F. No. 26-03/2021-CIR-I
Government of India
कृषि एवं किसान कल्याण मंत्रालय
Ministry of Agriculture & Farmers Welfare
कृषि, सहकारिता एवं किसान कल्याण विभाग
Department of Agriculture, Co-operation & Farmers Welfare
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE
केंद्रीय कीटनाशी बोर्ड एवं पंजीकरण समिति
Central Insecticides Board and Registration Committee
एन. एच. 4, फरीदाबाद (हरियाणा)-121001
N.H. IV, FARIDABAD (HARYANA)-121001
******

Dated: 16th July, 2021

PUBLIC NOTICE

Subject: Draft guidelines recommended by the sub-committee to review guidelines for registration of pesticides u/s 9(3b), 9(3) and 9(4) of IA, 1968- Inviting comments of stakeholders-reg.

Reference the decision taken by the Registration Committee at Agenda Item No. 10.31 in the 429th RC meeting held on 24.06.2021, 28.06.2021 and 30.06.2021.

Accordingly, the draft guidelines recommended by the sub-committee to review guidelines for registration of pesticides u/s 9(3b), 9(3) and 9(4) are enclosed at Annexure for inviting comments of all stakeholders.

All stakeholders are requested to submit their comments, if any, on the draft guidelines within 60 days of hoisting of this Public Notice on the website of Dte. of PPQ&S through email at cibsecy@nic.in , sandhyak@nic.in and snehapotdar27@gmail.com.

This has the approval of APPA & Secretary (CIB&RC).

Suman

(Suman Jakhar)
Section Officer

Copy to:
(i) All Pesticide Associations
(ii) Chairman, Registration Committee
(iii) PPS to JS(PP)/ PPS to PPA/PPS to APPA & Secretary (CIB&RC)
(iv) IT Cell, Hq. Faridabad for uploading the same on the official website.

REPORT OF THE SUB-COMMITTEE FOR REVISITING THE GUIDELINES FOR DATA RQUIREMENT FOR REGISTRATION OF INSECTICIDES (PESTICIDES) UNDER THE INSECTICIDES ACT, 1968

Chairperson

Dr. (Mrs.) Sandhya Kulshrestha
Consultant (Pharmacology)
Central Insecticides Board & Registration Committee
N.H.-IV, Faridabad-121 001

REVISITING GUIDELINES FOR DATA REQUIREMENT FOR REGISTRATION OF PESTICIDES

BACKGROUND

The Registration Committee noted that over the years , need based separate guidelines have been issued above the existing approved guidelines u/s 9(3b), 9(3) and 9(4) resulting in large number of guidelines that cause confusion and require repeated intervention of the RC, causing unnecessary delays and dis-contention among applicants because of disharmony among various guidelines. Hence, there was requirement to revisit these guidelines.

The Registration Committee (**RC**), in its 410th Meeting held on 05th November, 2019, constituted a Sub-committee to revisit current guidelines for registration of pesticides u/s 9(3b), 9(3) and 9(4) of the Insecticides Act, 1968 vide agenda item no. 1.3. The composition of the Committee is as under:

1. Dr. Sandhya Kulshrestha, Consultant (Pharma) – Chairperson
2. Dr. Anupama Singh, Principal Scientist &Head, Department of Agro Chemical, IARI, Member
3. Dr. Rohit Mishra, Assistant Industrial Advisor, Shastri Bhawan, New Delhi – Member
4. Dr. Sarita Bhalla, Consultant (Pharma)– Member
5. Sh. Kiran W. Deshkar, DD (E) – Member
6. Sh. A. K. Reddy, DD (WS) – Member
7. Dr. Vandana Pandey, AD (PP) – Member
8. Sh. Avnish Tomar, AD (Pack) – Member
9. Member from IARI, Entomology Division – Member
10. Dr. Archana Sinha, JD (Chem) – Member Secretary

The sub-committee was empowered to co-opt any expert to contribute in the endeavor and to submit its report within three months.

The RC, in its 413^{tht} meeting (Item No. 10.24), held on 03rd March, 06th March and 09th March, 2020, reconstituted the Sub-committee vide agenda item no. 3.3 and replaced Dr. Rohit Mishra, Assistant Industrial Advisor, Shastri Bhawan, New Delhi – Member with Dr. Vishal Choudhary, Deputy Industrial Advisor, M/o Chemicals & Fertilizers, Department of Chemicals and Petrochemicals, Shastri Bhawan, New Delhi as a member. Nomination of Dr. Subhash Chander, Professor & Principal Scientist, Entomology Division, IARI, New Delhi was also received. Dr Sushil K. Khurana, Consultant (Pathology) was the special invitee in the meetings of the Sub-committee.

Subsequently, the RC made slight modification in the composition of the Sub-committee in its 421st Meeting, held on 21st August, 2020, due to internal transfers in the Department and assigned the responsibility of Member-Secretary to Dr. (Mrs.) S.S. Potdar, Deputy Director (Chemistry) and Mr. Avnish Tomar, Asstt. Director (Chemistry) was replaced by Dr. Brijesh Tripathi, Asstt. Director (Chemistry). The revised composition is at **Annexure I.**

The Sub-committee held three meetings on 21.09.2020, 28.09.2020 and 02.11.2020. The Sub-committee members were asked to submit draft proposals requirements for discussion in the Sub-committee meetings. The Sub-committee deliberated the proposals and draft was circulated to all members for comments. Based on the inputs from members, the current guidelines have been prepared.

INTRODUCTION

As per the provisions of the Insecticides Act, 1968 (**the Act**), any person desiring to import or manufacture any pesticide, may apply to the Registration Committee in form-I with such particulars as may be prescribed. The Registration Committee after evaluation of comprehensive scientific data and claims made by the applicant about efficacy and safety to human beings and animals, when satisfied that the pesticide is effective for the intended purpose and does not pose any unacceptable risk to human health or animal or the environment, then issues the certificate of Registration on conditions, as it considers necessary. The broad framework of scientific data and other information required to support the claims made by the applicant regarding efficacy and safety and some other (not all) statutory and other requirements are defined in the 'Guidelines for Data Requirement for Registration of Pesticides' as recommended by the Registration Committee. These guidelines guide the stakeholders to generate data and submit application with the indicated requisites. **However, scientific circumstances and scenarios may necessitate requirement for additional data or waiver for data requirement on some parameters**.

OBJECTIVES

The main objectives for revision of these guidelines are to reduce the number of guidelines and to simplify them to understand, maintain transparency to incorporate scientific developments and harmonize with international requirements keeping in view the conditions prevalent in our country. The policy of Government of India for "Atmanirbhar Bharat" was also kept in mind during the revision of guidelines.

SCOPE OF GUIDELINES:

The revised guidelines for registration of pesticides would provide guidance to the applicants for registration of pesticides under the Act so as to facilitate stakeholders for submission of data/information to apply for pesticide registration for import or manufacture in the country. The efforts have been made to describe the circumstances and use patterns wherein different types of requirements are appropriate and suitable. **The pesticides used in agriculture as well as public health or household are covered under the guidelines**. **These guidelines address the data requirements for chemical pesticides as well as for bio-pesticides.** The data requirements of chemical pesticides are also applicable for Plant Growth Regulators. The Guidelines provide the

requirement of data and legal documents for registration of pesticides for import or manufacture in the country.

In view of rising concerns about the impact of conventional chemical pesticides on human and animal health and environment, the development and use of alternatives like bio-pesticides are being promoted by the Government. Bio-pesticides for which data requirement have been included in the guidelines are - Microbial Pest Control Agents (MPCA;), botanical or plant origin pesticides and semiochemicals. The invertebrates or macro-organisms used for biological control are not covered under these guidelines. Also, the MPCA, plant origin pesticides and semiochemicals derived from or based on Genetically Modified Organisms (GMOs) or other gene editing techniques are not covered under these guidelines as they need special considerations.

Further, semiochemicals (Pheromones) which are used for the purpose of monitoring in traps or for mass trapping are not covered as they do not require registration. However, the registration is required for semiochemicals used for mating disruption, hence, data requirement has been suggested for the semiochemicals used for mating disruption to control pest population..

It is further clarified that traditional remedies or products prepared by the individuals for their own use do not need registration if the produce is not sold. If the product prepared or the treated produce is to be sold in the market, then the registration is required under the provisions of the Act.

THE REQUIREMENTS/GUIDELINES FOR REGISTRATION OF INSECTICIDES EXCLUSIVELY FOR EXPORT REMAIN THE SAME AS APPROVED/RECOMMENDED BY THE REGISTRATION COMMITTEE IN ITS 380TH RC AND ARE AVAILABLE ON THE WEBSITE.

GUIDANCE TO STAKEHOLDERS:

1. Stakeholders generating data and submitting the application for registration should ensure that the tests are conducted and data is generated in accordance with sound scientific procedures following the test guidelines and the principles of Good Laboratory Practice. The data should be authentic, of good quality and useful. The complete study reports should be submitted.

2. The requirement for registration usually includes data and information on proposed application; data on identity of the insecticide (identity, composition, analysis and quality); data to assess risk to humans and the environment; data to assess efficacy of the product; and the packaging and labelling requirements.

3. The **data requirement for registration of insecticides varies with the type of insecticides to be registered (i.e. chemical or bio-pesticide and also type of bio-pesticide i.e. microbial pest control agent or botanical or semiochemical/pheromone); the type of material to be registered i.e. technical or formulation or Manufacturing Use Product (MUP); the type of formulation solid (WP, granules, powder) etc. liquid (EC, EW etc.) or vapour (vaporizer, fumigants etc.); the category of registration – i.e. provisional [u/s 9(3B)]; regular [u/s 9(3)] or subsequent 'Me-too' [u/s 9(4)] (Please refer section (9) of the Insecticides Act, 1968); purpose of registration – domestic use or export or for both domestic use and export; the intended use of the pesticide to be registered or its label claims etc.** Hence, before starting data generation or submitting application for registration, the applicant should ensure that the requirements are being complied correctly for the type of pesticide to be registered under the desired category and for the intended purpose.

4. The data submitted by the applicant at the time of registration under section 9 (3b) shall not be required to be submitted again at the time of submission of application for registration under

section 9(3) by the same applicant, if chemical composition and other claims remain unchanged.

GUIDELINES FOR DATA REQUIREMENT FOR REGISTRATION OF PESTICIDES

These guidelines provide the guidance to the stakeholders to generate data and submit application with the indicated requirements. **However, scientific circumstances and scenarios may necessitate requirement for additional data or waiver for requirement of data on some parameters**.

(A) Legal Requirements: The documents required from legal discipline are at **Annexure II**.
(B) The Data Requirements for Chemical Pesticides are at **Annexure III**.
(C) The Data Requirements for Microbial Pest Control Agents (MPCA) Pesticides are at **Annexure IV.**
(D) The Data Requirements for Botanical/ Plant origin Pesticides are at **Annexure V.**
(E) The Data Requirements for Pheromones/Semio-chemicals are at **Annexure VI.**

The abbreviations used in the guidelines are in APPENDIX- I

The terms used in the report are defined in APPENDIX- II

Annexure-I

Composition of the Sub-committee

Composition of the Sub-committee: -

1. Dr. Sandhya Kulshrestha, Consultant (Pharma) – Chairperson
2. Dr. Anupama Singh, Principal Scientist &Head, Department of Agro Chemical, IARI, Member
3. Dr. Subhash Chander, Professor & Principal Scientist Entomology Division, IARI –Member
4. Dr. Vishal Choudhary, Deputy Industrial Advisor, Department of Chemicals & Petrochemicals, Shastri Bhawan, New Delhi – Member
5. Dr. Sarita Bhalla, Consultant (Pharma)– Member
6. Dr. Archana Sinha, JD (Chem.)- Member
7. Sh. Kiran W. Deshkar, DD (E) – Member
8. Sh. A. K. Reddy, DD (WS) – Member
9. Dr. Brijesh Tripathi, DD (Chem.)– Member
10. Dr. Vandana Pandey, AD (PP) – Member
11. Dr. Sneha S. Potdar, DD (Chem.)– Member Secretary.

