

**Report of the Expert Group constituted by the Registration Committee in 374<sup>th</sup> meeting under the Chairmanship of Dr. Sandhya Kulshrestha, Consultant (Pharma) for review of Export guidelines :-**

**General Remarks:**

1. The registration for manufacture or import of pesticides for export is required under the provisions of the Insecticides Act. The 'Certificate of Registration' is also a requirement by the companies/firms exporting pesticides because importing countries usually require this document to ensure that the pesticide proposed for import is legally permitted for manufacture/import in the country of export.

2. As per the provisions of the Act, the registration for manufacture or import of pesticides has to be granted after satisfying the efficacy of the product and its safety to human health and environment. However, considering the fact that the pesticide is exclusively for export, not going to be used in our country, no bioefficacy information/data is asked from the applicant, but in order to ensure the identity of the product and prima facie its safety mainly w.r.t. the workers involved in various activities of manufacture including repacking, transport etc., minimum information on chemistry and on toxicity (only for those pesticides not registered for use in the country) is being asked so that the basic information about the pesticide to be manufactured/imported in our country for the purpose of export is available and prima facie its safety is assessed. Accordingly, precautions can be advised for safety of workers and environment. This is necessary for the Government in order to take precautions to avoid any disaster as happened in Bhopal and to act immediately in case of any untoward incidence happen.

3. Applications for registration of pesticides for export usually fall under following two categories: -

Category [A] : The pesticides already registered for use in the country, their higher or lower purity/concentration, any other formulation;

Category [B] : Pesticides not registered for use in the country.

**Approximately 90% of applications are under category [A] for which only basic information from chemistry to know the identity of the pesticide to be manufactured/ imported for export is being asked for. No other data/information is being asked.** Only for category [B] applications information on chemistry and toxicity to prima facie assess safety to workers is being asked.

4. Applications for registration of pesticides for export are processed on priority. However, to further facilitate the export and ensure that no exports should suffer for want of requirement of certificate of registration, besides 'Star Export House Applications', a new type, i.e. 'Fast Track Applications' is proposed. These are the applications wherein applicants have 'firm export order'. These applications will be processed on top priority with minimum information and certificate of registration will be issued in 5 working days to manufacture/import the quantity indicated in the export order. Thereafter, registrant can get the condition regarding 'quantity restriction' deleted on submission of requisite information as per the guidelines of export registration under relevant category of registration.

5. The following time frame for grant of registration has been suggested for export applications complete w.r.t. all required parameters :-

**I Fast Track Applications : 5 working days**

**II Star Export House applications:-**

Category [A] : 7 working days

Category [B] : 10 working days

**III All other applications for export only :-**

Category [A] : RC to RC basis

Category [B] : 3 months

6. **No separate registration is required by the company for export, if the product is already registered in his favour for use in the country.** The company can also export the said product. In order to facilitate such registrants to comply with the export requirements, the following conditions may be incorporated in all certificates of registrations sought for domestic consumption and export.

“In case of the consignments of the product for export purpose, the primary packaging may be as per the requirement of the importing country.”

7. In view of Government, 'Make in India' initiative and to prevent the diversion of unregistered material (which has not been evaluated completely for its efficacy and safety) in domestic market, it is proposed that import of technical or formulation for export of the pesticides/products already registered for use in the country, be permitted only from the source registered for use in the country. Further, if import is from unregistered source then it will be permitted only against 'Firm Export order' for quantity specified in the order. Further, 'Firm Export Order' should be accompanied by Certificate of registration in the country of import. In such cases, the quantity restriction will not be deleted( unlike 'fast Track Registration'), however, in case of receipt of repeat order, the additional quantity may be get endorsed after submitting the authentic documents from Government Authority regarding export of total quantity permitted earlier. Any other application for import from changed source of import/import from new source for export should comply with the data requirements under guidelines for registration for import from new source or formulation import for use in the country.
8. Thousands of Certificate of Registrations for export only have been issued till date. Further, exports can also be made against the registrations granted for manufacture/import for use in the country to several thousand registrants. As export registrations are being granted on highly relaxed guidelines, only prima-facie not completely ensuring safety, without ensuring efficacy or its quality, therefore, it is suggested that statistics regarding the licenses obtained for registrations issued exclusively for export and exports undertaken pesticide-wise, company-wise may be collected to decide future direction of the policy in this regard. It is important to analyze the use and misuse of pesticides in terms of quality, health, environment and economic security.

