MINUTES OF 389th MEETING OF REGISTRATION COMMITTEE HELD ON 13.06.2018 AND 15.06.2018 IN THE CHAMBER OF DR. S. K. MALHOTRA, AGRICUTLURE COMMISSIONER, ROOM NO. 231, KRISHI BHAWAN, NEW DELHI.

Guidelines for the Registration of Biocide and Biocide Products (Manufacturing Use Products)

Biocidal products are necessary for the control of organisms that are harmful to human or animal health and are required for the control of organisms that cause damage to natural or manufactured materials. These substances usually contains pesticides and can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns and hence are required to be regulated under the Insecticide Act, 1968 and the Insecticide Rule, 1971, in order to ensure safety to human, animals and environment.

The purpose of these guidelines is to ensure safety of workers and the general public at large while handling and use of Biocides and products containing biocides and to provide guidance on its regulatory requirements under the Insecticides Act, 1968.

When the sole purpose of incorporation of biocide in the product (paint) is to protect the product (paint) itself, and no label claims are made for inhibiting the growth of micro-organisms which may cause odours or to inhibit the growth of mould and mildews or repelling or killing insects, then such products (paints) do not require registration under the Insecticides Act, 1968.

Guidelines for use of biocide in paint by the paint industry as preservatives to enhance the shelf life of the paints

The biocide (whether technical or formulated biocide product) used in paint by paint industry as preservatives to enhance the shelf --life of the paints and also as dry film preservative are required to be registered under the Insecticides Act, 1968.

Data required for registration of technical and formulated biocide product are annexed
(Annexur
e-I).

1. The TGAIs used in biocide products must be registered under the Insecticides Act.
2. In case of registration of biocide formulated product without registering technical grade pesticide, every biocide product manufacturer / importer is required to declare the source(s) of Biocide-TGAI/s in such products. Complete data of TGAI w.r.t.

chemistry, bio efficacy and toxicity must be submitted to CIBRC in case of import/ or indigenous manufacture of biocide product without registering its TGAI.

3. Only CIBRC registered Biocides-TGAIs should be used for manufacture of biocide products. In case the candidate TGAIs also qualify for direct/ indirect usages in agriculture, bio efficacy studies are mandatorily required to be conducted as defined for agricultural pesticides and data submitted for registration to CIBRC. Otherwise bio-efficacy study on TGAI Biocide/s may be done from the view point of relevant use / application needs of expected antimicrobial-performance in Industrial end-products. As a general principle, tests shall be conducted according to the methods described / recommended by international bodies / CIB&RC. In the event of, lack of an appropriate protocol, appropriately justified methods endorsed/ approved by CIBRC may be used. All toxicological tests should be GLP compliant. Tests on physico-chemical properties and safety-relevant data should be performed according to international standards. Effect of biocides, on environment and surface under protection, bio-efficacy, etc., must be carried out as per the internationally accepted protocols (like ASTM 5589, 5590) / protocols approved by CIB&RC.

4. Paint Industry (as also other industries) must use the CIB&RC registered biocide products at the recommended dosages as per the defined maximum limit of usage of TGAI in the end product/s (especially Diuron and Carbendazim). At present, the set-limit on Diuron is 0.5% w/w of final composition of Paint, and for carbendazim it is 0.1% -0.5% (w/w). Products containing more than 1000 ppm (0.1%) carbendazim will attract "skull and crossbones" and "dead fish plus dead tree" labels together with the phrases "Toxic and Dangerous for the Environment", "Mutagen Category 2" and "Reprotox Category 2". Paint products with over 0.1% ppm of carbendazim will be restricted for sale to professionals only. However, for other TGAIs if any, concentrations will be specified as per defined maximum limits of usage (documented in the literature/ or as determined based on data generation and approved by CIBRC).

5. Where in no dosage limit has been defined the applicant must provide valid data to evaluate possible effects at species, population or community and ecosystem level. Studies must be carried out in systems representative to habitats to which the product is applied. Important aspects to consider are the use of reference areas, history of the (treated and non-treated) areas, climatic conditions, timing, duration of exposure, frequency, dosage and concentration, distribution in time and location, etc.
6. Biocide Product Manufacturers would be required to provide

    a. Bio-efficacy data of the antimicrobial products on the performance of a paint film to inhibit the microbial growth by generating the data on the representative sample of commercial paint at the dosage of the Biocide Product at its minimum required level, w.r.t. TGAI contents in the dosed Biocide Product.

b. Data to be provided on the actual dosage being recommended as safe dosage to ensure the inhibition of microbial growth on the film and from that what is retained in the paint film w.r.t. TGAI contents after leaching of such paint film by flow of water. Different leaching rates may be required, for example in relation to leaching during the washing of freshly preserved film, leaching from treated film outdoors with a risk of wetting, leaching from the treated film when washed indoors or otherwise in contact with water during its service life, and volatilisation from the treated film in contact with indoor or outdoor air.