ANNEXURE II

LEGAL REQUIREMENTS

(**A) Legal Requirements:**

1. Form – I duly signed

2. Copy of BOD Resolution/Affidavit/Partnership deed (**Notarized**)

3. Affidavit for Chemical composition on NJSP (**Notarized**)

4. Certificate as per category of Industry/ Manufacturing license (**Notarized**)

5. PAN No. (**Notarized**)

6. Incorporation Certificate **Notarized**)

7. Proof of Source of Technical to be used in formulation is duly registered. (In case of indigenous manufacture / import - Reference of RC meeting in which it was approved). {Only deemed registration status without issuance of Certificate of registration shall not be considered}.

8. Name of registrant of Formulation Import (Reference of Registration Committee Meeting in which formulation import was approved).

9. Letter of consent, duly legalized from Indian Embassy/High Commission/ Consulate in the Country of origin ***(Applicable in case of 9(4) TI/FI Applications)***

10. List of products for which the registration has been given to the firm and Manufacturing License obtained and products actually manufactured during the previous 2 (two) years ***(Applicable in case of 9(4) TI/FI & FIM Applications.***

11. Relevant Affidavit/Undertakings ***(Applicable in case of Bio pesticides Applications)*** as under:-
    (a) Affidavit on bio-pesticide composition on NJSP duly notarized.
    (b) Notarized copy of depositing microbial bio-pesticides strain sample in National Repository with reference code number.
    (c) Undertaking on NJSP duly notarized that product do not contain any genetically modified organism in the prescribed format.
    (d) Undertaking on NJSP duly notarized that product is free from chemical / botanical pesticides / other agro-chemicals.
    (e) Copy of 9(3B) Registration certificate, if relevant .

ANNEXURE III

DATA REQUIREMENTS FOR CHEMICAL PESTICIDES

(B) Data Requirements for Chemical Pesticides

Chemistry

Sl. No.	Parameter	9(3B)			9(3)				9(4)			
		TI	TIM	FIM	TI	TIM	FI	FIM	TI	TIM	FI	FIM
1	2	3	4	5	6	7	8	9	10	11	12	13
A. CHEMISTRY												
1.	Source of Supply of Technical	R	NR	R	R	NR	R	R	R	NR	R	R
2.	Chemical Composition (clearly showing claims of purity of active ingredient, impurities or adjuvants, as the case may be)	R	R	R	R	R	R	R	R	R	R	R
3.	Complete information on the active ingredient	R	R	R	R	R	R	R	R	R	NR	NR
4.	Physical and Chemical Properties of the active ingredient and, in case of a formulation, adjuvants	R	R	R	R	R	R	R	NR	R	NR	NR
5.	Technical Bulletin	R	NR	NR	R	NR	R	NR	NR	NR	NR	NR
6.	Specification in BIS format	R	R	R	R	R	R	R	NR	R	NR	NR
7.	Method of Analysis	R	R	R	R	R	R	R	NR	R	NR	NR

8.	Analytical Test Report (ATR) from an independent and GLP certified or NABL accredited laboratory in India	R	R	R	R	R	R	R	NR	R	NR	NR
9.	Characterization (Identity Test) of active ingredient by UV-VIS, IR, MS and NMR spectra)	R	R	NR	R	R	NR	NR	NR	R	NR	NR
10.	Identification& Quantification of Impurities	R	R	NR	R	R	NR	NR	NR	R	NR	NR
11.	Shelf-life claim	R	R	R	R	R	R	R	R	R	R	R
12.	Storage Stability Data (samples stored in three varied agro-climatic conditions) for six months in excess of claimed shelf-life alongwith meteorological data for corresponding period	R	R	R	R	R	R	R	NR	R	NR	NR
13.	Establishment of Chemical Equivalence (wherever applicable)	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR
14.	Detailed stepwise manufacturing process (provide chemical reactions explained with structural formulae and all applicable reaction	R	R	R	R	R	R	R	NR	R	NR	NR

	other conditions in case of technical grade insecticides).											
15.	Information about Raw Materials Used along with their source of supply	R	R	R	R	R	R	R	NR	R	NR	NR
16.	Flow sheet diagram of process of manufacture	R	R	R	R	R	R	R	NR	R	NR	NR
17.	Effluent Treatment method with complete details	R	R	R	R	R	R	R	NR	R	NR	NR
18.	Legalized letter of consent that the manufacturer is registered for the Technical Grade Pesticide/ Insecticide and that he consents supplying the Technical Grade Pesticide/ Insecticide to the applicant.	R	NR	R	R	NR	R	R	R	NR	R	R
19.	Documents such as registration certificate/Certificate of DNA.	R	NR	NR	R	NR	R	NR	R	NR	R	NR
20.	In case the supplies are to be made through a supplier, a duly legalized certificate from the exporting manufacturer that the supplier is his	R	NR	NR	R	NR	R	NR	R	NR	R	NR

	authorized agent and that the invoice would originate from the approved source of import (actual manufacturer).											
21.	The applicant shall provide a sample of the insecticide along with certified reference material (CRM) and standard impurities alongwith purity certificate in case of technical grade insecticides for pre-registration verification in the Central Insecticides Laboratory (CIL) after acceptance of the application by the Sectt. of the RC for scrutiny.	R	R	R	R	R	R	R	NR	R	NR	NR
22.	Methodology for residue estimation in BIS format.	R	R	R	R	R	R	R	NR	R	NR	NR

Remarks: 1. Adjuvant(s) shall be mentioned by their common names(s) and not by code numbers or names and their complete chemical identity shall be provided.

2. Analytical test report in case of the technical shall be 5-Batch report.

3.In case of the insecticides for Seed Treatment, 'Adhesion to Seeds Test' shall be invariably provided.

4. Same method of analysis should be used in generating ATR and shelf-life data.

5. Accelerated Storage Data can be considered for grant of provisional shelf-life. However, in such cases the Certificate of Registration (CR) shall be issued with a validity of two years. Shelf-life claim of up to 2-years or as the case may be (provisionally) be granted to the insecticides with a

condition that applicant is required to submit real time / actual storage stability study data in the proposed construct and container of sale for duration of minimum 30 months, within two and half years of submission of application for granting the registration, failing which Registration Certificate shall stand invalid.

6. Data requirement for registration of Long Lasting Insecticide Impregnated/ Incorporated Mosquito Bed Nets shall be as per the requirements of 9(3b) and 9(3) category only.

7. Data requirement for Registration of Petroleum derived products like spray oil - natural mineral oil products shall be same as per requirement of 9(3b) and 9(3) category only.

8. In case of FI-WRT (Formulation Import without registering Technical) OR FIM-WRT (Formulation Indigenous Manufacture without registering Technical), in addition to data on formulation, complete chemistry data on technical as per the guidelines of TI/TIM should also be submitted along with chemical composition on Rs 10/- Non-Judicial Stamp Paper (NJSP).

9. In case of 9(3b) TI, 9(3) TI/FI & 9(4) TI/FI category, a condition in CR to be incorporated as an analytical test report by the manufacturer (exporting to India) about the quality of the insecticide from a GLP certified laboratory. (Such analytical test report in respect of the batch(s) shall accompany each & every consignment exported to India)

Bio-efficacy (Insecticide/Fungicide/Herbicide/PGR)

Table - 1

Sr. No.	Parameters	9(3b)			9 (3)					9(4)
		TI	**TIM**	**FIM**	**TI**	**TIM**	**FI**	**FIM**	**Label expansion**	**TI/TIM/FI/FIM or endorsement of already approval label expansion.**
	Bio-efficacy									
1.	**Bio-effectiveness**	R$	R$	R*	R$	R$	R**	R**	R**	No data requirement. The claim will be granted as per approved formulation u/s 9(3)/ approval claims of label expansion.
2.	**Phytotoxicity**	R$	R$	R*	R$	R$	R**	R**	R**	
3.	**Minimum Inhibitory Concentration (MIC)**	NR	NR	R*	NR	NR	R	R	R	
4.	**Effect on germination of Seed (in case of seed treatment of fungicide and insecticide)**	NR	NR	R*	NR	NR	R	R	R	
5.	**Effect on parasite and predators (in case of Insecticides and PGR)**	NR	NR	R*	NR	NR	R**	R**	R**	
6.	**Effect on beneficial soil micro-organisms & physico-chemical properties in case of Seed treatment and soil applied pesticides (Fungicides, Insecticide, Herbicides and PGRs)**	NR	NR	R*	NR	NR	R**	R**	R**	
7.	**Translocation in Plants**	R	R	NR	R	R	NR	NR	NR	
8.	**Metabolism in Soil**	R	R	NR	R	R	NR	NR	NR	
9.	**Metabolism in Water**	R	R	NR	R	R	NR	NR	NR	
10	**Metabolism in Plant**	R	R	NR	R	R	NR	NR	NR	

11	**Persistence in Soil**	R	R	R	R	R	R	R	NR	
12	**Persistence in Water**	R	R	R	R	R	R	R	NR	
13	**Persistence in Plant**	R	R	R	R	R	R	R	R	
14	**Compatibility with other chemicals, if claimed**	N R	NR	R	NR	NR	R	R	R	
15	**Residues in Plant**	NR	NR	R #	NR	NR	R#	R#	R	
16	**Residues in Soil**	NR	NR	R #	NR	NR	R #	R#	NR	
17	**Residue tolerance limits fixed by foreign countries**	NR	NR	R	NR	NR	R	R	R	
18	**Cost Benefit Ratio**	NR	NR	NR	NR	NR	R	R	R	
19	**Registration status in foreign countries**	R	NR	R	R	NR	R	R	R	
20	**MRL Performa along with CD/Pen drive in duplicate (other than seed treatment).**	NR	NR	R	NR	NR	R	R	R	
21	**Label and Leaflets**	R	R	R	R	R	R	R	R	R

R*: Two seasons/years data generated at minimum two different agro-climatic zones

R:** Two seasons/years data generated at minimum three different agro-climatic zones

R#: One season / year data generated at minimum four different agro-climatic zones for fungicides, insecticides and PGRs. **Whereas, in case of herbicides, two seasons/years data generated at minimum two agro-climatic zones in case of 9(3b) and two seasons/years data generated at minimum three agro-climatic zones in case of 9 (3).** In case of seed treatment one season / year data generated at minimum three different agro-climatic zones will be required. In case of soil applied Pesticides (Insecticide/ Fungicide/ Herbicide), if residue at harvest is above LOQ then 2nd season data will be required or else one season data will be suffice.

Note: for commercial non edible crops only, the data on residue and persistence in plant is not required.

R$: If Technical Import & Technical Indigenous Manufacture application which are submitted together with Formulation Import & Formulation Indigenous Manufacture applications, no bio-efficacy data required.

Note: In case of herbicides data on effect on soil Physico- chemical and biological properties and effect on normally cultivated three succeeding crops is required along with residue studies in the same plots of the field.

