Annexure - I

Guidelines for Registration of Chemical Pesticides U/S 9(3) & Technical Indigenous Manufacture U/S 9(4) for use in the Country

The guidelines are dynamic in nature and amended from time to time considering the scientific developments in the relevant field and their applicability under the prevailing conditions in the country. Accordingly, guidelines for Registration of Chemical Pesticides U/S 9(3) and Technical Indigenous Manufacture U/S 9(4) have been revised to provide required data by the interested applicants for registration of Herbicides, Fungicides, Insecticides and Plant Growth Regulators for use in the country. Earlier decisions taken during various meetings of Registration Committee with respect to these guidelines have also been incorporated. These revised guidelines shall replace all the relevant earlier approved guidelines for the listed categories including guidelines of 05-10-2011 on the website www.cibrc.nic.in.

Note:

(i) If an applicant is possessing a certificate of registration of a pesticide technical or formulation for indigenous manufacturing, the same applicant shall not be allowed for registration of the same pesticide technical or formulation under any import category.

(ii) If technical of a pesticide is registered for indigenous manufacture to any firm, then application for registration of Formulation Import (FI) of such pesticide molecule shall not be considered.

(iii) No application for Formulation Import (New Source) where import of formulation has been registered without registering technical U/s 9(3) category shall be considered.

(iv) For "Technical Import (new source) U/S 9(3)" category, only same or higher purity (% a.i. min.) than the already registered purity (% a.i. min) of the same pesticide technical shall be considered for registration.

1. **Guidelines for Registration for Indigenous manufacture of formulation U/S 9(3) without registering technical: (Applicable for Chemistry, Bioefficacy, Toxicity and Packaging)**

   If an applicant does not seek registration for indigenous manufacture of technical together with Formulation, in such a case the applicant shall be required to submit complete data as per the guidelines for Formulation Indigenous Manufacture (FIM) along with Technical Indigenous Manufacture (TIM) U/S 9(3), subject to fulfillment of condition that the technical and formulation products will be manufactured in the same premises. The condition regarding submission of data on shelf-life & information on packaging etc. shall be same as for the cases for import of formulation without registering technical (As per decisions of 272nd (17-01-2007) & 314th (24/27-01-2011) RC meetings.)

2. Guidelines for Registration for Import of formulation U/S 9(3) without registering technical: (Applicable for Chemistry, Bioefficacy, Toxicity and Packaging)

If an applicant does not seek registration for import of technical together with formulation, in such a case the applicant shall be required to submit complete data as per the guidelines for Formulation Import (FI) along with Technical Import (TI) U/S 9(3) categories. The requirements of data on technical w.r.t. shelf-life & information on packaging, as per decision of 313th RC meeting held 8th Nov., 2010, are subject to outcome of Appeal U/S 10 of the Insecticides Act, 1968 and Hon'ble High Court of Gujarat at Ahmedabad.

3. Guidelines for Registration for Chemical Plant Growth Regulator (PGR): (Applicable for Chemistry, Bioefficacy, Toxicity and Packaging)

Data requirements of chemical pesticides are also applicable for registration of chemical plant growth regulators.

4. Guidelines for Registration of Chemical Pesticides U/S 9(3) & Technical Indigenous Manufacture U/S 9(4)

Sl. No.	Parameter	9(3)							9(4)
		TI	TIM	FI	FIM	TIM vs TI	TIM vs FI*/ FIM*	TI (New Source)	TIM
1	2	3	4	5	6	7	8	9	10
A.	**COMMON PARAMETERS FOR CHEMISTRY, BIOEFFICACY, TOXICITY AND PACKAGING**								
1a.	Form-I (Complete in all respect)	R	R	R	R	R	R	R	R
1b.	Label & leaflet	R	R	R	R	R	R	R	R
1c.	Copy of RTT permit	R	NR*	R	NR*	NR*	NR*	R	NR*
2a.	Status of Registration of molecule in the country of Source / manufacture. (Registered/Banned/Restricted/ withdrawn)	R	NR	R	NR	NR	NR	R	NR
2b.	Status of molecule in the Rotterdam, Stockholm, Basal, Montreal, Minamata conventions (and other conventions thereafter ,if any)	R	R	R	R	NR	NR	R	NR
3.	Technical Bulletin & reference copy from pesticide manual	R	R	R	NR	NR	NR	R	NR

