

Guidance for Producers and Registration holders of Bt-based products

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 *Bacillus thuringiensis* (Bt)-based biopesticides, a globally recognized agent for biological vector control.

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 *Bacillus thuringiensis* var. israelensis (Bti) as a potential larvicide to control malaria. These biolarvicides are safe, effective, environmentally friendly and offer a sustainable alternative to DDT generally in urban settings.

Important Regulations

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

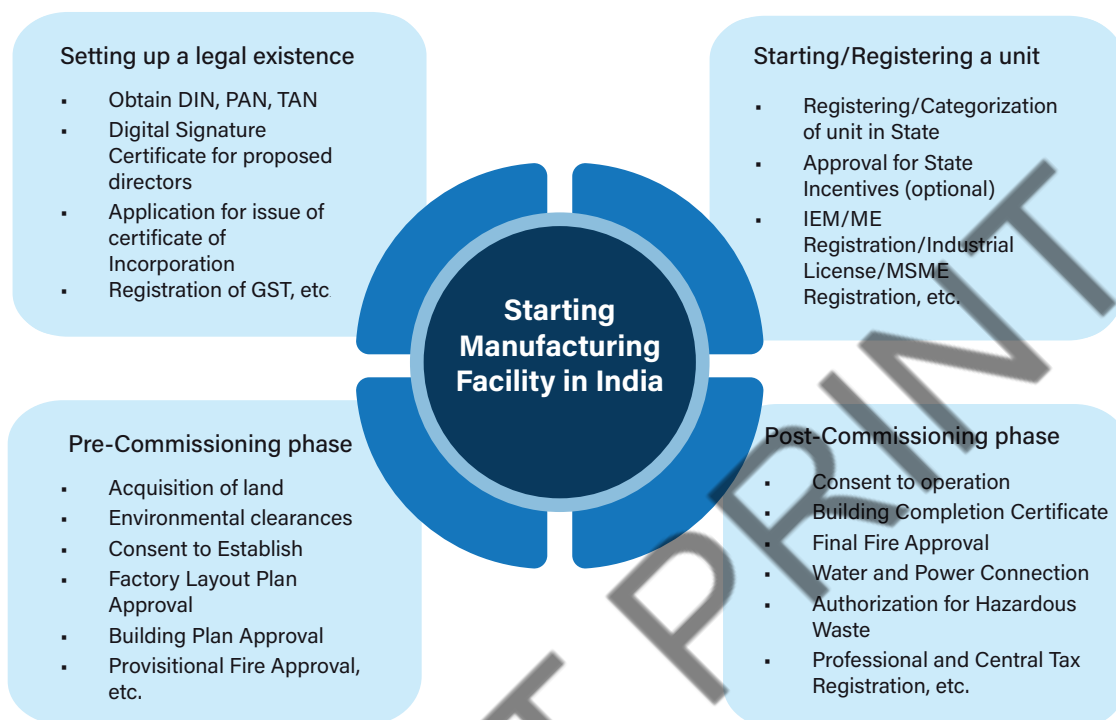
In light of India's commitment to phase out DDT production and the predicted rise in demand for DDT alternatives, there is a significant opportunity for producers and exporters of Bt-based products.



GUIDANCE FOR PRODUCERS AND EXPORTERS OF BT-BASED PRODUCTS

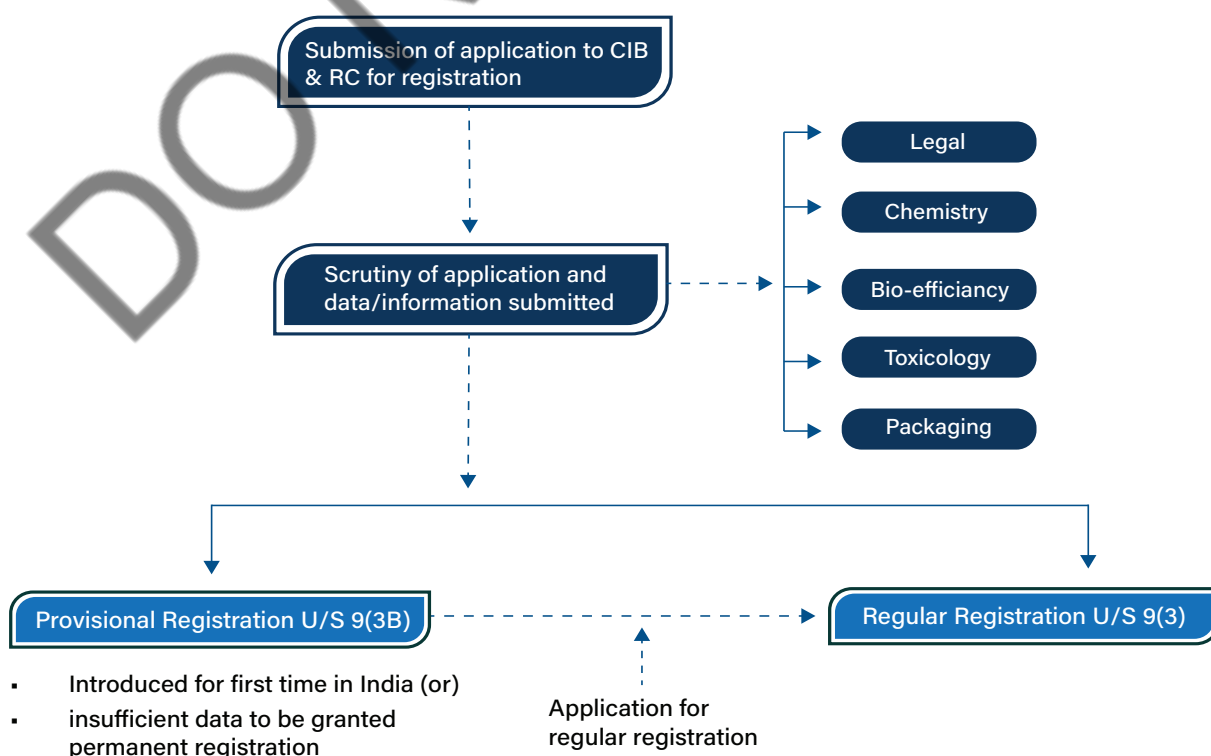
- ✓ Regulatory processes to be followed for setting up a manufacturing unit for indigenous use as well as export