***Example*:** for a herbicide intended to be registered for use in wheat crop data on effect on succeeding crops of maize at location one, green gram at location two and sesamum at location three may be generated along with residue studies. However, this is only an example and data on any other normally cultivated succeeding crop may be generated.

1. For Combination products**:** data is required as per the guidelines of Formulation Import / Formulation Indigenous Manufacture. However, data on Sr. No. 3, 11, 12, 13,15, 16 & 20 (Table – 1) if the a.i. content of either component of the combination product is higher than the already registered same formulations combinations, the applicant is required to submit the data.

2. If technical is already registered for import under section 9(3) and applicant want to apply for indigenous manufacture of the same pesticide then one season data on Sr. No. 1, & 2 (Table – 1) if any, on two representative crops at two different agro-climatic zones is required and one season residue data on two representative crops particularly on fruits and vegetables is required.

3. If formulation is already registered for import or for indigenous manufacture u/s 9(3) by any applicant and the same registrant want to apply for technical indigenous manufacture, data on Sr. No. 1, 2 & 15 (Table – 1) not required. Whereas, if other applicants want to apply for technical indigenous manufacture, one season data on Sr. No. 1 & 2 (Table – 1) on two representative crops at two different agro-climatic zones is required and one season data on Sr. No. 15 (Table – 1) on two representative crops particularly on fruits and vegetables is required.

4. In case of Technical Import from New Source, two seasons data on each crop mentioned in labels/ leaflets at least at two different agro-climatic Zones is required on Sr. No. 1 & 2 (Table – 1) and two years or seasons data on Sr. No. 15 (Table – 1) on representative crops of each group on which pesticide is approved.

   Note: Data on Sr. No. 1 & 2 (Table – 1) is required on all registered formulations of same technical on all approved crops at the time of Issue of import permit provided the application for registration is received within 4 years of issue of import permit.

5. **(a)** For registration of pesticide formulation for indigenous manufacture having the identical chemical composition that of formulation already registered for import U/s 9(3). No data on bioefficacy is required provided the technical of the source to be used in formulation is duly registered as per guidelines of the Registration Committee and the label

claims are same. Whereas, for registration of pesticide formulation for indigenous manufacture having different chemical composition that of formulation already registered for import u/s 9(3), complete data on Bioefficacy to be submitted as per already existing guidelines for formulation indigenous manufacture (FIM) U/s 9(3) provided the technical (source) to be used for making formulation is duly registered as per guidelines of the Registration Committee.

6. In case of Formulation Import without registering technical or Formulation Indigenous Manufacturing without registering technical**,** in addition to data on formulation, complete bioefficacy data on technical as per the guidelines of Technical Import or Technical Indigenous Manufacture is required.

7. For petroleum derived product like spray oil and natural mineral oil products, in case of 9(3) and 9(3b) data on Sr. No. 1, 2, 3, 5, 14, 15, 16, 17 & 19 (Table – 1) is required.

8. For Manufacturing Use Product (MUP) of pesticide u/s 9(3),

a. If the technical grade pesticide is not registered, complete data with respect to product technical on Bioefficacy as per guidelines for technical import u/s 9(3) to be submitted along with data on MUP as listed below.

b. If the technical grade and source for import is duly registered as per guidelines of the registration committee, no data on
Bioefficacy will be required except Registration status of MUP in foreign countries.

c. Rationale for import and registering the MUP to be submitted in Bioefficacy.

9. For use of Surfactant with registered pesticide Formulations**,** data on two seasons Sr. No. 1 & 2 (Table – 1) from minimum three different agro-climatic zones are to be generated with surfactant (tank mix) and without surfactant. The data on Sr. No. 11, 12 13, 15 & 16 (Table – 1) are to be generated with surfactant as per the requirement of the general guidelines u/s 9(3) of the Insecticides Act, 1968.

10. For registration of twin pack of two registered Herbicides and Surfactant**,** data on Sr. No. 1, 2, 3 & 14 (Table – 1) if proposed to mix, Sr. No. 11, 12 & 13, 15, 16, 19 & 20 (Table – 1) is required.

Note: Two season data on Sr. No. 1 & 2 (Table – 1) are to be generated on combination of the two herbicides with & without surfactant and individual herbicide from minimum three different agro climatic conditions. The bioefficacy data on other parameters are to be generated on the combination of the two herbicides with surfactant as per the requirement of general guidelines u/s 9(3) of the Insecticide Act, 1968.

11. MRL fixation may be required for seed treatment products on those crops which are being consumed within one month of sowing.

Data requirements for Registration for Post-Harvest Treatment of crop produce

a) Data requirements for Registration of Technical -

Note:

1. The data should be submitted on Parameters for Bio-efficacy as per the guidelines approved by the RC from time to time for registration of Chemical pesticides under TIM / TI U/s 9(3) category, as the case may be. The specific data requirements / information for registration of technical (TC/TK) are as under: -

   (i) Fate and behaviour in treated crop produce
   (ii) Fate and behaviour in air
   (iii) Fate and behaviour in water
   (iv) Fate and behaviour in soil & data on Sr. No. 17 & 19 (Table – 1) is required.
   (v) If the product technical is not in gas form and/or also to be used to make formulation(s) for use for other than fumigation of post-harvest crop produce (e.g. for use in field crops, household purposes etc.), the additional data requirements on technical to be submitted as per the guidelines approved by the RC from time to time for registration under TIM / TI category U/s 9(3), as the case may be.

b)Data requirements for Registration of MUP (Manufacturing Use Product) –

Note: -

1) If technical grade of the pesticide is not registered, complete data with respect to product technical on Bio-efficacy as per above guidelines under I. above for technical indigenous manufacture (TIM) / technical Import (TI) U/S 9(3), as the case may be, to be submitted along with data on MUP as listed below.

2) If the technical grade and source for import is duly registered as per guidelines of the Registration Committee, data on MUP to be submitted as listed below.

(i) Registration status of MUP in other countries.

(ii) If the product MUP is not in gas form and/or also to be used to make formulation(s) for use other than fumigation of post-harvest crop produce

(e.g. for use in field crops, household purposes etc.) the additional data requirements for registration of MUP to be submitted as per the guidelines approved by the RC from time to time for registration of Chemical Pesticides U/s 9(3).

c) Data requirements for Registration of formulation –

Note:

1) For registration of a formulation under FIM / FI U/s 9(3) category, the technical (TC/TK) and / or MUP from which formulation to be manufactured, should be registered under the Insecticides Act, 1968.

2) An applicant seeking registration of a formulation without registering technical for import/indigenous manufacture U/s 9(3), required to submit complete data as per the guidelines for registration of formulation listed below, along with complete data as per above guidelines for registration of technical for import/indigenous manufacture U/s 9(3) category, as the case may be.

3) The data parameters for Bio-efficacy shall be as per the guidelines approved by the RC from time to time for registration of Chemical pesticides under FIM / FI U/s 9(3) category, as the case may be. The specific data requirements / information for registration of formulation of 1-MCP and such other products for use on post-harvest crop produce are as under: -

Table – 2

1. Data on bio-effectiveness 2.Adverse effect on postharvest crop produce, if any (phytotoxicity, change in appearance and flavour etc.) 3. MIC	For label claim of controlled atmospheric conditions (same temperature and relative humidity) data on 1. And 2. To be submitted for two repeated trials from minimum three crop specific locations, irrespective of seasons **And/or** For label claim of ambient atmospheric conditions (same temperature and relative humidity) data on 1. And 2. To be submitted for two season from minimum three agro climatic zones. Crop specific locations shall be considered for those crops where agro climatic zones are not available.
4. Residue and persistence at different interval (immediately after treatment, start from 0 hours till BDL or acceptable level) in post-harvest crop produce.	For label claim of controlled atmospheric conditions (same temperature and relative humidity) data to be submitted for one trial from minimum four crop specific locations, irrespective of seasons **And/or**

	For label claim of ambient atmospheric conditions (same temperature and relative humidity) data to be submitted for one seasons from minimum four agro climatic zones. Crop specific locations shall be considered for those crops where agro climatic zones are not available.
5. For fumigants, estimated concentration from air to soil deposition (wet/dry). If, formulation is other than fumigant, data on persistence in soil (wet/Dry)	
6. For fumigants, estimated concentration from air to water deposition. If, formulation is other than fumigant, data on persistence in water.	
7. Registration status of formulation in other countries	Required
8. MRL Performa and label leaflets	Required
9. Label claims as per product Bioefficacy (eg. Increase in shelf life of post-harvest crop produce in storage) must include details like: duration of increase in shelf life, interval between harvest and treatment of post-harvest crop produce, application rate (dose rate in detail), method and time of application, concentration in air, treatment duration, re-entry period, went out duration, safe waiting period, target diseases, precautions and other relevant information as per gazette notifications issued by Govt of India from time to time.	

Note: Post harvest application of any pesticide should be under expert supervision (PCO's)

Imp. Note: 1. For Fungicides the efficacy trials should be conducted in areas where the claimed crop is the main crop of that particular area and the area should be hot spot of the claimed disease i. e disease pressure should be more than 30 % during the trial period and the fungicide should show minimum 70 % control. This must be certified by the SAU/ICAR institute where the study has been done. In case of insecticide reduction over control should not be less than 70% and in case of herbicides Weed Control Efficiency (WCE) of individual weed species should be minimum 70%, which is duly authenticated by ICAR/SAUs.

vi) Bio-efficacy data on target pests (diseases, insects, nematodes and weeds etc.) should be generated by ICAR/SAUs and institutes under National Agriculture Research System.

12. <u>Registration of Long Lasting Insecticide Impregnated mosquito bed nets and Long Lasting Insecticide</u>

<u>Incorporated mosquito net for registration U/S 9(3) :</u>

1. Three years' bio-efficacy trial in three locations. Out of three locations, two locations should be in endemic areas. The bio-efficacy trial has to be conducted by adopting the protocol devised by the Malaria Research Centre/VCRC (ICMR).
2. Baseline data on persistence of insecticides on the net and its analysis for comparison on yearly basis.
3. Sustainability of fabrics.

13. Registration of insecticides for control of Ecto-parasites (Mites, Bedbugs, Ticks etc.) in poultry u/s 9(3) & 9(3b):

a) Technical 9(3) & 9(3b) – Data on parameters on Sr. No. 8, 9, 11, 12, 17 & 19 are required.

b) Formulation 9(3) & 9(3b) – Data on parameters on Sr. no. 14, 17 & 19 are required. In addition to Sr. no. 14, 17 & 19 data on Effect on layers (duration 3 months, study to commence preferably at the age of 40 weeks) – data generated in National/ ICAR/SAU Laboratories [three for 9(3) and 2 for 9(3B)] on [(i) change in body weight, (ii) feed intake, water intake, Feed Conversion Ratio (FCR) (iii) mortality and morbidity pattern, (iv) * Clinical symptoms/morphological changes in organs, (v) * Blood profile and Enzymology,(vi) egg production records for 15 days.], Persistence and residue on treated surface, Residues in various organs of birds and edible products, Residue in birds excreta.

Note: In case of import of formulation without registering technical, whole set of data on technical shall be submitted along with the application.

14. Registration of insecticidal formulations for use in aircraft disinfection

General requirement:

1. All insecticides for aircraft disinfection must be manufactured only from the technical grade insecticides which are registered under the Insecticides Act, 1968
2. Data on insecticides formulation shall be considered along with the data on technical grade insecticides and not in isolation.

Bioefficacy and residue data: Bioefficacy test on the proposed formulation should be conducted in Indian conditions minimum 2 trials in each of 3 National Laboratories / NABL accredited laboratories, recognized by Government of India.