7. No change will be permitted thereafter in the composition of biocide products so- registered (unless under exceptional conditions in accordance with Government policy).

8. Data related to Product-stability and performance under actual usage- have to be generated under Indian Climatic conditions.

9. Biocide (Technical) / Biocide formulated products should follow the labelling requirements as provided under the Insecticides Act, 1968.

10. Labelling on the containers with respect to its composition and specific end use is required to be incorporated on Biocide products.

11. Labelling is mandatorily required on the container when the Registered Biocide Products are present in dosage in excess to the prescribed dosage (Diuron - 0.5% w/w of final composition of Paint, Carbendazim - 0.1% to 0.5% w/w and 0.1 (%)??? for others until the limit is amended based on the generated data/ scientifically documented literature) in exterior and interior decorative Paints/similar products and meant as formulations of Insecticides.

12. No labelling is required if these biocide products are being added in the product as antimicrobials to ensure sufficient surface protection from the likely microbial attack and as per the dosage not exceeding the maximum permissible content of Active ingredients coming from the said biocide products.

13. As the Biocide Industry falls under the realms of the Insecticide Act, 1968, records on the import/ manufacture /consumption of TGAIs in biocide products and formulated must be submitted to CIB&RC monthly and annual basis.

II. <u>Guidelines for registration of biocides OR pesticides to be used in paints for killing or repelling insects with label claim</u>

Following are required for Paint Industry who propose to manufacture Insect Repellent /Killing Paints (pesticide formulation) :

a. Insect Repellent /Killing Paints (pesticide formulation) are required to be registered under the Insecticides Act as Pesticide Formulation **(Annexure II)**.

Annexure – I

S. No.	Parameter	TI	TIM	FI	FIM	TI (New Source)	Comments
A.	**Chemistry**						
1	Source of Supply of Technical	R	NR	R	R	R	
2	Chemical Composition	R	R	R	R	R	
3	Chemical Identity of technical	R	R	R	R	R	
4	Physico - Chemical Properties of adjuvants	R	R	R	R	R	
5	Technical Bulletin	R	R	R	NR	R	
6	Specification	R	R	R	R	R	
7	Method of Analysis	R	R	R	R	R	
8	Analytical Test Report	R	R	R	R	R	
9	Identification & Quantification of identifiable Impurities	R	R	NR	NR	R	
10a.	Shelf-life claim	R	R	R	R	R	
10b.	Shelf-life Data	R	R	R	R	R	
11a.	Process of Manufacture	R	R	R	R	R	
11b.	Information about Raw Materials Used	R	R	R	R	R	
11c.	Their Source of Supply.	R	R	R	R	R	
11d.	Chemical Equation	R	R	R	R	R	
11e.	Formula	R	R	R	R	R	
11f.	Flow sheet diagram of process of manufacture	R	R	R	R	R	
11g.	Effluent Treatment method	NR	R	NR	R	NR	
12	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	R	
13	Certificate from manufacturer that the dealer/ trader is an authorized dealer/ trader of the manufacturer.	R	NR	R	NR	R	

14	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	R	
15	The applicant should provide sample along with standards technical sample from the principals/ authorized dealers for chemical verification. In case of technical grade pesticides u/s 9(3), samples of std. impurities are also to be provided for chemical verification. In process sample to be provided in case of indigenous manufacture of technical u/s 9(3) TIM & 9(4) TIM with undertaking	R	R	R	R	R	
B.	**BIOEFFICACY-**						
16a.	Bio-effectiveness	R /NR	R /NR	R	R	R/NR	Required if TGAI goes directly into end use product
		R /NR	R /NR	R	R	R	Effectiveness against target organism using a representative end use product
17	Metabolism in soil	R/ NR	R/ NR	R/ NR	R/ NR	R/ NR	
18	Metabolism in water	NR/ R	NR/R	NR/ R	NR/ R	NR/ R	
19	Persistence in soil	NR	NR	NR	NR	NR	
20	Persistence in water	NR	NR	NR	NR	NR	
21	Residues in soil	NR	NR	NR	NR	NR	
22	Cost benefit ratio	NR	NR	NR	NR	NR	

