



STANDARD OPERATING PROCEDURE (SOP) FOR INTRODUCTION OF PUBLIC HEALTH PESTICIDES INCLUDING BIOLARVICIDES IN THE NATIONAL VECTOR CONTROL PROGRAMME

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Indian Council of Medical Research
New Delhi



National Vector Borne Disease
Control Programme, Delhi



National Centre for Disease
Control, Delhi

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In India, insecticides are introduced into public health programmes based on entomological parameters and their impact on disease incidence/ prevalence. Insecticides are used in the programme for indoor residual and space spraying, treatment of mosquito nets and larval control for containment of vector borne diseases. The revised procedure to be adopted for the introduction of newer insecticides or insecticide formulations for public health use (under National Vector Borne Disease Control Programme (NVBDCP) is depicted in the Flow chart.

The NVBDCP considers introduction of new insecticides and amendment to the list of insecticides or deletion of insecticides in usage on the basis of data on bio-efficacy, vector susceptibility and epidemiological impact generated by state health departments, National Centre for Disease Control (NCDC), or Indian Council of Medical Research (ICMR) institutes.

The manufacturers/importers of new pesticides/ formulations of pesticides listed under the schedule of Insecticides Act (1968) need to submit requisite data to get it registered with Central Insecticides Board (CIB) before submitting the product to NVBDCP for incorporation to NVBDCP. The steps involved in the process (Flow chart) of getting the pesticides evaluated for efficacy against disease vectors, registration and approval for their use in the national programme are described below:

1. The manufacturer(s) or importer of pesticides who intend to get their product included for use in the public health programme will submit an application to NVBDCP requesting to initiate necessary steps to generate data through laboratory/ field trials by ICMR institutes or NCDC as per the Revised Common Protocol. For research trial and testing (RTT) samples, permission from Registration Committee of CIB is required prior to import. Data requirement of the CIB & RC in respect of chemistry, bio-efficacy, toxicology and packaging is available at www.cibrc.nic.in
2. The NVBDCP will screen the applications based on set criteria and will forward to the ICMR or NCDC requesting to undertake evaluation of the product.

(The step 1 and 2 will be completed within 1 month).

3. The ICMR/NCDC will examine the applications forwarded by the NVBDCP for their scientific merit and assign the work to the identified institute(s).
NCDC will follow steps as of ICMR for bio-efficacy evaluation

(This process will be completed within 2 months).

The identified institute will prepare a proposal (with appropriate budget component) in accordance with the revised common protocol and submit it to ICMR within 1 month. In case of

the proposals requiring clearance from Human Ethics Committee and or Animal Ethics Committee, the institutes will finalize and submit the protocol to ICMR within 2-3 months.

The ICMR will review the proposal and forward the approved proposal to NVBDCP for onward transmission to the concerned manufacturer/ importer for their concurrence. On receipt of the concurrence of the manufacturer/ importer from the NVBDCP, the ICMR conveys its approval to the Institute for taking up the evaluation. The manufacturer/importer will send the fund as well as the product to be tested directly to the institute.

4. The identified Institute will conduct the trial as per the common protocol and following ethical guidelines and submit the final report to ICMR.

Institutes assigned to carry out bio-efficacy trials should enter into MOU with the concerned manufacturer/importer. In the MOU, it should be clearly mentioned that plastic covers and used LLINs will be disposed of by manufacturer/importer in consultation with the Directorate of NVBDCP.