Data on persistence of pesticides on commonly used surfaces in the aircrafts and concentration in air, as applicable, should be generated in three National Laboratories/ NABL accredited laboratories.

15. Data requirement for registration of insecticides for use in public health programme u/s 9(3)

1. Bioefficacy data generated by ICMR / MOH&FW Institutes based on multi-centric three years / seasons as per their protocol.

16. Data requirements for registration of house hold pesticides

GENERAL REQUIREMENT:

1. All household pesticides as defined must be manufactured only from the technical grade pesticides which are registered under the Insecticides Act, 1968.

2. Data on household pesticides formulation shall be considered along with the data on technical grade pesticides and not in isolation

Data requirements from bioefficacy and residue parameters:

A. Bio-efficacy claims in case of formulation

vii) Bio-efficacy claims to be given on the labels

(i) A brief direction concerning the major usages of the pesticides should be given on the labels.

(ii) Whenever the Registration Committee has approved the product for restricted use, this should be indicated very clearly on the labels in capital letters. 'For use only.

(iii)Instruction regarding Insecticide 'Not to be used on any food crop to be given'.

(2) Bio-efficacy claims to be given on the leaflets

(i) Detailed information on the usages of insecticide indicating the name of insects, method of application, dosage, places of treatment, PP equipments to be used etc. should be given in paragraphs forms. Common name of the insects should be given.

(ii) Whenever the registration committee has approved the product for restricted use, this fact should be indicated very clearly on the leaflets in bold letters.

(iii) Instructions regarding Insecticides 'Not to be used on any food crop to be given'.

B. Bio-efficacy claims to be given on the labels and leaflets in case of technical grade material.

1. The purpose of import /manufacture of technical grade material is required to be given on the labels and leaflets.

C. Data requirements on Bioefficacy and Residues for formulation of pesticides for provisional registration of U/s 9(3B).

(I) The applicant should submit published / cited Indian data on bio-effectiveness in support of the claims indicated on the labels / leaflets. The data should be produced from 2 National laboratories based on minimum 2 repeated trials. This should be further supported with any published information available from elsewhere (overseas data).

(II) Information on secondary pests outbreaks particularly of ticks and mites should be given where residual pyrethroids are being used.

viii) **Data on Residues**:

Data on persistence, of the pesticides which should be on different types of surfaces should be submitted / generated obtained under foreign / Indian conditions from 2 laboratories. This may also be supported by data generated elsewhere.

(IV) Data on concentration of a.i. in Air – for Aerosols (e.g. Coil, mats, liquid vaporizer etc.). Registration Status in foreign countries.

D. Data requirements on Bio-efficacy & Residues data requirement for regular registration of formulations of pesticides U/s 9(3):

(ii) Bio-efficacy test on the proposed formulations should be conducted under Indian **conditions minimum on two trials in each two national laboratories with three replications.**

(iii) Data on persistence of pesticides on different types of surfaces should be generated in three national laboratories wherever applicable.

(iv) Information on secondary pests outbreaks particularly of ticks and mites should be given where residual Pyrethroids are being used.

(v) Data on concentration of a.i. in Air – for Aerosols (e.g. Coil, mats, liquid vaporizer etc.). (Added based on approval in 266th meeting of RC held on 20-07-2006)

(vi) Registration Status in foreign countries.

E. Data requirements for the registration of new formulations of the approved pesticides.

Data on bio-effectiveness and persistence on different surfaces as required in case of Registration of formulations for regular registration under section 9(3).

F. Data required for combination products.

Bio-efficacy data on combination products v/s individual products. Data on persistence on different types of surfaces should also be submitted. All above data should be generated as per the requirement indicated in case of pesticides required for regular registration under section 9(3).

G. <u>Methodology</u>: Flying/crawling insects

Residual films of insecticides prepared by spraying insecticides on different types of surfaces, such as Glass, Wood, Mud & Cement surfaces. Insects to be exposed for 30 minutes and then shifted to recovery chambers for 24 hours after which the mortality count should be made and the satisfactory mortality of insects would be more than 90%. The residual toxicity of insecticides should also be studied at different intervals. Evaluation of space spray against flying insects should be conducted in PEET GRADY Chamber as per **standard ISI specification 1824**, mats/coils could also be evaluated inside the Peet Grady Chambers against caged mosquitoes and the knock down effect is to be recorded at different intervals. Aerosols are to be evaluated inside a standard room. The test is to be conducted as per **WHO technical reports series No. 206**.

TOXICITY

Sl. No	Parameters	Technical		Formulation		Technical/ Formulation	
		9(3b)	9(3)	9(3b)	9(3)	9(4)	9(4)
		TI/TIM	TI/TIM	FIM	FIM/FI	TIM	TI/FIM/FI
1.	Acute oral Rat	R	R	R	R	R	NR
2.	Acute Dermal- Rat/ rabbit	R	R	R	R	R	NR
3.	Acute inhalation	R	R	R	R	R	NR
4.	Primary Skin Irritation	R	R	R	R	R	NR
5.	Acute Eye Irritation	R	R	R	R	R	NR
6.	Skin Sensitization Test	R	R	R	R	R	NR
7.	Repeated dose range finding oral toxicity study (28 days)*	R	R	NR/ R	NR/R	NR	NR
8.	Repeated dose 90 days oral (Rat)	R	R	NR/ R	NR/R	NR	NR
9.	Repeated dose 90 days oral (Dog)*	R	R	NR/ R	NR/R	NR	NR
10.	Repeated dose dermal toxicity	R	R	NR/ R	NR/R	NR	NR
11.	Repeated dose inhalation toxicity*#	R	R	NR/ R	NR/R	NR	NR
12.	Acute Neuro-toxicity- Rodent*	R	R	NR	NR/R	NR	NR
13.	Repeated dose Neurotoxicity- Rodent*	R	R	NR	NR/R	NR	NR
14.	Delayed Neurotoxicity- OP compound- Acute exposure	R	R	NR	NR/R	NR	NR
15.	Delayed neurotoxicity- OP compound-	R	R	NR	NR/R	NR	NR

	Repeated Administration						
16.	Developmental Neurotoxicity*	R	R	NR	NR/R	NR	NR
17.	Combined carcinogenicity/ Chronic toxicity study-Rat*	NR	R	NR	NR	NR	NR
18.	Carcinogenicity- Rat & Mice	NR	R	NR	NR	NR	NR
19.	Chronic toxicity-Rat	NR	R	NR	NR	NR	NR
20.	Developmental toxicity study- a) Rat & b) Rabbit	R	R	NR	NR	NR	NR
21.	Mutagenicity**	R	R	NR	NR	R	NR
22.	Pharmacokinetics and Metabolism- Rat	NR	R	NR	NR	NR	NR
23.	Pharmacokinetics and Metabolism in other mammals and its similarities or differences from humans.	NR	R	NR	NR	NR	NR
24.	Feeding study in live stock (Goat/ Cow/ Hen/ Poultry) including Metabolism in livestock	NR	R	NR	NR	NR	NR
25.	Toxicity studies on Metabolites*	NR	R	NR	NR	NR	NR
26.	Immunotoxicity study*	NR	R	NR	NR	NR	NR
27.	Acute Avian toxicity *	R (Two species)	R (Two pecies)	R (One species)	R (One species)	NR	NR
28.	Repeated dose Avian toxicity (One species)	R	R	NR	NR	NR	NR
29.	Avian Reproduction	R	R	NR	NR	NR	NR

	toxicity (One species)						
30.	Acute toxicity to Fresh Water Fish (One species)	R	R	R	R	NR	NR
31.	Acute toxicity- Freshwater invertebrate	R	R	R	R	NR	NR
32.	Acute Toxicity- Honey Bee (Oral & Contact)	R	R	R	R	NR	NR
33.	Effect on Soil microbial activity	R	R	R	R	NR	NR
34.	Acute Toxicity- Earthworm	R	R	R	R	NR	NR
35.	Algal toxicity- Tier I	R	R	R	R	NR	NR
36.	Medical data	R	R	R	R	NR	NR
37.	Human toxicity information from foreign countries	R	R	R	R	NR	NR
38.	Operators/ workers exposure assuming (i) Recommended Personal Protective Equipment (PPE) is Used (ii) Without use of recommended PPE	NR	NR	NR	R	NR	NR
39.	Health records of Industrial workers	NR	R	NR	R	NR	NR
40.	International report on Carcinogenicity & Genotoxicity	NR	R/NR	NR	NR	NR	NR

Notes:-

1) **Technical (TI and TIM) u/s 9(3b) and 9(3) :- In case of Technical, name and Percentage of relevant and toxic impurities and/or metabolites should be indicated. Also data/information should be provided about their toxicity.)**

2) Technical u/s 9(3):-

-TI u/s 9(3):- In case of Technical Import, data from Sl. No. 1 to 40 are required.

-TIM u/s 9(3):- In case of Technical Indigenous Manufacture, data of Sl. No. 37 and S. No. 39 are not required.

3) Technical Import from new Source u/s 9(3):- Data on parameters 1 to 11; 21, 36-37 and 40 is required.

4) Technical Indigenous Manufacture u/s 9(3) in case same technical is registered for import or formulation made from the same technical is registered for import or indigenous manufacture:

i.) If impurities are identified , quantified and impurities are within limits (i.e. within maximum of already registered technical) ,then data on parameters 1-6 and 21 is required.

ii.) In case impurities which are not toxic and not relevant and are not within maximum limits of registered technical however are within +3%) and no new impurity is there, then same data as above (Parameters 1 to 6 and 21) will be required.

iii.) If impurities are identified, quantified and are not within limits of registered technical or if impurities are not within +3%) and/or any additional impurity is present then in addition to the tests as indicated in (4) above, additional tests based on the nature and quantity of impurity and QSAR alert will be taken on case to case basis.

5) Technical indigenous manufacture u/s 9(3) in case same technical is registered for import or formulation made from the same technical is registered for import BY THE SAME APPLICANT WITH SAME COMPOSITION, PROCESS OF MANUFACTURE ETC.:- Data on Ames Test only is required.

6) 9(4) TIM:- In case of Technical indigenous Manufacture u/s 9(4), data from Sl. No. 1 to 6 and Sl. No. 21 data of *@AMES Test (Tier-I)* is required.

7) Formulation u/s 9(3b):- Data as per FIM u/s 9(3b) required as indicated in table above.

8) Formulation u/s 9(3):-

-For FI data is required as indicated in table above.

-For FIM :- as indicated in table except data of Sl. No. 37 and S. No. 39 are not required.

9) In case of FI WRT (Formulation Import without registering Technical) OR FIM WRT (Formulation Indigenous Manufacture without registering Technical), in addition to data on formulation, complete toxicity data on technical as per the guidelines of TI , or TIM (as the case may be) should also be submitted.

10) 9(4) TI/FIM:- No data is required, in case of Technical Import(TI) or Formulation Indigenous Manufacture (FIM) u/s 9(4) application.

11) For LLIN: Acute toxicity studies (Six pack) i.e. S.No. 1 to 6 are required with Premix and health monitoring studies in users as per approved protocol is required with final product (LLIN).

12) MUP: i.) Data on the parameters from S.No. 1 to 6, should be submitted. ii.) If the Technical grade pesticide from which MUP is to be prepared is not registered, complete data with respect to product Chemistry (along with sample and reference standard of technical grade pesticide and impurities), Bioefficacy, Toxicity and Packaging as per the applicable guidelines for registration of technical should be submitted.

