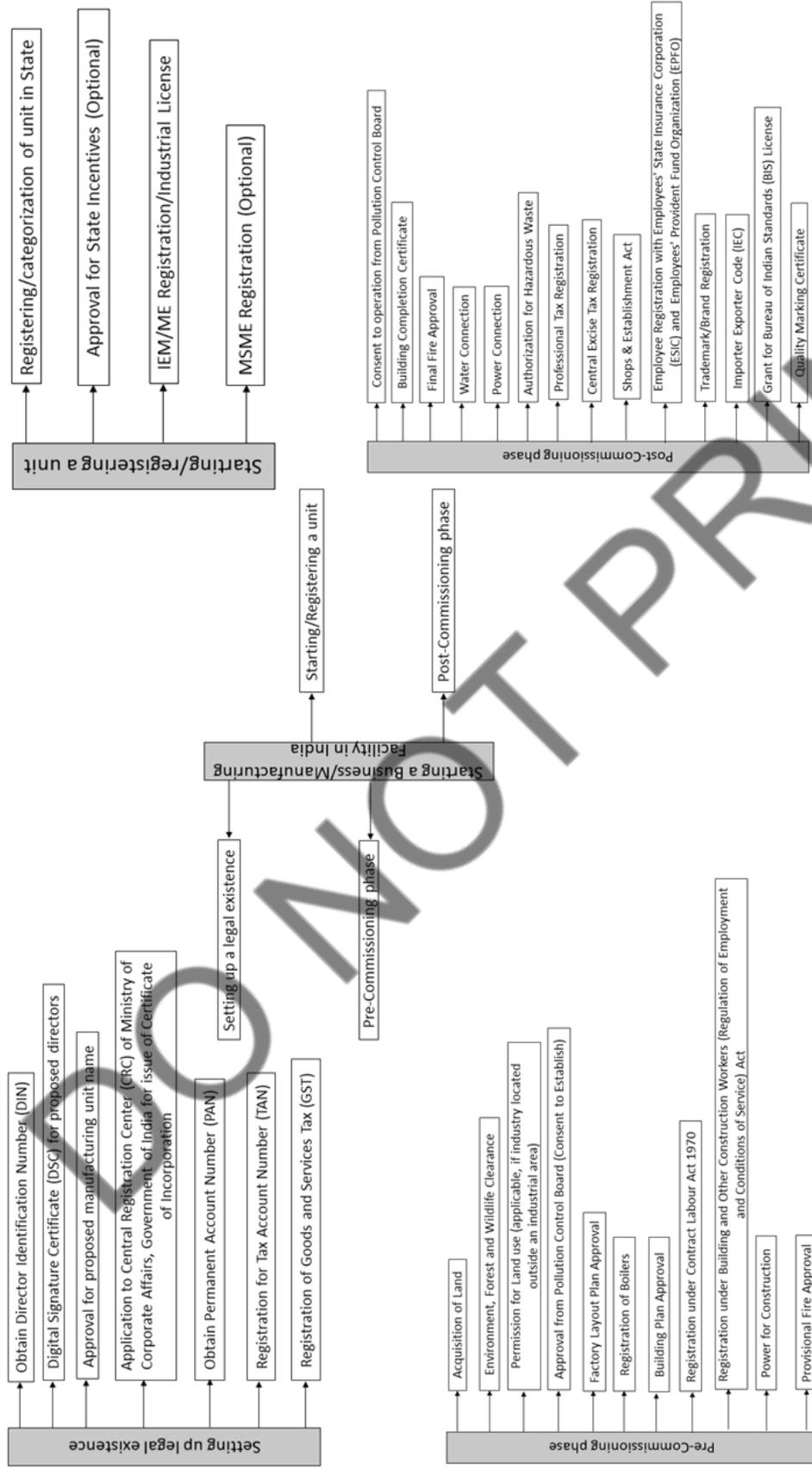


Figure 1. Regulatory processes to be followed to start a new business/manufacturing facility in India