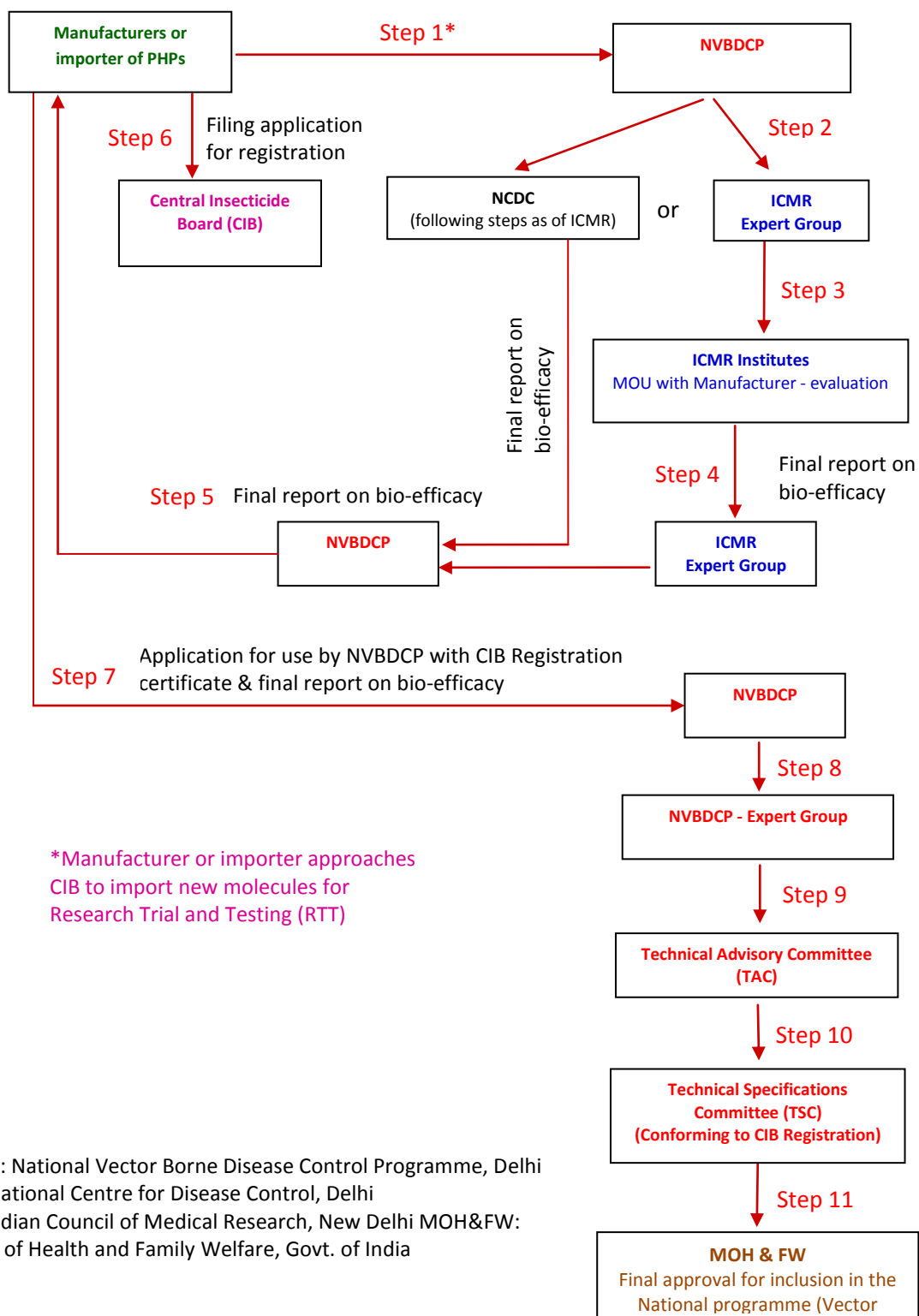
(The events under this step will be completed within 3 months, excluding the trial period)

5. The ICMR will review the final trial report and forward it to NVBDCP, and in turn the NVBDCP will send the final trial report to the manufacturer/ importer.

(This step will be completed within 3 months).

6. The manufacturer/importer, with the final trial report received from the NVBDCP, can file an application with the Central Insecticides Board (CIB) for their product's registration.
7. The manufacturer/ importer, after obtaining the certificate of registration from the CIB, can approach NVBDCP with the final trial report for consideration for inclusion of the product in the programme. .
8. The NVBDCP will place the application of the manufacturer/ importer along with the necessary dossiers to its Expert Group for reviewing. The application, if recommended, will be forwarded by the NVBDCP to its Technical Advisory Committee (TAC). Details are available at www.nvbdcpc.nic.in
9. The TAC will deliberate on the recommendations of the NVBDCP Expert Group and will grant its approval for inclusion in the NVBDCP. In case the product is not recommended appropriate scientific justification will be provided to manufacturer/ importer.
10. Based on technical specifications of CIB & RC, NVBDCP Technical Specifications Committee finalizes the product specifications.
11. TAC approval is endorsed by Ministry of Health & Family Welfare, Govt. of India for inclusion of the product in the programme.