4.	Rationale for importing formulation	NR	NR	R	NR	NR	NR	NR	NR
	Note: 1. NR*: The indigenous manufacturer shall submit information online at the time of manufacture / submission of sample for data generation.								
B.	**CHEMISTRY**	**TI 9(3)**	**TIM 9(3)**	**FI 9(3)**	**FIM 9(3)**	**TIM vs TI 9(3)**	**TIM vs FI*/ FIM* 9(3)**	**TI (New Source) 9(3)**	**TIM 9(4)**
5.	Source of Supply of Technical	R	NR	R	R	NR	NR	R	NR
6.	Chemical Composition	R	R	R	R	R	R	R	R
7.	Chemical Identity of technical	R	R	R	R	R	R	R	R
8.	Physico-Chemical Properties of adjuvants	R	R	R	R	R	R	R	R
9.	Specification	R	R	R	R	R	R	R	R
10.	Method of Analysis	R	R	R	R	R	R	R	R
11.	Analytical Test Report	R	R	R	R	R	R	R	R
12.	Identification& Quantification of identifiable Impurities	R	R	NR	NR	R	R	R	R
13a.	Shelf-life claim	R	R	R	R	R	R	R	R
13b.	*Shelf-life Data	R	R	R	R	R	R	R	NR/R
14.	Establishment of Chemical Equivalence with undertaking	NR	NR	NR	NR	R	R	NR	R
15.	Process of Manufacture	R	R	R	R	R	R	R	R
15a.	Information about Raw Materials Used	R	R	R	R	R	R	R	R
15b.	Their Source of Supply.	R	R	R	R	R	R	R	R
15c.	Step-wise Manufacturing Process.	R	R	R	R	R	R	R	R
15d.	Chemical Equation	R	R	NR	NR	R	R	R	R
15e.	Formula	R	R	NR	NR	R	R	R	R
15f.	Flow sheet diagram of process of manufacture	R	R	R	R	R	R	R	R
15g.	Effluent Treatment method	NR	R	NR	R	R	R	NR	R
16.	Documents such as registration certificate / Certificate of DNA /manufacturing licence or any other approval under any Govt. regulation will be acceptable to support that manufacturer is actual producer	R	NR	R	NR	NR	NR	R	NR
17.	Certificate from manufacturer that the dealer/ trader is an	R	NR	R	NR	NR	NR	R	NR

	authorized dealer/ trader of the manufacturer.								
18.	A test report about the quality of the product from a laboratory as per GLP scheme or from a company of ISO-9000. This requirement will be provided along with first consignment. Thereafter, each consignment should have proper analytical test report of the manufacturer.	R	NR	R	NR	NR	NR	R	NR
19a.	The applicant should provide sample of standards technical from the principals/ authorized dealers for chemical verification. In case of technical grade pesticides u/s 9(3), reference standards of impurities are also to be provided for chemical verification.	R	R	R	R	R	R	R	R
19b.	In process sample to be provided in case of indigenous manufacture of technical u/s 9(3) TIM / TI(new source) & 9(4) TIM with undertaking	NR	R	NR	NR	R	R	R	R
20.	Methodology for residue estimation as per BIS format.	R	R	R	R	R	R	R	R
	NOTE: 1. Guidelines for TIM Vs FI*/FIM* approved in 359th meeting of RC, are subject to outcome of the writ petition in the Hon'ble High Court of Gujarat at Ahmedabad, in this category of Guidelines, Chemistry data requirements read at sl. No. (15): Process of manufacture (1st step onward); sl. no. (15e): Formula of impurities etc.; and (an additional requirement): Certificate of manufacturing license if issued or any other approval under any government regulation to support that applicant is a manufacturer. 2. *Shelf-life data for TIM U/s 9(4) is required (R), only if Packaging material is different.								
C.	**BIOEFFICACY**	**TI 9(3)**	**TIM 9(3)**	**FI 9(3)**	**FIM 9(3)**	**TIM vs TI 9(3)**	**TIM vs FI*/ FIM* 9(3)**	**TI (New Source) 9(3)**	**TIM 9(4)***
21a.	Bio-effectiveness	NR	NR / R** if claimed	R**	R**	R+	R+	R++	NR
21b.	Phyto-toxicity	NR	NR / R** if claimed	R**	R**	R+	R+	R++	NR
21c.	Effect on parasites & predators (only for insecticides)	NR	NR	R**	R**	NR	NR	NR	NR
22.	Translocation in plants	R	R	NR	NR	NR	NR	NR	NR