[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. It may also be mentioned that, the necessary clearances for setting up a new production unit and applying for registration of neem-based products for use as household insecticides may be done simultaneously.
- All the producers/importers/exporters must register their neem-based products (botanical pesticides) with Central Insecticides Board & Registration Committee (CIB&RC), Directorate of Plant Protection, Quarantine & Storage (PPQS), Ministry of Agriculture & Farmers Welfare, Government of India, as per various provisions under **Section 9 of the Insecticides Act, 1968**.
- Once neem-based products are 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 neem-based products will be set up. 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 manufacturers can refer to the guidelines for [minimum infrastructure](#) facilities to be created by the manufacturers of botanical pesticides to meet the requirements for the issue of license by the respective state governments. 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 obtain 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 neem-based insecticides.
- After the issue of manufacturing license, it is necessary to obtain a license to sell, stock, or exhibit for sale or distribute insecticides, including neem-based products, and applications for the same shall also be made to the licensing officer
- If the product is proposed 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
- All the importers of neem pesticides importing for the purpose of sale in the country need to obtain the Certificate of Registration from the CIB&RC. Similarly, the exporters of neem pesticides indigenously manufactured 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 neem-based insecticides with the CIB&RC

The Central Insecticide Board & Registration Committee (CIB&RC) of 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 pesticides. 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 neem-based products containing Azadirachtin for household uses must be registered by the producers with the CIB&RC under the **Insecticides Act, 1968** before they can be imported/ manufactured for sale and distribution in India or produced for export only
- The producers need to check different provisions for the registration of insecticides as mentioned in **Section 9 of the Insecticides Act, 1968**
- If the neem-based pesticides 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 any 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 in case a neem-based product containing Azadirachtin for use as a household insecticides has already been registered in India on the application of any producer, any other producer desiring to manufacture or import that insecticides has to apply under **Section 9(4) of the Insecticides Act, 1968**. This is also known as “Me-too” registration
- The latest details on the [registration of neem-based products containing Azadirachtin for use as household insecticides](#) are given on the CIB&RC website. The producers can also refer to the [latest guidelines on the registration of all insecticides](#) under **Section 9(4)** on the PPQS website
- Some of the important provisions to be considered while registration of neem-based products for household use are:
 - The active ingredients should be only Azadirachtin, and other constituents associated during extraction of neem
 - Data on persistence on residual toxicity of insecticides on different types of surfaces should be generated
 - Health monitoring study of the users and/or spray operators by the household insecticides (which emit vapours, e.g., mats and coils) in actual use
- The producers/importers need to refer to Rules under **Chapter III of the Insecticides Rules, 1971** for further guidance on registration of the neem-based products.
- 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 **Sections 9(3) and 9(4)**, 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 product 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 need to follow the Insecticides (Price, Stock Display and Submission of Reports) Order, 1986² issued under the **Essential Commodities Act, 1955**³ that regulates the display of stock and price list of insecticides, manufacturers and dealers to give memorandum to purchasers; compliance by manufacturers with certain requirements in regard to packing; maintenance of records and submission of returns, etc.

The producers who are interested in participating in the international bidding and exporting neem-based products 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](#)

1.1.3 Guidelines for quality of neem-based insecticides

The producers must ensure the same quality of products and their constituents during the production of neem-based products 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.

1.1.4 Procedures to be followed for transport and storage

The producers need to follow the guidelines for the storage and transport of insecticides in line with the **Insecticides Rules, 1971**.⁴ As the insecticides are generally transported by railways, the packages

² [Insecticides \(Price, Stock Display and Submission of Reports\) Order, 1986](https://upload.indiacode.nic.in/showfile?actid=AC_CEN_23_31_00001_196846_1517807318487&type=notification&filename=28_january_1986_g.s.r._71(e).pdf) (https://upload.indiacode.nic.in/showfile?actid=AC_CEN_23_31_00001_196846_1517807318487&type=notification&filename=28_january_1986_g.s.r._71(e).pdf)

³ [Essential Commodities Act, 1955](https://legislative.gov.in/sites/default/files/A1955-10.pdf) (https://legislative.gov.in/sites/default/files/A1955-10.pdf)

⁴ [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)

containing insecticides shall 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**.

1.2 Regulatory Requirements of neem-based products as drugs

In India, any formulation containing any part(s) of the neem plant as a wholesome ingredient are considered as Ayurvedic drugs and regulated under the **Drugs and Cosmetics Act, 1940** and **Drugs Rules, 1945** as amended from time to time. The producers of neem based mosquito repellent creams, liquid vaporizer, room spray, incense sticks need to get these products register as Ayurveda medicine/drugs under the **Drugs and Cosmetics Act, 1940**.