## GUIDANCE AND REQUIREMENTS FOR APPLICANTS FOR REGISTRATION UNDER EXPORT ONLY CATEGORY

### GENERAL GUIDELINES

#### **1. TYPES OF APPLICATIONS FOR EXPORT**

The export applications will be considered under following three types–

(Based on priority and time frame for grant of registration)

- I. **Fast track applications:** with 'FIRM EXPORT ORDER'. These are the applications wherein applicants have 'firm export order'. These applications will be processed on top priority with minimum information and certificate of registration will be issued in 5 working days to manufacture/import the quantity indicated in the export order. Thereafter, registrant can get the condition regarding 'quantity restriction' deleted on submission of requisite information as per the guidelines of export registration under general category.
- II. **Star Export Houses applications:** The accreditation of Star Export Houses shall be on the same basis as that of the Ministry of Commerce and the fee shall also be charged accordingly.
- III. All other applications for export only.

#### **2. CATEGORY OF APPLICATIONS**

All above applications are categorized under following two categories.

- A. Applications for pesticides already registered for use in the country.
- B. Applications for pesticides not yet registered for use in the country.

These A and B categories are further classified into sub-categories based on whether application is for indigenous manufacture or import; for chemical pesticides or botanical pesticides or Microbial Pest Control Agents (MPCA) etc.

**3. Time Frame for Registration** : The following time frame for grant of registration for export applications complete w.r.t. all required parameters has been suggested : -

- I. **Fast Track Applications** (with 'firm export order'): 5 working days

## **II. Star Export House applications:-**

Category [A] : 7 working days

Category [B] : 10 working days

## **III. All other applications for export only :-**

Category [A] : RC to RC basis

Category [B] : 3 months

### **4. Guidance for toxicity information**

For toxicity requirements, published information on the parameters shall be acceptable from any of the following sources:

- i) From the reviews undertaken by International organization/institutions like WHO, Joint bodies of FAO/WHO, International Registry for Potential Toxic Chemicals (IRPTC), International Agency on Research on Cancer (IARC), Pesticide Manual, Merck Index etc.
- ii) Any evaluation / Fact Sheet by Registration authorities of USA or EU or Canada or Japan including Material Safety Data Sheet shall be accepted. Information from other reliable sources including TOXNET, EXTONET can be provided.

If published information is not available data are to be submitted.

### **5. Information on Packaging**

For packaging, labelling an undertaking with respect to type of packaging and Label and Leaflet as per Insecticides Rules, 1971 are required to be submitted for all categories and types of registration.

**6. Bio-pesticides:** A condition in case of Biopesticides (Botanical and microbial) shall be incorporated in the certificates of registrations for export category:-

“The product being exported is in compliance of Biological Diversity Act, 2002.”

7. An Undertaking be obtained and condition on Certificate of Registration be incorporated w.r.t. compliance of provisions of PIC, CWC, WMD and Biological warfare.
8. An undertaking shall be submitted by the applicant that the product manufactured / imported for export shall not be used in the country, if export could not be undertaken.

## **SPECIFIC REQUIREMENTS FOR DIFFERENT TYPES OF APPLICATIONS UNDER VARIOUS CATEGORIES-**

### **I. For fast track applications**

- i. Firm Export Order from the importer.
- ii. The documents regarding the registration of product in the country of import.
- iii. Documents for registration in any developed country like EU, USA, Australia, Japan, and Canada etc with its Decision Guidance Document. [Required only for B II, B III & B IV categories]
- iv. **Registration will be issued by Secretary CIB&RC for the production/import for the quantity of the export order, and subjected to ex post facto approval by the Registration Committee.**
- v. The applicant may then submit the requirements/ information as per the applicable category to get the condition deleted with reference to restriction on quantity.

### **II. Guidelines for Type II & III applications for Registration of Pesticides Exclusively for Export**

#### **1. Category – A I**

**Products registered for the use in the country by any registrant (including plant based products, but not microbial pest control agents) for indigenous manufacture of technical with same and different impurity profile/formulations (including combination formulations) for indigenous manufacture made out of these technical and having same lower or higher concentrations, different adjuvants or new type of formulations.**

- i Data/ information on chemistry as per table 1 (parameter 1 & 2)
- ii. An undertaking w.r.t. type of packaging & Label and leaflet as per Insecticides Rule, 1971.

## **2. Category – A II**

**Technical import or formulation import exclusively for export from ‘already registered source of import for use in the country’.**

- i. Information on chemistry is required on parameters 1, 2 and 6 on table
- ii. An undertaking w.r.t. type of packaging & Label and leaflets as per Insecticides Rules, 1971.

## **3. Category – A III**

**In case of Microbial Pest Control Agents if application is for export of already registered strain.**

- i. Information on chemistry as per table 2 (except 4, 5 and 6).
- ii. An undertaking w.r.t. type of packaging & Label and leaflet as per I rule, 1971.

## **4. Category – B I**

**The technical once registered exclusively for export (for indigenous manufacture or import), then subsequent registrants applying registrations for the same products (with different impurity profile their higher lower conc. or its formulations including combination formulations).**

- i. Information on chemistry on parameters 1, 2, 3, 4 and 6 in table 1.
- ii. An undertaking w.r.t. type of packaging & Label and leaflet as per Insecticides Rule, 1971.