13) Household Pesticide Formulations a.) Data on the parameters from S.No. 1 to 6, should be submitted for pesticides in Solid & Liquid form. In case of Pesticides in Vapour form or which emits vapour/fumes, in addition to parameters from S.No. 1 to 6, Health monitoring study of the user by using the household pesticides in its actual use should also be submitted. The study should be as per the protocol approved by the RC. b.) Data on household pesticides formulation shall be considered along with the data on technical grade pesticides and not in isolation.

14) Pesticide Formulation for use in Public Health : Data on the parameters from S. No. 1 to 6, 27, 28, 30 & 31 should be submitted. Recommendations from National Vector Disease Control Program, M/o Health & Farmers Welfare are also required.

15) Formulation for use for Aircraft Disinsection: If the technical grade is duly registered as per guidelines of the Registration Committee, data on the parameters from S.No. 1 to 6 should be submitted.

16) Herbicides in twin pack with no other herbicide or with surfactant: MSDS and Acute toxicity information on surfactant should be submitted along with data on herbicide formulation.

*** PLEASE REFER TO GUIDANCE DOCUMENT ON TOXICOLOGY FOR REGISTRATION OF CHEMICAL PESTICIDES IN INDIA.**

**** In Mutagenicity test; an Ames test, any two *in-vitro* and one *in-vivo* Mutagenicity tests are required.**

 # Repeated Dose Inhalation toxicity Study for 90 days exposure would be required if there is likelihood of significant repeated inhalation exposure as in case of gas, vapours , aerosols, fumigants or likely duration of human exposure via inhalation is long viz. Mosquito coils; sprays used repeatedly.

PACKAGING

Chapter V of the Insecticides Rules 1971 in the Insecticides Act, 1968, the rule 16 to 20 of the said chapter deals with the Packaging and Labeling.

Sl. No.	Parameter	Section 9(3B)			Section 9(3)				Section 9(4)			
		TIM	FIM	TI	TIM	FIM	TI	FI	TIM	FIM	TI	FI
1.	**Labels and Leaflets per IR-1971, all fields (as applicable) and as amended from time to time**	R	R	R	R	R	R	R	R	R	R	R
2.	**Manner of labeling and Leaflet**	R	R	R	R	R	R	R	R	R	R	R
3.	**Type of packaging (Ultra small, small or Big whichever is applicable)**	R	R	R	R	R	R	R	NR	NR	NR	NR
4.	**Manner of packaging**	R	R	R	R	R	R	R	R	R	R	R
5.	**Specification for primary, Secondary and Transport packages (whichever is applicable)**	R	R	R	R	R	R	R	R	R	R	R
6.	**Details of packaging material and its compatibility with content**	R	R	R	R	R	R	R	NR	NR	NR	NR
7.	**Performance of container with content during storage stability test(Shelf life Study)**	R*	R*	R*	R	R	R	R	NR	NR	NR	NR
8.	**Transport worthiness test**	R*	R*	R*	R	R	R	R	NR	NR	NR	NR

R*- Before Commercialization the data will be required.

Note:

1. In case of additional packaging endorsement applications, the data at Sl. No. 05, 06, 07& 08, are not required if similar packaging (material) is being sought by the applicant as has been granted to earlier 9(3) registrant.

2. Specification of Bureau of Indian Standard (BIS) must be followed for all the packaging requirements (Wherever available and applicable).
3. All Packaging tests must be carried out with the product of same batch and in its commercial package preferably in Indian condition.
4. The duration of the test and the conditions including geographical conditions must be mentioned.
5. Storage stability data should be generated keeping at least the following parameters in test protocol such as test temperature, test duration, test packaging material, content of active ingredient (a.i.) and relevant impurities in the product during and after storage, test humidity, exposure to light, physical and chemical properties of the product during and after storage etc.
6. The testing protocols must have their basis in the WHO/FAO/ CIPAC/ASTM recommendations or other validated methodology of GLP/ NABL accredited laboratory having packaging testing (chemical / mechanical as applicable etc.) in the scope.
7. The Accelerated storage study (ASS) test must be conducted at 54± 2^{o}C (wherever applicable) for 14 days as per FAO/ WHO manual for claiming appropriate shelf life of the product which can be maximum two years, subject to the condition of providing the ambient storage stability study data of thirty months or as the case may be within thirty months from the date of application for the registration.

ANNEXURE- IV

DATA REQUIREMENTS FOR MICROBIAL PEST CONTROL AGENTS (MPCA) PESTICIDES

Microbial Pest Control Agents (MPCA)

1. Example of MPCA are Entomopathogenic/ Entomotoxic Bacteria, Antagonistic Bacteria, Entomopathogenic Fungi, Antagonistic Fungi, Nuclear Polyhedrosis Virus (NPV) & Granulosis virus (GV).

2. The applicant needs to submit MOU/license agreement between the applicant and the inventor (either own R&D Laboratory or outsourced Research Institute/Facility). MOU between Research Organization (who conducted independent trials/experiments for bio-efficacy, toxicology, chemical, packaging studies for data generation).

3. Updated Stakeholder list for all members in Association/Organization claiming for MOU/authorization for data/technology utilization for mass multiplication/commercialization of the strain.

4. If registration is granted to a strain from a particular source, then the subsequent applicants for the same strain from the same source may apply for registration under section 9(4) based on DNA finger-printing for the strain verification from Mau Bhahjan (ICAR Institute designated by the Registration Committee for maintaining repository), if the strain designation and accession number are same.

(C)The Data Requirements for Microbial Pest Control Agents (MPCA) Pesticides

I - Microbial Pesticides

i) Entomopathogenic/ Entomotoxic Bacteria
ii) Antagonistic Bacteria
iii) Entomopathogenic Fungi
iv) Antagonistic Fungi
v) Nuclear Polyhedrosis Virus (NPV) & Granulosis Virus (GV)

Sl. No.	**Characteristics**	**Microbial (Antagonistic bacteria, Entomopathogenic/Entomotoxic bacteria, Entomopathogenic fungi, Antagonistic fungi, and Baculovirus**					
		Primary culture/mother culture			Formulated product		
		9(3B)	**9(3)**	**9(4)**	**9(3B)**	**9(3)**	**9(4)**
1. 1.1	Systematic name (Genus and species) Strain name	R R	R R	R R	R R	R R	R R
2.	Common name, if any	R	R	R	R	R	R
3.	Source of origin	R	R	R	R	R	R
4.	Specification of the product Habitat, Physical appearance and morphological description, pH, particle size, suspensibility, miscibility	R	R	R	R	R	R
5.	Manufacturing process.	R	R	NR	R	R	NR

6.	Methods of analysis including Quantitative analysis	R*	R*	R*	R*	R*	R*
7.	Shelf life claims	R	R	R	R	R	R
7.1	Data on storage stability as per shelf life claims	R	R	NR	R	R	NR
8.	Composition of the product	R	R	R	R	R	R
8.1	Potency of product by bioassay method (LC 50 (Beta,Delta , Cry toxin endotoxin content, classification (delta endotoxin)	NR#	NR#	NR#	NR#	NR#	NR#
8.2	CFU/g or ml	R	R	R	R	R	R
8.3	POB/Capsule count	NR	NR	NR	NR	NR	NR
8.4	pr ml/g of the product	R	R	R	R	R	R
8.5	Adjuvants	R	R	R	R	R	R
8.6	Human pathogens (culture method)	R	R	R	R	R	R
	Percent content of the Bio-control organism in the formulation & nature of biomass.						

8.7 8.8	Percentage of carrier/filler, wetting/ dispending agent, stabilizers/ emulsifiers, contaminants/ impurities etc. Moisture content	R R	R R	R R	R R	R R	R R
9. 9.1	Contaminants: Pathogenic contaminants such as Salmonella, Shigella, Vibrio and such other microbials, not exceed 1 x 10^4 count per ml or per g of formulation Chemical and botanical pesticide contaminants	R R	R R	R R	R R	R R	R R
10.	Natural occurrence of the organism	NR	NR	NR	NR	NR	NR
11.	Immunology assays: Elisa	NR	NR	NR	NR	NR	NR
12.	Separation and purification of crystals	NR	NR	NR	NR	NR	NR
13.	A sample for verification (500 g or 500mL as the	R	R	R	R	R	R

	case may be) DNA fingerprinting for the strain verification from Mau Bhanjan. Pre registration verification at Central Insecticide laboratory (CIL)	R R	R R	R R	R R	R R	R R

* Test procedure and criteria used for identification – morphology, biochemistry, serology/ Immunology
for Entomotoxic bacteria.
these parameters are required for Entomotoxic bacteria.

- POB/Capsule count per ml/g of the product only for NPV.
- Viral unit: NPVs $1x10^9$ POB/ml or gm. minimum, GVs: $5x10^9$ capsules /ml or gm. minimum.

- Dual culture to attain at least 50% reduction in target organism (35% for antagonistic bacteria). Bioassay: based on diseased severity and root colonization.
- Natural occurrence of the organism, Immunology assays: Elisa and Separation and purification of crystals are required for Entomotoxic bacteria.
- Test procedure and criteria used for identification by DNA test (Restriction enzymes analysis test).
- Biological assays for determining the LC_{50} / LD_{50} of the formulation for Entomotoxic bacteria..
- Manufacturing process including type of fermentation and biological end products. The microbial cultures are multiplied by liquid solid fermentation. Information pertaining to use of entire mycelia mats with spores separated must be provided in terms of biomass.

Documents to be mandatorily furnished by applicant applying u/s 9 (3)/ 9(3b) for all categories of bio pesticides

1. Verification of the Authorization letter submitted by the applicant via e mail by Secretariat from the original inventor/source of the strain for data utilization for mass multiplication.

2. MOU /license agreement between the applicant and the inventor (either own R & D Laboratory or outsourced Research Institute / Facility). MOU between Research Organization (who conducted independent trials/experiments for bioefficacy, toxicology, chemical, packaging studies for data generation)

3. Updated Stakeholder list for all members in Association/ Organization claiming for MOU/authorization for data /technology utilization for mass multiplication/commercialization of the strain.

Note: 1. Applicants are required to submit an undertaking that strain is indigenous, naturally occurring, not exotic in origin, and not genetically modified as per **Annexure -A**

2. Bt products should be labeled with biopotency and (or) toxin content. In addition, the labels will have to contain a measurement of toxin protein as percent protein, referring to the Lepidopteran-active toxin(s) present in the crystal.

3. The presently used Bt var. kurstaki standard is HD-1-S-1980 and its potency was calculated at 16,000 IUs per milligram of powder (Beegle et al. 1986. Standardization of HD-1-S-1980: US Standard for Lepidopterous-active *Bacillus thuringiensis*. Bulletin Ent. Soc. America 32: 44-45.). This standard strain is now available with PDBC, Bangalore and DOR, Hyderabad.

4. Defined potency and toxin concentration – Bioassay would require the use of an insect species. Normally manufacturers could select *Trichoplusia ni* / *Helicoverpa armigera* for Lepidopteran specific Bt formulations. *Spodoptera* Units (SPU), *Leptinotarsa* Units (LTUs) or International Toxin Units (ITUs) are to be used for denoting a specific insect.

5. No test for beta exotoxin is required for *Bacillus sphaericus*, because this species is not known to produce exotoxins.

6. The biopotency of products based on *B. thuringiensis* subsp. *israelensis* (*Bti*) is compared against a reference strain IPS82, 1884 using early fourth-instar larvae of Aedes aegypti (strain Bora Bora). The toxicity of IPS82 has an arbitrarily assigned toxicity of 15,000 ITU/mg powder.