- The producers who intend to develop neem based Ayurvedic formulations for the production of the drugs for mosquito control can refer to the [general guidelines provided by the Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH](#), Government of India for the purpose of safety/toxicity studies, clinical trials and overall drug development.
- All the producers of neem-based Ayurvedic drugs have to apply license to the concerned State Licensing Authority to produce, sale or distribute Ayurvedic drugs in the respective states. The application for manufacturing Ayurvedic drugs shall be processed through [portal e-AUSHADHI](#)
- The producers can refer to the various provisions on quality standards of neem based products issued by the concerned agencies.
 - Ayurvedic Pharmacopoeia of India (API) published by [Pharmacopoeia Commission for Indian Medicine & Homoeopathy](#), Ministry of Ayush
 - Neem Leaf: API Part 1-Vol (2)
 - Neem Stem bark: API Part 1-Vol (2)
 - Neem Root bark: API Part 1-Vol (5)
 - Neem Flower: API Part 1-Vol (5)
 - Neem Fruit: API Part 1-Vol (5)
 - [Quality Standards of Indian Medicinal Plants](#) published by Indian Council for Medical Research (ICMR)⁵
 - Herbal Monographs, [Indian Pharmacopoeia Commission](#), Ministry of Health & Family Welfare (MoHFW)

In case of export purposes, the producers should also know about [guidelines for efficacy testing of mosquito repellents for human skin](#) provided by WHO

⁵ [Quality Standards of Indian Medicinal Plants-Volume XI](https://mpd.icmr.org.in/qs11.php) (<https://mpd.icmr.org.in/qs11.php>)

- The producers and importers of new neem-based phytopharmaceutical drugs for mosquito control need to take the approval from the CDSCO, Directorate General of Health Services, MoHFW, Government of India under the regulatory provisions for 'Phytopharmaceuticals' as has been defined in Rule 2(eb) of the **Drugs Rules, 1945**.

1.3 Other relevant regulations for neem-based products

- The producers need to comply with the state specific regulations, if any to regulate the raw materials for neem-based products. For example, in the State of Uttar Pradesh (U.P.) under the **Protection of Trees in Rural and Hill Areas Act, 1976**⁶, notifications have been issued to prohibit cutting of neem trees from forests and grove-lands, for preservation of neem trees, and prescribing procedure for seeking permission for felling of neem trees among others. In Tamil Nadu, **Warehouses Act, 1951**⁷ regulates licensing of warehouses in Tamil Nadu for storage of neem seeds, neem oil cakes and neem oil. Similarly, the **Tamil Nadu Agricultural Produce Marketing (Regulation) Act, 1987**⁸ regulates Neem seeds (under the category of Oil Seeds) as an agricultural produce.
- Importers of neem dried seeds and neem cake also need to obtain a phytosanitary certificate issued by the exporting country under the **Plant Quarantine (Regulation of Import into India) Order, 2003**⁹ issued in exercise of the powers conferred under the **Destructive Insects and Pests Act, 1914**¹⁰.
- The exporters need to know that neem seeds are a restricted category¹¹ with exports permitted under license and is regulated under the **Foreign Trade (Development and Regulation) Act 1992**¹².

The producer needs to refer various standards on neem based products issued by the Bureau of Indian Standards (BIS).

IS 4765:1975-Specification for neem kernel oil and depulped neem seed oil

IS 7787:1975-Grading for neem kernel and depulped neem seeds for oil milling

IS 14299:1995-Neem extract concentrate containing azadirachtin

IS 14300:1995-Neem based EC containing azadirachtin

The producers can get the [detailed IS specification](#) on the BIS website

The address and the contact details of BIS are in **Appendix-IV**.

6 **Uttar Pradesh Protection of Trees in Rural and Hill Areas Act, 1976** (https://forest.uk.gov.in/uploads/general_rules/1616585726.pdf)

7 **Tamil Nadu Warehouses Act, 1951** (https://lawsofindia.blinkvisa.com/pdf/tamil_nadu/1951/1951TN15.pdf)

8 **Tamil Nadu Agricultural Produce Marketing (Regulation) Act, 1987** (https://www.indiacode.nic.in/bitstream/123456789/13245/1/act-27-1987_final_marketing.pdf)

9 **Plant Quarantine (Regulation of Import into India) Order, 2003** (<https://plantquarantineindia.nic.in/PQISPub/pdf/files/pqorder2015.pdf>)

10 **The Destructive Insects and Pests Act, 1914** (<https://www.indiacode.nic.in/bitstream/123456789/2354/1/A1914-02.pdf>)

11 **Export Restrictions-DGFT** (<https://customsandforeigntrade.com/Find Export Policy.pdf>)

12 **The Foreign Trade (Development and Regulation) Act, 1992** (<https://www.indiacode.nic.in/bitstream/123456789/1947/3/A1992-22.pdf>).