23a.	Metabolism in soil	R	R	NR	NR	NR	NR	NR	NR
23b.	Metabolism in water	R	R	NR	NR	NR	NR	NR	NR
23c.	Metabolism in plant	R	R	NR	NR	NR	NR	NR	NR
24a.	Persistence in soil	R	R	R	R	NR	NR	NR	NR
24b.	Persistence in water	R	R	R	R	NR	NR	NR	NR
24c.	Persistence in plant	R	R	R	R	NR	NR	NR	NR
25.	Compatibility with other chemicals, if claimed	NR	NR	R	R	NR	NR	NR	NR
26a.	Residues in plant	NR	NR	R** for herbicides) R#: for Insecticides & Fungicides	R** for herbicides) R#: for Insecticides & Fungicides	R^	R^	R^^	NR
26b.	Residues in soil	NR	NR	(R** for herbicides) R#: for Insecticides & Fungicides	(R** for herbicides) R#: for Insecticides & Fungicides	NR	NR	R^^	NR
26c.	Effect on physicochemical & biological properties of soil (only for Herbicides)	NR	NR	R	R	NR	NR	R	NR
26d.	Effect on succeeding crops (only for herbicides)	NR	NR	R	R	NR	NR	R	NR
27.	Residue tolerance limits fixed by foreign countries	NR	NR	R	R	NR	NR	NR	NR
28.	Registration status in foreign countries	R	R	R	R	NR	NR	NR	NR

R:** Two seasons/years data generated from minimum three agro-climatic conditions. Locations+: Prescribed crop specific locations shall be applicable for the crops for which required agro-climatic conditions are not available.

R#: One season / year data generated at minimum four agro-climatic conditions.
(Residue data requirements for Insecticides & Fungicides which are repeatedly used in the same locations, are two seasons from three agro-climatic locations).

Note:

1. International data on pesticide technical on translocation in plant, metabolism in soil, water and plant together with the nature of significant metabolites and their persistence shall be required. In addition, data on technical pesticide on Persistence in soil and water generated under Indian conditions are also required.

2. Data on persistence of pesticides formulation in soil, water & plant are required to be generated under Indian conditions.

3. In case of herbicides data on effect on soil Physico-chemical and biological properties, and effect on normally cultivated three succeeding crops are 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 1, green gram at location 2, sesamum at location 3, 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.)*

4. **R+**: In case of TIM Vs TI and TIM Vs FI*/FIM* U/S 9(3), one season data on bioefficacy including phytotoxicity, if any, on two representative crops from two climatic zones is required to be submitted.

5. **R^**: One season residue data on two representative crops particularly on fruits and vegetables is required in case of TIM Vs TI and TIM Vs FI*/FIM* U/S 9(3).

6. **R++:** In case of TI (New Source) two seasons data on bio-effectiveness and phytotoxicity on each crop mentioned in labels/ leaflets at least from two agro-climatic Zones. **(NOTE**: Data on Bioeffictiveness & Phyto-toxicity to be submitted on all registered formulations of same technical as per RC guidelines 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 as per the decision of 313th meeting of RC held on 8th Nov, 2010).