FLOW CHART OF THE STANDARD OPERATING PROCEDURE FOR INTRODUCTION OF PUBLIC HEALTH PESTICIDES INCLUDING BIOLARVICIDES IN THE NATIONAL VECTOR CONTROL PROGRAMME



Composition and Terms of Reference of Expert Group/Committees

I. NVBDCP Screening Committee (Internal)

Composition

1. Director, NVBDCP (Chairman)
2. Members (Internal)

Terms of reference

Screening of applications submitted by the manufacturer/ importer to initiate laboratory/ field evaluation.

II. NVBDCP Expert Group

Composition

3. Chairman (external)
4. Three subject experts (external, one each in Entomology, Chemistry and Toxicology)
5. Director, NVBDCP, Delhi
6. Two Directors of ICMR Institutes
7. Director, NCDC, Delhi
8. Head, ECD, ICMR
9. Health Officer, Municipal Corporation of Delhi
10. CIB & RC (Entomologist)
11. Jt. Director (Entomology), NVBDCP, Delhi (Member Secretary)

Terms of reference

Discussing the outcome of the final trial report and convey the specific recommendation to TAC for approval.

III. ICMR Expert Committee

Composition

1. Chairman (An external eminent subject expert)
2. Three additional subject experts (External, one each in Entomology, Chemistry and Toxicology)
3. Director, NVBDCP or nominee
4. Director, NCDC or nominee
5. Secretary, CIB & RC or nominee
6. Head, ECD - Member Secretary.

Terms of reference

1. To examine the scientific merit of the applications forwarded by the NVBDCP and identify the research institute for evaluation following the common protocol.
2. To review the progress of the work on the projects.
3. Approval of the final evaluation report for communicating to the manufacturer/ importer.

IV. Technical Advisory Committee (TAC), NVBDCP

Composition

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|--|----------------|
| 1. The Director General of Health Services (DGHS), MOH & FW, GOI | Chairperson |
| 2. Special Director General of Health Services (DGHS), MOH & FW, GOI | Co-chairperson |
| 3. DG, ICMR's nominee from ECD | Member |

4. Chairperson, NVBDCP Expert Group	Member
5. Director , PHFI or nominee	Member
6. Drug Controller General (India)	Member
7. Director, National Centre for Disease Control (NCDC)	Member
8. Three Director General of Health Services, State Governments	Member
9. Director of two Govt. Medical Colleges	Member
10. Prof. of Medicine, Govt. Medical Institution	Member
11. Plant Protection Advisor, Ministry of Agriculture, GOI	Member
12. VHA Representative	Member
13. DGAFMS (Health), New Delhi	Member
14. Director (PH), MOH & FW, GOI	Member
15. Three subject experts on Vector Control	Member
16. Director, NIMR	Member
17. Director, VCRC	Member
18. Director, Directorate of NVBDCP	Member Secretary

Terms of reference

1. To review the recommendations of the NVBDCP Expert Group and approve the products for introduction in to the programme
2. To review drug policy and suggest alternative drugs for treatment of malaria and other VBD cases
3. To review and suggest diagnostics and case management practices under NVBDCP for all vector borne diseases.
4. To identify and review whether the preventive measures undertaken have been consistent with the agreed plan of action and or leading to measurable target of achievements.
5. To suggest mid-course changes in strategy including use of insecticides, diagnostics and drugs, if resistant patterns are evident.
6. Any other technical issue related to programme strategies and implementation.

Apart from the above members, representative from WHO could be invited to attend the meetings, whenever necessary. The Chairman is empowered to co-opt any other expert, so required, to assist the committee from time to time.

V. Technical Specification Committee (TSC), NVBDCP

Composition

1. Special DGHS (GOI)
2. Secretary, CIB & RC
3. Director, NCDC
4. Director, Procurement, DGHS
5. Two Technical Subjects Specialists from Central Govt. institutions
6. Director, NVBDCP – Member Secretary

Terms of reference

1. To finalize the technical specifications/ parameters and the quantum of stores to be procured.
2. To finalize the delivery schedule, formulary and the source of procurement i.e. National – Global, limited/ open tenders etc. to form the basis of the indent (equipment, drugs, medicines & insecticides for the Dept. of Health; contraceptives, vaccines & equipments required by the Dept. of Family Welfare).