2. Guidance for Registration/License holders of neem-based products

2.1 Guidance for Registration holders of neem-based insecticides

All the neem-based insecticides to be sold/used in India must be registered with the CIB&RC, Ministry of Agriculture, Cooperative and Farmers Welfare, Govt. of India, as per the provisions of the **Insecticides Act, 1968** and the **Insecticides Rules, 1971**. This mandatory registration is applicable for the producers of neem-based insecticides in India as well as exporters of neem-based insecticides. The producers/exporters need to apply using separate application for different products to obtain the Certificate of Registration. After the producers receive the Certificate of Registration, they will be considered registration holders of neem-based insecticides and will be able to commercialize their products as specified in their respective Certificate of Registration.

Currently, the neem-based insecticides are not included under the public health programme i.e., National Vector Borne Disease Control Programme (NVBDCP). Therefore, neem-based products are not used for public health programmes in India. However, the registration holders can sell their products in the retail market. The neem-based insecticides for vector control should be sold for the said purpose only. The registration holders need to apply for the grant of license to sell, stock or exhibit for sale or distribute neem-based products to the respective states where they intend to do so.

In case of export purposes, the producers can refer to the [guidance on the management of household pesticides](#) given by WHO and Food and Agriculture Organization (FAO)

2.2 Guidance for License holders of neem-based drugs

All the neem-based mosquito repellents and other neem-based products, which fall under the category of drugs are regulated by the **Drugs and Cosmetics Act, 1940**. For such products, the producers should apply for license to manufacture for sale of Ayurvedic drugs to the concerned State licensing authority for ASU drugs where the production facility will be set up. In addition to the manufacturing license of Ayurvedic medicines, the producers need compliance to Good Manufacturing Practices (GMP) and the standards prescribed in the Ayurvedic Pharmacopoeia.

3. Guidance for users of neem-based products

The neem-based products are not recommended under the public health programme (NVBDCP), but are available in the open retail market. Therefore, the users are the general public/consumers who need to be aware of how to use these products.

For any product for vector control, the users need to consider the following while using these products:

- They should go through the instructions for use, precautions to be taken while use, and the suitability of the product carefully. The users should avoid certain uses of the product if the manufacturer has mentioned it on the product e.g. In the case of mosquito repellent cream, avoid applying the cream on any cuts or wounds on the skin
- The products should be used for their intended use only. The mosquito repellent products are not intended to diagnose, prevent, cure, or treat any ailment or disease. Therefore, the producers should provide necessary information/leaflets to make the users aware of how to use these products
- The users should also be made aware that if the product is for external use such as room sprays; it should not be applied to the body
- The users should store the products according to the storage conditions mentioned on the label
- The users should ensure that the products they are using are approved by the regulatory authorities and safe to use
- The users should also check the expiry date of the product and should not use the product if it has passed the expiry date
- Any household insecticides, including neem-based insecticides, should always be applied in accordance with the label instructions. Before applying the insecticides, the user should read the label carefully, or have someone else read it aloud if the user is not able to read it to determine the recommended dose and application method, the recommended number and spacing of treatments if more than one is needed, and the recommended timing of treatment
- The insecticides should not be overused, or the users should not exceed recommended dose
- The used insecticides containers and unused or expired insecticides are hazardous wastes and should be discarded as per instructions on the label
- The users should dispose of the used can/pouch as per the **Solid Waste Management Rules, 2016**

Appendices

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

Approvals/Clearances Required	Department to be Approached and Consulted
Business registration	
Incorporation of the Company	Registrar of Companies
Starting/Registering a unit in state	
Registration/IEM/Industrial license	District Industry Centre 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.
Pre-Commissioning Phase	
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 Construction Workers Act (BOCW), 1996	State labour department or competent state authority
Registration under Contract Labour Act, 1970	State labour department or competent state authority
Post-Commissioning Phase	
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

Approvals/Clearances Required	Department to be Approached and Consulted
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 & Trademarks
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/>

Contact person

Secretary CIB&RC
 Tel: +91-129 2413002/+91-129 2476210
 E-mail: 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 ³ [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: www.bis.gov.in

Ph: +91-11-23230131

Email: info@bis.gov.in

Appendix V: Contact details of Ministry of Ayush, Government of India

Ministry of Ayush

Ayush Bhawan, B Block,
GPO Complex, INA, New Delhi - 110023
www.ayush.gov.in

Web Information Manager

Contact no - 1800-11-22-02 (9:00 AM to 5:30 PM) (IST)