7. **R^^:** In case of TI (New Source) data on residues in plant & soil are required on representative crops of each group on which pesticide is approved, for two years / seasons from one location for herbicides. For Insecticides and fungicides residue data in plant & soil are required for one season from two agro-climatic locations, whereas, for repeatedly used fungicides / insecticides these data required for two years/seasons from one location.

8. **TIM U/s 9(4)***: If chemical equivalence fails in the sample submitted by the applicant / in-process sample, applicant is required to submit data on bioefficacy as per the guidelines for TIM vs TI U/S 9(3).

D.	**TOXICITY**	**TI 9(3)**	**TIM 9(3)**	**FI 9(3)**	**FIM 9(3)**	**TIM vs TI 9(3)**	**TIM vs FI*/ FIM* 9(3)**	**TI (New Source) 9(3)**	**TIM 9(4)***
29a.	Specification (same as submitted in Chemistry)	R	R	R	R	R	R	R	R
29b.	Physico-Chemical Properties of adjuvants	R	R	R	R	R	R	R	R
30.	Acute oral in rat	R	R	R	R	R	R	R	NR
31.	Acute dermal (rat/rabbit)	R	R	R	R	R	R	R	NR
32.	Acute inhalation	R	R	R	R	NR	NR	R	NR
33.	Primary skin irritation	R	R	R	R	NR	NR	R	NR
34.	Acute eye irritation	R	R	R	R	NR	NR	R	NR
35.	Skin Sensitization	R	R	R	R	R	R	R	NR
36a.	Repeated dose range finding oral toxicity (upto 28 days)	R	R	NR	NR	NR	NR	R	NR
36b.	Repeated dose 90 days oral (a) Rodent (b) Non Rodent (dog*)	R	R for Rodent & NR*	NR	NR	NR	NR	R	NR

			for Non-Rodent						
37.	Repeated dose dermal toxicity	R	R	NR	NR	NR	NR	R	NR
38.	Repeated dose inhalation toxicity	R	R	NR	NR	NR	NR	R	NR
39a.	Acute Neurotoxicity-Rodent	R	R	NR	NR	NR	NR	NR	NR
39b.	Repeated Dose Neuro toxicity-Rodent	R	R	NR	NR	NR	NR	NR	NR
39c.	Delayed Neurotoxicity-OP Compound- Acute Exposure	R	R	NR	NR	NR	NR	NR	NR
39d.	Delayed Neurotoxicity-OP Compound- Repeated Administration	R	R	NR	NR	NR	NR	NR	NR
39e.	Developmental Neurotoxicity	R	R	NR	NR	NR	NR	NR	NR
40.	Synergism & potentiation	NR/R	NR/R	NR/R	NR/R	NR	NR	NR	NR
41a.	*Chronic toxicity-Rat	R	R	NR	NR	NR	NR	NR	NR
41b.	*Carcinogenicity -Rat & Mice	R	R	NR	NR	NR	NR	NR	NR
42.	Developmental Toxicity-Rat & Rabbit	R	R	NR	NR	NR	NR	NR	NR
43.	Two generation Reproduction Toxicity Study (Rat)	R	R	NR	NR	NR	NR	NR	NR
44.	Metabolism in Rat	R	R	NR	NR	NR	NR	NR	NR
45.	Feeding studies in livestock (Goat/ Ruminant/ Hen / Poultry) including metabolism in livestock (R for Direct application on Animal for Treatment on Ectoparasites /Any crop or parts treated with pesticides used as feed or fodder)	R/NR	R/NR	NR	NR	NR	NR	R/NR	NR
46.	Mutagenicity (Genotoxicity) (AMES, 2 in-vitro & 1 in-vivo)	R	R	NR	NR	R	R	R	R Only AMES test (1st Tier)
47.	Immuno-toxicity	R	R	NR	NR	NR	NR	NR	NR
48.	Acute Avian Toxicity	R (two species)	R (two species)	R (one species)	R (one species)	NR	NR	R (two species)	NR
49a.	Repeated Dose Avian Toxicity (one species)	R	R	NR	NR	NR	NR	R	NR
49b.	Avian Reproduction Toxicity (one species)	R	R	NR	NR	NR	NR	NR	NR
50.	Acute Toxicity to fresh water fish (one species)	R	R	R	R	NR	NR	R	NR