23	Registration status in foreign countries	R	R	R	R	R	
C.	**TOXICITY**						
24	Acute oral in rat	R	R	R	R	R	
25	Acute dermal	R	R	R	R	R	
26	Acute inhalation	R	R	R	R	R	
27	Primary skin irritation	R	R	R	R	R	
28	Irritation to mucous membrane	R	R	R	R	R	
29	Allergy/Sensitization	R	R	R	R	R	
30	Sub-acute oral rat	R	R	R/ NR	R/ NR	R	
31	Sub-acute oral dog*	R/ NR	R/NR	R/ NR	R/ NR	R/ NR	*In case no data is available, information may be submitted
32	Sub-acute dermal	R	R	R/ NR	R/ NR	R	
33	Sub-acute inhalation	R	R	R/ NR	R/ NR	R	*if inhalation exposure is major route and pesticides does not have use in agriculture
34	Neuro-toxicity	R	R	NR	NR	NR	
35	Teratogenicity (rat & rabbit)	R	R	NR	NR	NR	
36	Effect on reproduction	R	R	NR	NR	NR	
37	Carcinogenicity (rat & mice)	R	R	NR	NR	NR	
38	Metabolism (rat)	R	R	NR	NR	NR	
39	Mutagenicity	R	R	NR	NR	R	
40	Toxicity to birds (two)	R	R	R	R	R	
41	Toxicity to fish (fresh water) a) Fresh water fish b) Marine water fish (When the claim is for marine use)	R R/ NR	R R/ NR	R R/ NR	R R/ NR	R R/ NR	
42	Toxicity to live stock	NR/ R*	NR/ R*	NR	NR	NR/R*	*based on the end use

							of products made out from the technical
43	Medical data	R	R	R	R	R	
44	Human toxicity information from foreign countries	R	NR/ R	NR	NR	R	
45	Health records of Industrial workers.	R/ NR	R/ NR	R/ NR	R/ NR	R/ NR	
46	International report on carcinogenicity & genotoxicity status	R	R/NR	R	NR/ R	R	
D.	**PACKAGING**						
47	Labels and leaflets as per IR-1971 existing norms (i) for size 250 ml & below (ii) for 500 & above.	R	R	R	R	R	
48	Labels to contents	R	R	R	R	R	
a.	Detailed Chemical composition	R	R	R	R	R	
b.	Purpose for import / manufacture.	R	R	R	R	R	
c.	Antidote	R	R	R	R	R	
d.	Toxicity triangle	R	R	R	R	R	
e.	Cautionary statement	R	R	R	R	R	
f.	Brief direction concerning usages	R	R	R	R	R	
g.	Restriction if any	R	R	R	R	R	
49	Leaflets to contain						
a.	Detailed Chemical composition on leaflets accompanying small labels (upto 250 ml size container)	R	R	R	R	R	
b.	Introductory para about the pesticide	R	R	R	R	R	
c.	Detailed directions concerning usages	R	R	R	R	R	
g.	Symptoms of poisoning	R	R	R	R	R	
h.	First Rd measures	R	R	R	R	R	
i.	Antidote & treatment	R	R	R	R	R	
j.	Restriction, if any	R	R	R	R	R	
k.	Instruction for storage	R	R	R	R	R	
l.	Information regarding disposal of used packages.	R	R	R	R	R	
50	Type of packaging (pkg material + compatibility with content)	R	R	R	R	R	
51	Manner of packaging	R	R	R	R	R	

51.1	Specification for primary package	R	R	R	R	R	
51.2	Specification for secondary packaging.	R	R	R	R	R	
51.3	Specification for transport packaging.	R	R	R	R	R	
52	Manner of labelling	R	R	R	R	R	
53	Performance of container during storage stability test	R	R	R	R	R	
54	Transport worthiness test	R	R	R	R	R	

TI : Technical Import

TIM : Technical Indigenous manufacture

FI : Biocide Formulated product for Import

FIM : Biocide Formulated product for Indigenous manufacture

Annexure – II

Guidelines for registration of biocides or pesticide to be used in paint for killing or repelling insects with label claim.