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



- ✓ Mandatory registration of Bt-bioinsecticide by all domestic producers (Imported Bt-insecticides cannot be registered)

Registration process of Bt-based products



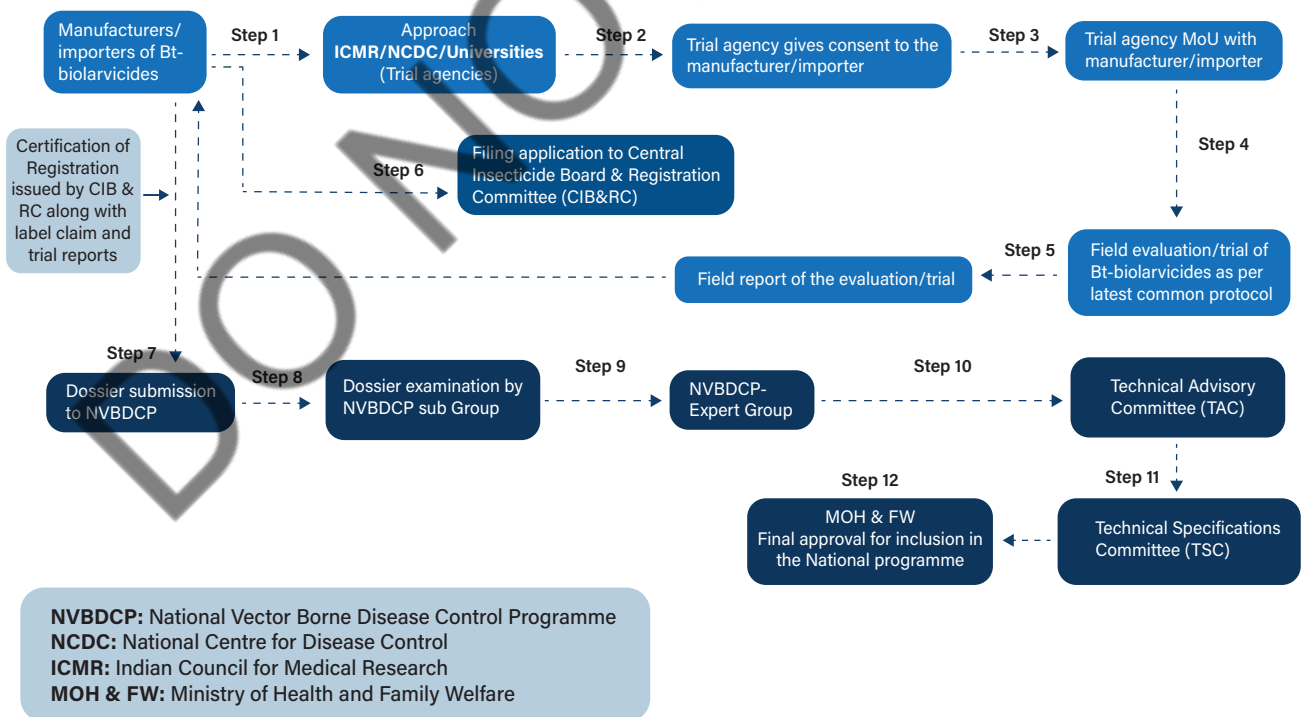
- ✓ Approval from the respective state governments, where the production unit is established (Manufacturing license)
- ✓ Complying with Regulations
 - Compliance with stipulated conditions (for example, technical specifications, labelling and packaging, quality of raw materials, etc.) specified in the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

GUIDANCE FOR REGISTRATION HOLDERS OF BT-BASED PRODUCTS

All Bt-based products intended for sale or export must be registered individually with CIB&RC. Once the Certificate of Registration is issued to the producers, they become the registration holders.

- ✓ Inclusion of the registered Bt-bioinsecticide in public health programmes (National Vector Borne Disease Control Programme, NVBDCP) under NCVBDC
 - Currently, Bt-bioinsecticides are only permitted for use in public health programs, not for sale at retail markets.
 - Registration holders need to approach the (Directorate of National Vector Borne Disease Control Programme under NCVBDC) for inclusion of their Bt-bioinsecticide in the national public health programmes.

Steps to be followed by the producers/registration holders for inclusion of LLINs in the public health programme under NCVBDC



Steps for inclusion of Bt-bioinsecticides in the public health programme under (NVBDCP) under NCVBDC

- ✓ Commercialization of Bt-bioinsecticide through public health programmes
 - Registration holders must fulfil pre-requisites for tenders issued by the government procurement agency
 - If selected, strictly follow the technical parameters/specifications specified in the bidding document and deliver the required quantity on time

IMPORTANT WEB LINKS

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

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