51.	Acute Toxicity-Honey bee (Oral & Contact)	R	R	R	R	NR	NR	R	NR
52.	Acute Toxicity-Earthworm	R	R	R	R	NR	NR	R	NR
53.	Medical data	R	R	R	R	R	R	R	R
54.	Human toxicity information from foreign countries	R	NR	R	NR	NR	NR	R	NR
55.	Health records of Industrial workers.	R	NR	R	NR	R/NR (NR for new manufacturing unit)	R/NR (NR for new manufacturing unit)	R	NR
56.	International report on carcinogenicity & genotoxicity status	R/NR	R/NR	NR	NR	NR	NR	NR	NR
57.	Global status of pesticide molecule w.r.t. Ban / restriction/ withdrawn and reasons thereof	R	R	R	R	R	R	R	NR

NR*: Data is not required, however, any peer reviewed published data/information shall be acceptable.

TIM U/S 9(4)*: If chemical equivalence fails in the sample submitted by the applicant / in-process sample, required to submit data on toxicity as per the guidelines for TIM vs TI U/S 9(3).

Note:

1. For complete details latest "Guidance Document on Toxicology for Registration of Pesticides in India" available on CIBRC website may be seen.
2. *Chronic toxicity-Rat and *Carcinogenicity-Rat studies may be combined (Combined carcinogenicity).
3. TIM vs FI*/FIM* guidelines, are subject to the outcome of the writ petition in the Hon'ble High Court of Gujarat at Ahmedabad.

3. Acute oral (mice), Acute inhalation (Rat), Primary Skin irritation, irritation to mucous membrane in case of TIM category U/S 9(3) shall not be required where chemical equivalence is established except in case of first registrant of the molecule.

4. All the studies non-adhering to GLP principles conducted by GLP certified laboratory shall be accepted henceforth for all categories of applications for indigenous manufacturing.

5. Toxicology studies conducted by Non-GLP laboratories shall also be accepted for two years from dated 05-04-2017 to encourage indigenous manufacturing and ease out in the process of registration of TIM/ FIM category.

E.	**PACKAGING**	**TI 9(3)**	**TIM 9(3)**	**FI 9(3)**	**FIM 9(3)**	**TIM vs TI 9(3)**	**TIM vs FI*/ FIM* 9(3)**	**TI (New Source) 9(3)**	**TIM 9(4)**
58.	Labels and leaflets as per IR-1971 existing norms (i) for size 250 ml & below (ii) for 500 & above.	R	R	R	R	R	R	R	R
59.	Labels to contain								
59a.	Detailed Chemical composition	R	R	R	R	R	R	R	R
59b.	Purpose for import / manufacture.	R	R	R	R	R	R	R	R