Email: webmanager-ayush@gov.in

Appendix VI: Contact details of Central Drugs Standard Control Organization (CDSCO)

Central Drugs Standard Control Organization (CDSCO)

Ministry of Health and Family Welfare, Directorate General of Health Services, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi - 110002
www.cdsc.gov.in

Ph: +91-11-23236973

PRO Toll Free No. 1800 11 1454

Email: dci@nic.in

Appendix VII: Contact details of Indian Pharmacopoeia Commission

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201 002
www.ipc.gov.in

Office of the Secretary-cum-Scientific Director
Tel: 0120-2783400, 2783401, 2783392, FAX: 0120-2783311
Email: lab.ipc@gov.in

Appendix VIII: Contact details of Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H)

Pharmacopoeia Commission for Indian Medicine & Homoeopathy

Kamla Nehru Nagar, Post Kavi Nagar
Ghaziabad, Uttar Pradesh-201002
www.pcimh.gov.in

Telephone: +91-120-2787014
E-mail: dir.pcimh-ayush@gov.in

Appendix IX: Contact details of Indian Council of Medical Research

Indian Council of Medical Research

V. Ramalingaswami Bhawan, P.O. Box No. 4911
Ansari Nagar, New Delhi - 110029, India
www.icmr.gov.in

Ph: +91-11-26588895/+91-11-26588980, +91-11-26589794/+91-11-26589336, +91-11-26588707
Fax: +91-11-26588662
Email: icmrhqds@sansad.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 [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 botanical pesticides to meet the requirements for the issue of license by the respective state governments.
<http://ppqs.gov.in/sites/default/files/c2.32011.doc> [Last Accessed: 10 May 2022]
4. Guidelines/data requirements for registration of neem-based products containing Azadirachtin to be used as household insecticides
<http://ppqs.gov.in/sites/default/files/2.2.22011.doc> [Last Accessed: 10 May 2022]
5. (Example) Regulatory requirements for establishing a pesticide manufacturing facility in the State of Maharashtra
<https://maitri.mahaonline.gov.in/> [Last Accessed: 10 May 2022]
6. Guidelines for Endorsement of Additional Manufacturing Site <http://ppqs.gov.in/sites/default/files/4.22012.doc> [Last Accessed: 15 July 2022]
7. 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]
8. Guidelines for the registration of all insecticides under Section 9(4) on the PPQS website
<http://ppqs.gov.in/sites/default/files/1.32011.doc> [Last Accessed: 10 May 2022]
9. Checklist for registration of insecticides under Sections 9(3) and 9(4)
<http://ppqs.gov.in/divisions/cib-rc/checklist> [Last Accessed: 10 May 2022]
10. Good labelling practices for pesticides recommended by World Health Organization (WHO)
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11. Insecticides (Price, Stock Display and Submission of Reports) Order, 1986 [https://upload.indiacode.nic.in/showfile?actid=AC_CEN_23_31_00001_196846_1517807318487&type=notification&filename=28_january_1986_g.s.r._71\(e\).pdf](https://upload.indiacode.nic.in/showfile?actid=AC_CEN_23_31_00001_196846_1517807318487&type=notification&filename=28_january_1986_g.s.r._71(e).pdf) [Last Accessed: 15 July 2022]
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<https://legislative.gov.in/sites/default/files/A1955-10.pdf> [Last Accessed: 15 July 2022]
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(Search Indian Standard by IS number equal to neem)
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15. Quality Standards of Indian Medicinal Plants-Volume XI
<https://mpd.icmr.org.in/qs11.php> [Last Accessed: 01 July 2022]
16. **Drugs and Cosmetics Act, 1940 and Rules, 1945**
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf [Last Accessed: 10 May 2022]
17. General Guidelines for Drug Development Of Ayurvedic Formulations
<https://www.ayush.gov.in/docs/guideline-drug-development.pdf> [Last Accessed: 10 May 2022]
18. Guidelines for efficacy testing of mosquito repellents for human skin by WHO
<https://www.who.int/publications/i/item/WHO-HTM-NTD-WHOPES-2009.4> [Last Accessed: 10 May 2022]
19. Guidance on the management of household pesticides given by WHO and FAO
<https://apps.who.int/iris/bitstream/handle/10665/337126/9789240011915-eng.pdf> [Last Accessed: 10 May 2022]
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21. **Tamil Nadu Warehouses Act, 1951** https://lawsofindia.blinkvisa.com/pdf/tamil_nadu/1951/1951TN15.pdf [Last Accessed: 15 July 2022]
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