7. The biopotency of products based on *B. sphaericus* (*Bsh*) is determined against a reference standard SPH88, strain 2362 using early fourth-instar larvae of Culex pipiens pipiens (strain Montpellier). The toxicity of SPH88 has an arbitrarily assigned toxicity of 1,700 ITU/mg of the powder (Guidelines for laboratory and field testing of mosquito larvicides, WHO 2005 pp 45).

8. The use of alternative bacterial reference powders and / or strains must be approached cautiously. Such alternatives must be the subject of careful cross-calibraation against the reference powders and should be conducted by recognized laboratories and should be made available to anyone who wishes to use, or check, the test with the alternative powders/strains.

9. Water content should not exceed 5 %, to preclude premature degradation of the product.

Annexure-.A

UNDERTAKING BY MANUFACTURERS OF MICROBIAL PESTICIDES

I,----------,aged-------years, s/o----------, R/o----------and----------of M/s.----------Registered Office at----------do hereby undertake as follows:

(a) That the product----------based on----------, Strain----------, manufactured by M/s.----------and /or imported by M/s……..does not contains any genetically modified organism (GMO) .

(b) That I/We shall abide by the provisions contained in the International Plant Protection Convention with regard to the import of this product.

(c) That I/We shall abide by the provisions in context of International Standards for Phyto-Sanitary Measures-Code of Conduct for the import and release of exotic biological control agents of the International Plant Protection Convention (IPPC), FAO, Rome.

(d) That I/We shall provide the samples of our----------product as and when desired by the competent authorities of Government of India for verification.

(e) That I/We further undertake that in the event of the above product having proved otherwise by any competent authority and resulting in environmental damage, I/We shall inform the Central Insecticides Board and Registration Committee, the relevant authorities for Manufacturing Licensing, Pollution Control and of appropriate District/State/National Level and shall comply with the directions/decisions from them.

(f) That my/our above undertaking is true, and no portion is false and I have concealed nothing relevant to the above matter.

Signature:----------

Date-------

Name--------- ----------

Place:----------

Designation----------

Seal of the Company- -----

Bio-efficacy

Sr. No.	Particulars	Primary culture/mother culture			Formulated product		
		9(3B)	9(3)	9(4)	9(3B)	9(3)	9(4)
1	**Field studies:** Data on bio-effectiveness and phytotoxicity generated at ICAR, SAUs, CSIR / ICMR institutes. The data should be certified either by the Director or Head of the Institute.	NR	NR	No bio-efficacy data required. Certificate of Registration will be granted as approved u/s 9(3)	R **	R***	No bio-efficacy data required. Certificate of Registration will be granted as per approved formulation u/s 9(3)
2	**Laboratory studies:** The product should be tested at a laboratory under ICAR/ SAU/ CSIR/ICMR. **2.1)** LC50 values for each insect species under laboratory conditions should be generated at least at two institutes of ICAR, SAUs, CSIR and ICMR. **2.2)** Data on LC50 values for each target insect species should be generated at a laboratory under ICAR/ SAU/ CSIR/ICMR	R	R		R	R	
3	Data on non-target organism: One season/one year on effect on product against natural parasites/ predators .	NR	NR		R	R	

R - Two seasons/years data on bio-effectiveness from two agro-climatic Zones**

R * - Two seasons/years data on bio-effectiveness from minimum three agro climatic Zones.**

2.1) - Applicable for Entomotoxic Bacteria

2.2 – Applicable for NPV & GV.

Sr. No. 3 - Required in case of Entomopathogenic fungi, Antagonistic Bacteria.

Toxicity

Data required for registration of microbial bio-pesticides - Antagonistic bacteria, Entomopathogenic/Entomotoxic bacteria, Entomopathogenic fungi, Antagonistic fungi, and Baculovirus

S. No.	Parameters	Microbial (Antagonistic bacteria, Entomopathogenic/Entomotoxic bacteria, Entomopathogenic fungi, Antagonistic fungi, and Baculovirus					
		Primary culture/mother culture			Formulated product		
		9(3b)	9(3)	9(4)	9(3b)	9(3)	9(4)
	Single Dose Oral – Rat (Toxicity/Infectivity/Pathogenicity)	R	R	No data required for already registered strain from the same source with same strain designation and accession number.	R	R	No data required for already registered strain from the same source with same strain designation and accession number.
	Single Dose Dermal – Rabbit (Toxicity/Infectivity/Pathogenicity)	R	R		R	R	
	Acute Inhalation (a)	R	R		R	R	
	Single Dose Pulmonary – Rat (b) (Toxicity/Infectivity/Pathogenicity)	R	R		R	R	
	Single Dose Intraperitoneal – Rat (c) (Toxicity/Infectivity/Pathogenicity)	R	R		R	R	
	Single dose intravenous (d)	R	R		R	R	
	Primary Skin Irritation - Rabbit	R	R		R	R	
	Primary Eye Irritation - Rabbit	R	R		R	R	
	Skin Sensitization - Guinea pig	R	R		R	R	
	Cell culture (d)	R	R		R	R	
	Human Safety Records (Effect/Lack of effects)	NR	R		NR	R	
	Toxicity to bird (2 species) (Toxicity/Infectivity/Pathogenicity)	NR	NR		NR	R	
	Toxicity to Fresh water Fish (Toxicity/Infectivity/Pathogenicity)	NR	NR		NR	R	
	Toxicity to Honey bees (e)	NR	NR		NR	R	
	Toxicity to Silkworm (f)	NR	NR		NR	R	
	Toxicity to Earthworm (g)	NR	NR		NR	R	

Note: a - Inhalation toxicity study required for registration of entomopathogenic/entomotoxic bacteria

b - Pulmonary toxicity study required for registration of antagonistic bacteria, antagonistic fungi, entomopathogenic fungi, baculovirus

c - Intraperitoneal toxicity study required for registration of antagonistic fungi, entomopathogenic fungi, antagonistic bacteria

d - Cell culture and Intravenous study required for registration of baculovirus.

e and f – required for all except antagonistic fungi

g- required for all except entomopathogenic/entomotoxic bacteria

PACKAGING

Chapter V of the Insecticides Rules 1971 in the Insecticides Act, 1968, the rule 16 to 20 of the said chapter deals with the Packaging and Labeling.

Sl. No.	Parameter	Primary culture/mother culture			Formulated product		
		9(3B)	**9(3)**	**9(4)**	**9(3B)**	**9(3)**	**9(4)**
1.	**Labels and Leaflets as per IR-1971, all fields (as applicable) and as amended from time to time**	R	R	R	R	R	R
2.	**Manner of labeling and Leaflet**	R	R	R	R	R	R
3.	**Type of packaging (Ultra small, small or Big whichever is applicable)**	R	R	R	R	R	R
4.	**Manner of packaging**	R	R	R	R	R	R
5.	**Specification for primary, Secondary and Transport packages (whichever is applicable)**	R	R	R	R	R	R
6.	**Details of packaging material and its compatibility with content**	R	R	R	R	R	R
7.	**Performance of container with content during storage stability test(Shelf life Study)**	R*	R	R	R*	R	R
8.	**Transport worthiness test**	R*	R	R	R*	R	R

R*- Before Commercialization the data will be required.

Note:

1. In case of additional packaging endorsement applications, the data at Sl. No. 05, 06, 07& 08, are not required if similar packaging (material) is being sought by the applicant as has been granted to earlier 9(3) registrant.
2. Specification of Bureau of Indian Standard (BIS) must be followed for all the packaging requirements (Wherever available and applicable).

3. All Packaging tests must be carried out with the product of same batch and in its commercial package preferably in Indian condition.
4. The duration of the test and the conditions including geographical conditions must be mentioned.
5. Storage stability data should be generated keeping at least the following parameters in test protocol such as test temperature, test duration, test packaging material, content of active ingredient (a.i.) and relevant impurities in the product during and after storage, test humidity, exposure to light, physical and chemical properties of the product during and after storage etc.
6. The testing protocols must have their basis in the WHO/FAO/ CIPAC/ASTM recommendations or other validated methodology of GLP/ NABL accredited laboratory having packaging testing (chemical / mechanical as applicable etc.) in the scope.
7. The Accelerated storage study (ASS) test must be conducted at 54± 2^{o}C (wherever applicable) for 14 days as per FAO/ WHO manual for claiming appropriate shelf life of the product which can be maximum two years, subject to the condition of providing the ambient storage stability study data of thirty months or as the case may be within thirty months from the date of application for the registration.

ANNEXURE V

PLANT BASED PRODUCTS

II: Plant Based Products

Botanical Pesticides/Pesticides of Plan Origin

Eucalyptol, Cymbopogon formulation, Neem Based Pesticides, Pyrethrum Extract & Rotenone for Pisci-culture (Formulation)] & Essential Oils (formulations only) etc.

General Guidance

1. It is clarified that traditional remedies or products prepared by the individuals for their own-self use do not need registration if the produce is not sold. If the product prepared or the treated produce is to be sold in the market, then the registration is required under the provisions of the Act.
2. Sometimes the active substances to be used as Plant origin or botanical bio-pesticides, are vastly studied and the information of good quality which is consistent with current methodology, information/data is available, then waivers for submission of certain data, if justified, can be granted. Further, in some cases, based on the information and characteristics or the results of studies, additional data may be required.
3. For registration of extract u/s 9(4): It shall be obtained from the same part of the plant with same process of extraction and should have identical chemical composition as of 9(3) registrant.
4. Formulation to be registered u/s 9(4) should have identical chemical composition and required to be prepared from the extract already registered under the Act for use in the country.

Chemistry

Plant extract like Eucalyptol, Cymbopogon, Neem Based Pesticides, Concentrate Pyrethrum Extract, Herbal/ Botanical plant growth regulator , Rotenone for Pisci-culture and Plant essential oil etc.

S. No	Parameter	Botanical					
		Plant extract/ concentrate			Formulation		
		9(3b)	9(3)	9(4)	9(3b)	9(3)	9(4)
1	Name of the Part of the Plant(s) to be used for extraction of the active ingredients.	R	R	R	R	R	R
2	Source of supply of the technical grade material	R	R	R	R	R	R
3	Outline of Process of Formulation.	R	R	R	R	R	R
4	Extract Contents active ingredient	NR	NR	R	R	R	R
5	Chemical composition of the formulations	R	R	R	R	R	R
6	Physico-chemical properties of a.i. & adjuvants	R/ NR	R/ NR	NR	R/ NR	R/ NR	R/ NR
7	Product Specifications as BIS format	R	R	R	R	R	R
8	Method of analysis (a.i.)	R	R	R	R	R	R
9	An undertaking that the product does not contain any other chemical pesticide except plant extract	R	R	R	R	R	R
10	Analytical test report	R	R	R	R	R	R
11	Shelf-life claim	R	R	R	R	R	R
12	Shelf-life data	NR	R	NR	NR	R	NR

Bio-efficacy

	Parameters	**Technical**			**Formulations**		
		9(3B)	**9(3)**	**9(4)**	**9(3B)**	**9(3)**	**9(4)**
1	Bio-effectiveness against target pest species in specified crops	R* (Two season data from min. Two agro climatic zones)	R* (Two season data from min. Three agro climatic zones)	No bio-efficacy data required. Certificate of Registration will be granted as per approved technical u/s 9(3)	R (Two season data from min. Two agro climatic zones)	R (Two season data from min. Three agro climatic zones)	No bio-efficacy data required. Claim will be granted as per approved formulation u/s 9(3).
2	Phytotoxicity (as per standard tests)	R* (same as above 1)	R* (same as above 1)		R (same as above 1)	R (same as above 1)	
3	Compatibility with other agro-chemicals, if claimed	R*	R*		R	R	
4	Stability of formulation (Photo, Thermal etc.) in aqueous dilution (acidic, neutral & basic)	R*	R*		R	R	
5	Direction concerning dosage for each target pest species	R*	R*		R	R	
6	Stage of crop for use and stage of target pest	R*	R*		R	R	
7	Waiting period	R*	R*		R	R	
8	Application equipment	R*	R*		R	R	
9	Information regarding registration status in other countries, if any.	R	R		R	R	
10	Time of Application	--	--		R	R	
11	Purpose of Manufacture	--	--		R	R	
13	Residue in Plant	--	--		R	R	
1	Residue in Soli	--	--		R	R	

4							
15	Registration status in foreign countries	--	--		R	R	
16	Residue tolerance limits fixed by foreign countries)	--	--		R	R	

R – Required NR – Not Required.