1. Manufactured Paints with claims to repel or kill insects, fungus, weeds or any other pesticide claims are considered as pesticide formulations of paint. The pesticides used in such pesticide formulations of paint must be obtained from the source registered under the Insecticides Act, 1968.
2. In case the paint industry wants to import / manufacture indigenously the pesticide for use in paint which are not registered for use in India then they have to take registration for import / indigenous manufacture of technical by submitting data as per guidelines for Technical for import (TI) / TIM u/s 9(3), as the case may be.
3. The data requirement remains the same as that of TI/ TIM u/s 9(3) and under FI/ FIM for registration for use in the country with following special conditions:

S.No	Parameter	Regular Registration U/s 9 (3)
A.	**Chemistry**	
1	Source of Supply of technical	R
2	Chemical Composition	R
3	Chemical Identity	R
4	Physico - Chemical Properties	R
5	Specification	R
6	Method of Analysis	R
7	Analytical test report about the quality of the product from a laboratory having NABL/ GLP accredited laboratory	R
8	Shelf-life claim	R
9	Shelf-life Data	R
10	Process of Manufacture	R
11	Information about raw materials used	R
12	Source of Supply of the raw materials	R
13	Stepwise Manufacturing Process	R
14	Flow sheet diagram of process of manufacture	R
15	Effluent Treatment	NR
16	Documents such as registration certificate / manufacturing license or any other approval under any Government regulation will be acceptable to support that manufacturer is actual producer of the product of the claimed chemical composition	R

(B) Bioefficacy:-

1. Data on evaluation of efficacy against designated pest.

2. Persistence on treated painted surface.

(C) Packaging

S.No.	Parameter	Regular Registration U/s 9 (3)
1	Labels and leaflets as per IR-1971 existing norms (i) for size 250 ml &below (ii) for 500 & above.	R
I.	Labels to contents	R
II.	Detailed Chemical composition	R
III.	Purpose for import / manufacture.	R
IV.	Antidote	R
V.	Toxicity triangle	R
VI.	Cautionary statement	R
VII.	Brief direction concerning usages	R
VIII.	Restriction if any	R
IX.	Leaflets to contents	R
2	Detailed Chemical composition on leaflets accompanying small labels(up to 250 ml size container)	R
I.	Introductory para about the pesticide	R
II.	Detailed directions concerning usages	R
III.	Applications	R
IV.	Application equipment	R
V.	Persistence after application	R
VI.	Symptoms of poisoning	R
VII.	First Aid measures	R
VIII.	Antidote & treatment	R
IX.	Restriction, if any	R
X.	Instruction for storage	R
XI.	Information regarding disposal of used packages.	R
XII.	Type of packaging (packing material + compatibility with content)	R
XIII.	Manner of packaging	R
XIV.	Specification for primary package	R
XV.	Specification for secondary packaging.	R
XVI.	Specification for transport packaging.	R
VII.	Manner of labeling	R
VIII.	Performance of container during storage stability test	R

XIX.	Transport worthiness test	R

D. <u>Toxicology</u>

1. The insecticides registered with label claim in public health will not be allowed for use in paint formulations. Insecticides will be allowed on case to case basis in consultation with NVBDCP. Therefore, studies are to be initiated withprior permission of Registration Committee.

2. The technical source of the insecticides should be registered with CIBRC. Otherwise, data must be provided on the technical counterpart of the active ingredient intended for use in the formulations.

3. All acute mammalian studies as prescribed in "Guidance Document of Toxicity for the Registration of Pesticides in India" i.e. acute oral – rat, acute dermal, acute inhalation, Primary skin irritation, Mucous Membrane irritation, skin sensitization.

4. Eco-toxicity studies depending on use pattern.

5. The chemical composition of the formulation (Paint) to be disclosed under the affidavit and Material Safety Data Sheet (MSDS)/Safety Data Sheet (SDS) must be provided for each component along with prevailing literature.

6. The applicant must undertake?? a statement?? or certify that no component present in formulation (Paint) are known to cause Carcinogenicity, Teratogenicity (Developmental toxicity) and effect on reproduction and other chronic disorders to human beings at the dosages/ concentration in use.

7. The persistence of the pesticides in the paint, rate of degradation during use along with residue data in paint scrap, for the shelf life period

8. Use pattern of the paint with intended insecticide across the globe and its registration status with label claims.

9. The air concentration of insecticide in the air near the painted surface at different time interval.

10. Human and environmental toxicity information from foreign countries with use of insecticidal paint.

11. Specify the use pattern of these paints in the country and mention how publicity will be done if, allowed to use.

12. Label and leaflets as per Insecticides Rules 1971 supported by Safety related issues to be provided.