## **5. Category – B II**

**Indigenous manufacture/import of technical and its formulations for pesticides not registered for use in the country and is for sole purpose of export.**

- i. Information on chemistry on parameters 1 to 6 for both technical and formulations.
- ii. Information for toxicity would be required on parameters 1 to 12 for technical and on 12 for formulation as per Table 3. In case of

registration of formulation without registering technical, information on its technical is required on parameters 1 to 12 and on formulation on parameter 12.

- iii. An undertaking w.r.t. type of packaging & Label and leaflet as per I rule, 1971.

## **6. Category B III**

**Indigenous manufacture of Botanical (technical/formulation) Pesticides not registered for the use in the country.**

- i. Information on Chemistry is required as per Table 2 (All parameters).
- ii. Information for toxicity would be required on parameters 1 to 6, 10 and 12 as per Table 3.
- iii. An undertaking w.r.t. type of packaging & Label and leaflet as per I rule, 1971.

## **7. Category – B IV**

**If the MPCA or its strain is not registered for use in the country.**

- i. Information on Chemistry is required as per Table 2 (All parameters).
  - ii. Information for toxicity would be required on parameters 1 to 6 and 12 as per Table 3.
  - iii. An undertaking w.r.t. type of packaging & Label and leaflet as per I rule, 1971.
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: Table 1 :

Chemistry Information/data requirements for grant of registration of chemical/plant based pesticides exclusively for export (Category AI, AII, BI & BII)

Sl. No	Parameter	Category			
		AI	AII	BI	BII
1.*	Chemical composition OR Botanical/common name, Scientific name, common name, if any and place of origin in the country.	R	R	R	R
2.	Physico-chemical properties	R	R	R	R
3.*	Specification in BIS format along with undertaking for product quality OR Specification of the product along with undertaking that the product is naturally occurring and not genetically engineered.	NR	NR	R	R
4.	Method of analysis	NR	NR	R	R
5.	Outline of process of manufacture, raw materials used / process of extraction of active ingredient	NR	NR	NR	R
6.	Source of import/supply	NR	R	R	R

\* Whichever is applicable as per product.

: Table 2 :

**Chemistry Information/Data requirements for grant of registration of MPCA or its strain not registered for domestic use in the country exclusively for export (Category BIII) and bio-pesticides for export, already registered strain (category AIII) and indigenous manufacture of MPCA and its strain not registered for use in the country (Category BIV).**

Sl. No.	Parameters	Category		
		AIII	BIII	BIV
1.	Botanical/common name, Scientific name, common name, if any, and place of origin in the country.	R	R	R
2.	Specify the microbial strain/plant part for the given biological activity and its location of existence in India.	R	NR	R
3.	Composition of the product with percentage of all ingredients/chemical composition and physic chemical properties	R	R	R
4.	Specification of the product along with undertaking that the product is naturally occurring and not genetically engineered.	NR	R	R
5.	Outline of process of manufacture, raw material used/process of extraction of active ingredient.	NR	R	R
6.	<b>Method of analysis</b> a. Determination of active ingredient by appropriate method b. Determination of toxin contents using the internationally recognized scientific methods & Standard Operating procedures in accredited and recognized laboratories only for <i>Bacillus sphaericus</i> (B.s) & <i>Bacillus thuringiensis</i> / similar products c. Determination of potency by bioassay method. OR d. Determination of Colony Forming Units(CFU)/ Polyhedral Occlusion Bodies(POB) counts by appropriate method	NR  NR  NR  NR	R  NR  NR  NR	R  R  R  R
7.	Specification in BIS format* along with undertaking for product quality.	NR	R	R

\* If no information on certain minor parameters is available the applicant should indicate so.

Table 3:

**Toxicology information/data requirements for grant of registration of pesticide exclusively for export.**

Sl. No.	Parameter	CATEGORY		
		Chemical and Plant based pesticides		MPCA
		B II	B III	B IV
1.	Acute Oral rat	R	R	R*
2.	Acute dermal	R	R	R*
3.	Acute inhalation	R	R	R*
4.	Primary skin irritation	R	R	R
5.	Irritation to mucous membrane	R	R	R
6.	Allergy / Sensitization	R	R	R
7.	Effect on reproduction	R	NR	NR
8.	Developmental Toxicity	R	NR	NR
9.	Carcinogenicity	R	NR	NR
10.	Mutagenicity	R	R(Ames test)	NR
11.	Neurotoxicity	R	NR	NR
12.	Sign & Symptoms of poisoning/First Aid, treatment & other precautionary measures	R	R	R

\* Single Exposure Studies.

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