Note :

1. Sr. No. 4 & 6 not required in case of Cymbopogan formulation (Plant extract) & Neem Based Pesticides

2. Sr. No. 1,2,3,,5,6,7,8,9,10 applicable for Essential oil for Formulation only.

Toxicology

	Parameters	**Extract/concentrate**			**Formulation**		
		9(3b)	9(3)	9(4)	9(3b)	9(3)	9(4)
1.	Acute oral toxicity – Rat	R	R	No data required if chemical equivalence is established with 9(3) registrant.	R	R	No data required if chemical equivalence is established with 9(3) registrant.
2.	Acute dermal toxicity – Rabbit	R	R		R	R	
3.	Acute Inhalation - rat	R	R		R	R	
4.	Primary Skin Irritation - Rabbit	R	R		R	R	
5.	Primary Eye Irritation - Rabbit	R	R		R	R	
6.	Skin Sensitization - Guinea pig	R	R		R	R	
7.	Sub- acute oral - rat	NR	NR/R		NR	NR	
8.	Sub - acute oral - dog	NR	R		NR	NR	
9.	Sub- acute dermal	NR	R		NR	NR	
10.	Sub- acute inhalation	NR	R		NR	NR	
11.	Neuro-behavioral toxicity	NR	R		NR	NR	
12.	Teratogenicity	NR	R		NR	NR	
13.	Effect on Reproduction	NR	R		NR	NR	

14.	Carcinogenicity/chronic toxicity/combined toxicity study) *	NR	R		NR	NR	
15.	Metabolism	NR	R		NR	NR	
16.	Mutagenicity* (AMES + 2 in-vitro +1 in-vivo)	NR	R		NR	NR	
17.	Toxicity to birds (2 species)	R	R		R	R	
18.	Toxicity to fresh water fish	R	R		R	R	
19.	Toxicity to Honey bees	R	R		R	R	
20.	Toxicity to Earthworm	R	R		R	R	
21.	Medical data	R	R		R	R	
22.	Human toxicity information	NR/R	NR/R		NR/R	NR/R	
23.	Health record of industrial workers	NR	R		NR	R	
24.	International report on carcinogenicity & genotoxicity study	NR/R	NR/R		NR/R	NR/R	

Note:

1. The requirement for sub-acute studies shall be determined on the basis of results of other toxicity study reports.

2. *PLEASE REFER TO GUIDANCE DOCUMENT ON TOXICOLOGY FOR REGISTRATION OF CHEMICAL PESTICIDES IN INDIA.

PACKAGING

Chapter V of the Insecticides Rules 1971 in the Insecticides Act, 1968, the rule 16 to 20 of the said chapter deals with the Packaging and Labeling.

Sl. No.	Parameter	Extract/concentrate			Formulation		
		9(3B)	9(3)	9(4)	9(3B)	9(3)	9(4)
1.	**Labels and Leaflets per IR-1971, all fields (as applicable) and as amended from time to time**	R	R	R	R	R	R
2.	**Manner of labeling and Leaflet**	R	R	R	R	R	R
3.	**Type of packaging (Ultra small, small or Big whichever is applicable)**	R	R	R	R	R	R
4.	**Manner of packaging**	R	R	R	R	R	R
5.	**Specification for primary, Secondary and Transport packages (whichever is applicable)**	R	R	R	R	R	R
6.	**Details of packaging material and its compatibility with content**	R	R	R	R	R	R
7.	**Performance of container with content during storage stability test(Shelf life Study)**	R*	R	R	R*	R	R
8.	**Transport worthiness test**	R*	R	R	R*	R	R

R*- Before Commercialization the data will be required.

Note:

1. In case of additional packaging endorsement applications, the data at Sl. No. 05, 06, 07& 08, are not required if similar packaging (material) is being sought by the applicant as has been granted to earlier 9(3) registrant.
2. Specification of Bureau of Indian Standard (BIS) must be followed for all the packaging requirements (Wherever available and applicable).

3. All Packaging tests must be carried out with the product of same batch and in its commercial package preferably in Indian condition.
4. The duration of the test and the conditions including geographical conditions must be mentioned.
5. Storage stability data should be generated keeping at least the following parameters in test protocol such as test temperature, test duration, test packaging material, content of active ingredient (a.i.) and relevant impurities in the product during and after storage, test humidity, exposure to light, physical and chemical properties of the product during and after storage etc.
6. The testing protocols must have their basis in the WHO/FAO/ CIPAC/ASTM recommendations or other validated methodology of GLP/ NABL accredited laboratory having packaging testing (chemical / mechanical as applicable etc.) in the scope.
7. The Accelerated storage study (ASS) test must be conducted at 54± 2^{o}C (wherever applicable) for 14 days as per FAO/ WHO manual for claiming appropriate shelf life of the product which can be maximum two years, subject to the condition of providing the ambient storage stability study data of thirty months or as the case may be within thirty months from the date of application for the registration.

***

ANNEXURE VI

III. THE DATA REQUIREMENTS FOR PHEROMONES/SEMIO-CHEMICALS

The Data Requirements for Pheromones/Semio-chemicals

Chemistry

Technical for import/indigenous manufacture:

S No	Parameters	9 (3b)	9(3)	9(4)
1.	Active ingredient/Tech conc.	R	R	R
2.	Chemical composition	R	R	R
3.	Chemical name (s)	R	R	R
4.	Common name	R	R	R
5.	Physical chemical properties	R	R	R
6.	Manufacturing process	R	R	R
7.	Analytical Test Report from GLP/ NABL accredited laboratory	R	R	R
8.	Storage condition with special reference to temperature	R	R	R
9.	Source of import (In case of import only)	R	R	R
10	Sample for PRV purpose	R	R	R
11	Purpose of import/indigenous manufacture	R	R	R

1. TECHNICAL FOR IMPORT/INDIGENOUS MANUFACTURE:

1. Active ingredient

2. Laboratory test: Lure manufactured from the particular ingredient will be tested by using wind tunnel
and should demonstrate minimum 50% attractancy.

LURE/DISPENSER FOR IMPORT/MANUFACTURE:

1. Laboratory test; The lure/dispenser should demonstrate at least 50% attractacy using the wind tunnel.

2. Field test: The data on bio-efficacy based on two seasons field trials from two different agro-climatic
conditions in the form of authentic/published report.

3. Compatibility: No data on compatibility are required unless the product is recommended for use in
combination with pesticides or other agrochemicals.

4. Time and method of application: Information on timing, disruption is to be furnished.

5. Intended uses.

6. Mode of action and degree of specificity.

7. Target pest (s) and crops or premises to be protected.

8. Application rate.

9. Manner, rate and frequency of application.

10. Limitations of use.

Note: As per decision of 248th meeting of R.C. Pheromones used for monitoring and mass trapping are not covered under the various provisions of the Insecticides Act, 1968.

Bio-efficacy

S. No.	Particulars	9 (3b)	9(3)	9(4)
1.	**Active ingredients**	**R**	**R**	No bio-efficacy data required. Claim will be granted as per approved formulation u/s 9(3).
2.	**Laboratory test (**attractancy) **:** Lure manufactured from the particular ingredient will be tested by using wind tunnel and should demonstrate minimum 50% attractancy	**R**	**R**	
LURE/DISPENSER FOR IMPORT/MANUFACTURE:				
3.	**Laboratory test:** The lure/dispenser should demonstrate at least 50% attractacy using the wind tunnel.	R	R	
4.	Field test	The data on bio-efficacy based on two seasons field trials from one agro-climatic conditions in the form of authentic/published report.	The data on bio-efficacy based on two seasons field trials from two different agro-climatic conditions in the form of authentic/published report.	
5.	Compatibility: No data on compatibility are required unless the product is recommended for use in combination with pesticides or other agrochemicals.	**R**	**R**	
6.	Time and method of application: Information on timing, disruption is to be furnished.	**R**	**R**	
7.	Intended uses.	**R**	**R**	
8.	Mode of action and degree of specificity.	**R**	**R**	
9.	Target pest (s) and crops or premises to be protected.	**R**	**R**	
10.	Application rate.	**R**	**R**	
11.	Manner, rate and frequency of	**R**	**R**	

	application.			
12.	Limitations of use.	**R**	**R**	

Note: As per decision of 248th meeting of R.C. Pheromones used for monitoring and mass trapping are not covered under the various provisions of the Insecticides Act, 1968.

SPECIFICATIONS FOR PHEROMONE TRAPS AND LURES

The committee after detailed discussions on the existing specification of various models of pheromones traps decided not to make any change in these specifications. However, these specifications may further be examined by SAU and SDAS of various States:

1. **Funnel shaped trap:** This trap is generally used for trapping the moths of Hellcovarpa armigera, Spodoptera litura, Earisa spp. etc.

Colour: Any colour other than black.

Structure: The funnel trap may have three parts (1) canopy (2) funnel shapped "trap base"and (3) a collection device.

Canopy: Dia : 120-160mm

Thickness : 1.0-3.0mm
(There should be a provision for fixing the canopy to the "trap base" and also the (pheromone lure)

Trap base:

Dia of the mouth : 75-120mm
Height of funnel : 45-190mm
Dia of the bottom hole : 20-30 mm

Should possess a "L" or "T" shaped handle or any other device by which the other device by which the "trap" may be fixed to the support.

The "Trap base" may be provided with 2 to 4 stalks for fixing the canopy to the "trap base". The canopy should be firmly rest on stalks so that the canopy is not dialodged due to wind.

Collection device: It should be made of polythene or other suitable material. It should withstand wind, temperature and rain water.

Should be fixed to the "trap base" in such a way that the device remains attached to the trap under field conditions.

II. **Sticky trap (for pink boll worm etc.):**

* Corrugated DVC, Plastic laminated card board, tin or any other suitable material that should be water-proof.

* The sticky glue should be non- drying.

* The outer surface of trap should be water proof.

* The colour may be except black.

* There should be provision for fixing the trap for support.

III. **Fly trap (For fruit/vegetable flies):**

* Material construction as described in sticky/funnel trap.

* Any colour except black.

* Should withstand rainfall, heat/temperature and wind.

* Should be structured in such a way that the trap is escape proof.

Specification of Lures:

1. Lure made of sulphur free rubber/polypropylene/PVC, Impregnated with specific pheromone blends.

2. Field efficacy should be minimum for 15 days after application.

3. Impregnated lures should be packed singly in individual trilaminated pouches with 30 M1 Aluminum foil.

4. Shelf-life of Lure in original pack should be minimum 6 months at room temperature.

5. Lures should attract insect species only, with 50% insect attractancy by pheromone/lure/dispenser by using wind tunnel method.