59c.	Antidote	R	R	R	R	R	R	R	R
59d.	Toxicity triangle	R	R	R	R	R	R	R	R
59e.	Cautionary statement	R	R	R	R	R	R	R	R
59f.	Brief direction concerning usages	R	R	R	R	R	R	R	R
59g.	Restriction if any	R	R	R	R	R	R	R	R
60.	Leaflets to contain								
60a.	Detailed Chemical composition on leaflets accompanying small labels (up to 250 ml size container)	R	R	R	R	R	R	R	R
60b.	Introductory para about the pesticide	R	R	R	R	R	R	R	R
60c.	Detailed directions concerning usages	NR	NR	R	R	NR	NR	NR	NR
60d.	Time of application	NR	NR	R	R	NR	NR	NR	NR
60e.	Application equipment	NR	NR	R	R	NR	NR	NR	NR
60f.	Waiting Period	NR	NR	R	R	NR	NR	NR	NR
60g.	Symptoms of poisoning	R	R	R	R	R	R	R	R
60h.	First Rd measures	R	R	R	R	R	R	R	R
60i.	Antidote & treatment	R	R	R	R	R	R	R	R
60j.	Restriction, if any	R	R	R	R	R	R	R	R
60k.	Instruction for storage	R	R	R	R	R	R	R	R
60l.	Information regarding disposal of used packages.	R	R	R	R	R	R	R	R
61a.	Type of packaging	R	R	R	R	R	R	R	R
61b.	*Container compatibility with content (Packaging material)	R	R	R	R	R	R	R	NR/R
62.	Manner of packaging	R	R	R	R	R	R	R	R
63a.	Specification for primary package	R	R	R	R	R	R	R	R
63b.	Specification for secondary packaging.	R	R	R	R	R	R	R	R
63c.	Specification for transport packaging.	R	R	R	R	R	R	R	R
64.	Manner of labelling	R	R	R	R	R	R	R	R
65.	*Performance of container during storage stability test	R	R	R	R	R	R	R	NR/R
66.	*Transport worthiness test	R	R	R	R	R	R	R	NR/R
67.	Undertaking w.r.t. IMDG Guidelines	R	NR	R	NR	NR	NR	R	NR
	Note: 1. * Container compatibility with content for TIM U/s 9(4) is R if packaging material is different. 2. *Performance of container during storage stability test for TIM U/s 9(4) is R if packaging material is different.								

	3. *Transport worthiness test for TIM U/s 9(4) is R if packaging size and/or packaging material is different.	

Abbreviations :

R: Required
NR: Not Required
TIM: Technical Indigenous Manufacture
TI : Technical Import
FI: Formulation Import
FIM: Formulation Indigenous Manufacture
FI*: FI without registering technical
FIM*: FIM without registering technical
U/S: Under Section

Annexure – II

MANDATORY REQUIREMEN OF DOCUMENTS FOR REGISTRATION
U/S 9(4) FIM/TI/FI CATEGORY

Sl No.	Parameters	FIM	FI	TI
1	Completely filled and duly signed Form I[under clause (1a), the name of the person signing the verification potion i.e. proprietor/managing partner/person duly authorized by Board of Directors Resolution (BOD) shall be mentioned along with the name of the company for which registration required].	R	R	R
2	Notarized copy of BOD Resolution/Partnership/Proprietorship Deed.	R	R	R
3	Notarized copy of Incorporation Certificate (In case of Ltd. /P. Ltd. Company).	R	R	R
4	Notarized PAN Card of the company (In case of Ltd. /P. Ltd. Company) and PAN of the Proprietor (In case of Proprietorship Firm)/ one of the partners (in case of partnership)	R	R	R
5	Notarized and Valid Documentary proof of category of industry i.e. SSI/DGPP/MRTP and other.	R	R	R
6	Notarized and Valid Manufacturing License in case of existing unit.	R	R	R
7	List of the products for which registration has been given and manufacturing license obtained during last 02 years.	R	R	R
8	Notarized copy of consent letter from the manufacture of technical grade material (Annexure-I)*	R	NR	NR
9	Consent letter duly authorized by the source of import and authenticated by the Consulate General of India (Indian Embassy).	NR	R	R
10	Copy of Registration Certificate of Pesticide, registered in exporting country.	NR	R	R
11	The list of products actually manufactured during last two years.	R	R	R
12	Affidavit as per the prescribed language approved by RC stating that the registration for the same product was not been taken earlier. (Annexure-II)	R	R	R
13	Registration Fees as per Insecticides Act, 1968 rules framed there under.	R	R	R
14	An affidavit on NJSP stating that the applicant does not possess/holding any certificate of registration under any category of indigenous manufacture of same technical or formulation of higher and lower concentration	NR	R	R

R- Required, NR-Not Required

*** Receipt of verification of consent letter from the original manufacturer of technical grade pesticide would be 20 days including two reminders from the date of initial communication.**