Toxicology

S. No	Parameters	Semiochemicals (pheromones)		
		9(3b)	9(3)	9(4)
1.	**Acute oral toxicity- rat**	R	R	**No data required if chemical equivalence is established with 9(3) registrant**
2.	**Acute dermal toxicity- rat**	R	R	
3.	**Acute Inhalation – rat**	R	R	
4.	**Primary Skin Irritation - Rabbit**	R	R	
5.	**Primary Eye Irritation - Rabbit**	R	R	
6.	**Skin Sensitization - Guinea pig**	R	R	
7.	**Sub- acute oral- rat**	NR	R	
8.	**Sub-acute dermal**	NR	R	
9.	**Sub- acute inhalation**	NR	R	
10.	**Neurotoxicity**	NR	R	
11.	**Teratogenicity**	R	R	
12.	**Effect on Reproduction**	NR	R	
13.	**Carcinogenicity/chronic toxicity/combined toxicity study***	NR	R	
14.	**Metabolism**	NR	R	
15.	**Mutagenicity (AMES + 2 in-vitro +1 in-vivo)***	R	R	
16.	**Cellular immune response**	R	R	
17.	**Toxicity to bird (2 species)**	R	R	
18.	**Toxicity to fresh water fish**	R	R	
19.	**Toxicity to Honey bees**	NR	R	

Note: 1. Lepidopterean Pheromones that are naturally occurring compound designated by an unbranched aliphatic chain (between 9 and 18 carbons) ending in an alcohol, aldehyde or acetate functional group and containing upto 3 double bonds in aliphatic backbones can be exempted from the sub-acute toxicity carcinogenicity, effect on reproduction and metabolism if their use rates do not exceed 150 gm/acre/year with Good Agricultural Practices (GAP) and used in solid matrix dispensers.

2. For formulation products no toxicity data are required unless it is added with some other pesticides.

3. * **PLEASE REFER TO GUIDANCE DOCUMENT ON TOXICOLOGY FOR REGISTRATION OF CHEMICAL PESTICIDES IN INDIA.**

PACKAGING

Chapter V of the Insecticides Rules 1971 in the Insecticides Act, 1968, the rule 16 to 20 of the said chapter deals with the Packaging and Labeling.

Sl. No.	Parameter	Semiochemicals (pheromones)		
		9(3b)	9(3)	9(4)
1.	**Labels and Leaflets per IR-1971, all fields (as applicable) and as amended from time to time**	R	R	R
2.	**Manner of labeling and Leaflet**	R	R	R
3.	**Type of packaging (Ultra small, small or Big whichever is applicable)**	R	R	R
4.	**Manner of packaging**	R	R	R
5.	**Specification for primary, Secondary and Transport packages (whichever is applicable)**	R	R	R
6.	**Details of packaging material and its compatibility with content**	R	R	R
7.	**Performance of container with content during storage stability test(Shelf life Study)**	R*	R	R
8.	**Transport worthiness test**	R*	R	R

R*- Before Commercialization the data will be required.

Note:

1. In case of additional packaging endorsement applications, the data at Sl. No. 05, 06, 07& 08, are not required if similar packaging (material) is being sought by the applicant as has been granted to earlier 9(3) registrant.
2. Specification of Bureau of Indian Standard (BIS) must be followed for all the packaging requirements (Wherever available and applicable).
3. All Packaging tests must be carried out with the product of same batch and in its commercial package preferably in Indian condition.

4. The duration of the test and the conditions including geographical conditions must be mentioned.
5. Storage stability data should be generated keeping at least the following parameters in test protocol such as test temperature, test duration, test packaging material, content of active ingredient (a.i.) and relevant impurities in the product during and after storage, test humidity, exposure to light, physical and chemical properties of the product during and after storage etc.
6. The testing protocols must have their basis in the WHO/FAO/ CIPAC/ASTM recommendations or other validated methodology of GLP/ NABL accredited laboratory having packaging testing (chemical / mechanical as applicable etc.) in the scope.
7. The Accelerated storage study (ASS) test must be conducted at 54± 2^{o}C (wherever applicable) for 14 days as per FAO/ WHO manual for claiming appropriate shelf life of the product which can be maximum two years, subject to the condition of providing the ambient storage stability study data of thirty months or as the case may be within thirty months from the date of application for the registration.

The abbreviations used in the guidelines are in APPENDIX- I

1. **ASS: Accelerated Storage Stability**
2. **ASTM: American Society for Testing and Materials**
3. **ATR: Analytical Test Report**
4. **CFU: Colony Forming Unit**
5. **CIL: Central Insecticide Laboratory**
6. **CIPAC: Collaborative International Pesticides Analytical Council**
7. **CRM: Certified Reference Material**
8. **CR: Certificate of Registration**
9. **CSIR: Central Scientific Industry and Research**
10. **DNA: Designated National Authority**
11. **ELISA: Enzyme Linked Immunosorbate Assay**
12. **EPN: Entomopathogenic Nematode**
13. **FAO: Food and Agriculture Organization**
14. **FI: Formulation Import**
15. **FIM: Formulation Indigenous Manufacturing**
16. **FI-WRT: Formulation Import without registering Technical**
17. **FIM-WRT: Formulation Indigenous Manufacturing without registering Technical**
18. **GAP: Good Agriculture Practices**
19. **GLP: Good Laboratory Practices**
20. **GV: Granulosis Virus**
21. **ICAR: Indian Council of Agricultural Research**
22. **ICMR: Indian Council of Medical Research**
23. **IR: Insecticides Rules**
24. **ISI: Indian Standards Institutions**
25. **LC: Lethal Concentration**
26. **LD: Lethal Dose**
27. **LLIN: Long Lasting Impregnated Nets**
28. **MIC: Minimum Inhibitory Concentration**
29. **MOH&FW: Ministry of Health and Family Welfare**
30. **MOU: Memorandum of Understanding**
31. **MRL: Minimum Residue Limit**
32. **MUP: Manufacture Use Products**
33. **NABL: National Accreditation Board of Testing and Calibration Laboratories**
34. **NBAIR: National Bureau of Agriculture Insect Resources**
35. **NIBSM: National Institute of Biotic Stress Management**
36. **NPV: Nuclear Polyhedrosis Virus**
37. **NR: Not Required**
38. **PGR: Plant Growth Regulators**
39. **POB: Polyhedral Occlusion Bodies**

40. PVC: Poly Vinyl Chloride
41. R: Required
42. RC: Registration Committee
43. SAU: State Agriculture University
44. SDAS: State Designated Agencies
45. TC/TK: Technical Grade
46. TI: Technical Import
47. TIM: Technical Indigenous Manufacturing
48. VCRC: Vector Control Research Centre
49. WHO: World Health Organization

The terms used in the report are defined in APPENDIX- II

1. **Active ingredient**: The part of the product that provides the pesticidal action.

2. **Applicant**: The party (manufacturer, importer or their representative) that makes an application for registration of a pesticide to the responsible authority.(Please refer to Form-1 foot note under the Insecticide Rule 1971)

3. **Bio-pesticides :** Biopesticides is a generic term generally applied to a substance derived from nature, such as a microorganic or botanical or semiochemical that may be formulated and applied to control the pest and diseases.

4. **Contaminant or impurity in MPCA:** Any microorganism or substances it produces that are present in a product, other than the specified microorganism (or substances it produces) of the microbial pest control agent (MPCA); an alternate/mutant form of the MPCA is considered to be a microorganism impurity.

5. **Equivalence :** The determination of the identical similarity of the purity, impurity and toxicological profile as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers/place.

6. **Formulation:** The combination of various ingredients in order to render the product useful and effective for the purpose claimed in the manner recommended.

7. **Good Laboratory Practice (GLP):** A quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

8. **Herbicide**, an agent, usually chemical, for killing or inhibiting the growth of unwanted plants, such as residential or agricultural weeds and invasive species.

9. **Household pesticides** are commonly used indoors to control pests such as ants, cockroaches, houseflies, mosquitoes, fleas, ticks, bedbugs, termites, rodents, mites and microbes. ... Household pesticides may contain one or a combination of active ingredients of synthetic (chemical) or natural (plant or microorganism) origin.

10. **"Import"** means bringing into any place within the territories to which this Act extends from a place outside those territories;

11. **Infective or Infectivity:** The ability of a microorganism to invade and persist in a viable state and to multiply within or on an organism, with or without disease manifestation. The nature of an infection can vary widely with respect to severity, location and number of organisms involved

12. **"Insecticide" (Pesticide)** means - -
    - **i)** Any substance specified in the Schedule; or
    - **ii)** Such other substances (including fungicides and weedicides) as the Central Government may, after consultation with the Board, by notification in the Official Gazette, include in the Schedule from time to time; or
    - **iii)** Any preparation containing any one or more of such substances.

13. **"Label"** means any written, printed or graphic matter on the immediate package and on every other covering in which the package is placed or packed and includes any written, printed or graphic matter accompanying the insecticide.

14. **"Manufacture"** in relation to any insecticide, include :-
    - **i)** Any process or part of a process for making, altering, finishing, packing labeling, breaking up or otherwise treating or adopting any insecticide with a view to its sale, distribution or use but does not include the packing or breaking up of any insecticide in the ordinary course of retail business; and
    - **ii)** Any process by which a preparation containing an insecticide is formulated.

15. **"Package"** means a box, bottle, casket, tin, barrel, case, receptacle, sack, bag, wrapper or other thing in which an insecticide is placed or packed.

16. **Pathogenicity:** The ability of a microorganism to cause disease and/or inflict damage on the host. Many pathogens cause disease by a combination of (i) toxicity and invasiveness or (ii) toxicity and colonizing ability. However, some invasive pathogens cause diseases that result from an abnormal reaction of the host's defense system.
17. **Pesticide product:** The formulated product (pesticide active ingredient(s) and co-formulants) in the form in which it is packaged and sold.

18. **Plant growth regulators** (PGRs) are chemicals used to modify plant growth such as increasing branching, suppressing shoot growth, increasing return bloom, removing excess fruit, or altering fruit maturity.

19. **Plant extract/concentrate:** a botanical substance produced from the defined source(s) and by the described manufacturing processes, and which is the "active substance". For botanical active substances, the extract will be in most cases a mixture of components from the plant and in addition all components that result from the cultivation, harvest, post- harvest storage and primary processing and manufacturing. It may be difficult to identify and characterize all individual components. Some of these components may be considered as components of concern which may be considered in the same way as "relevant impurities" in chemical pesticide.

20. **Post-harvest** :In agriculture, postharvest handling is the stage of crop production immediately following harvest, including cooling, cleaning, sorting and packing etc.

21. **Public Health pesticides:** Pesticides that are used in the control of pests of public health significance under public health programs in the country.

22. **Registration Dossier:** The set of data that is submitted by applicants, in a structured manner, in support of their application for registration. as per the requirements of the registration committee.

23. **Semiochemicals :** Chemicals emitted by a plant or animal that evoke a behavioral or physiological response in another organism. When the semiochemical affects an individual of the same species, it is called a 'pheromone'. When it affects an individual of a different species, it is called 'allelochemical'.

24. **Technical material :** Technical-grade materials and technical concentrates; also known as technical-grade active ingredient (TGAI).

25. **Technical grade of MPCA:** Microbial material used for manufacture of microbial pest control products. It is the purest preparation of the MPCA resulting from a typical production process, and contains no additives except for purposes of MPCA growth or replication, or typical purification and preparation. It may be commercially distributed to manufacturers of microbial pest control products either in its pure form or augmented with preservatives, stabilizers, and diluents; or it may be a hypothetical stage in the manufacture of the microbial pest control product.