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भारत सरकार
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
Central Insecticides Board and Registration Committee
एन. एच. 4, फरीदाबाद (हरियाणा)-121001
N.H. IV, FARIDABAD (HARYANA)-121001
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Dated 06 May, 2020

## PUBLIC NOTICE

Subject: Report of the Sub-Committee to review certain issues related to Registration of Pesticides-reg.

The Registration Committee(RC) in its 408th meeting (vide agenda item no. 11.1) held on 09.09.2019 had constituted a Sub-Committee under the Chairpersonship of Dr. Sandhya Kulshreshta, Consultant(Pharma) to address some miscellaneous issues being faced while considering various applications under different categories.

The report of the Sub-Committee was considered by the RC in its 412th meeting (vide agenda item no. 3.1) held on 18.12.2019 and decided that comments of the Stakeholders may be invited on the Report giving 30 days time from the date of uploading the report on the website. Accordingly, the report was displayed for comments of the Stakeholders vide Public Notice dated 14.01.2020.

On the basis of the Comments received from the Stakeholders, the final report submitted by the Sub-Committee was considered by the RC in its 413th meeting (vide agenda item no. 3.11) held on 03.03.2020, 06.03.2020 and 09.03.2020 respectively and approved the same. The RC further directed that the final report may be uploaded on the website. Accordingly, the final report is brought to the notice of all concerned through this Public Notice for information. This Report may be read with guidelines/checklists available on the website of PPQ&S and not in isolation.

(Vivek Narayan) 6/5/2020
Sr. Administrative Officer (CIB&RC)

Distribution:

1. All Pesticides Associations
2. Sr. PPS to Agriculture Commissioner & Chairman(RC)
3. PPS to Direcor(PP) & PPA
4. PPS to Secretary(CIB&RC)
5. IT cell for uploading on the website of PPQ&S
6. All Experts/Unit Incharges in the Secretariat of CIB&RC

# REPORT OF THE SUB-COMMITTEE TO REVIEW CERTAIN ISSUES RELATED TO REGISTRATION OF PESTICIDES

## Background

Registration Committee in its 408th Meeting constituted a Sub-Committee in view of some miscellaneous issues being faced while considering various applications under different categories. The minutes of the RC are as under :

*11.1 Any other item with the Permission of Chair*

*The committee observed that the there is need to have guidance on some issues causing discrepancies/difficulties in arriving the decision. RC decided to constitute a subcommittee comprising following*

i. *Dr. Sandhya Kulshrestha, Consultant (Pharma): Chairperson*
ii. *Dr. Vandana Seth, JD(Chem), CIL: Member*
iii. *Ms. Kamlesh Miglani, JD (Chem): Member*
iv. *Sh. Niraj Kulshrestha, Law officer: Member*
v. *Dr. Archana Sinha, JD(Chemistry): Member Secretary*

*TORs to be addressed:*

i. *Difference in the purity of the already registered product and fresh application for additional manufacturing site to import the same product.*
ii. *Difference in the purity of the already registered product from the same source.*
iii. *Endorsement of additional approved source having different chemical composition for the same product.*
iv. *Implementation of change in name of source and supplier (if applicable) uniformly to all registrants*

## Conduct of Business

The Sub-Committee held three meetings on 15.10.19, 10.12.19 and 11.12.19 under the chairmanship of Dr. Sandhya, Consultant (Pharmacology).

The members discussed the issues related to mandated TORs in detail considering the existing guidelines/ checklists of the Registration Committee; past decisions of the Registration Committee; representation received from various pesticide Associations; Guidelines for JMPS specifications and practices in other countries. After detailed deliberations and discussion, the sub-committee observed and recommended as follows:

a. The recommendations made for the different TORs (I to iv) are true for the chemical pesticides and doesnot address the issues related to technical material of Microbial Pest Control Agent (MPCA) or technical material of plant origin or poorly defined chemical composition.

***TOR i. Difference in the purity of the already registered product and fresh application for additional manufacturing site to import the same product.***

Sub-Committee deliberated the issue at length and pointed out following:

1. Grant of endorsement for additional manufacturing site for a product which is already registered for import and use in the country is a translation of the same technology to be used at another manufacturing site situated in a different country.
2. It was also opined that endorsement for additional manufacturing site is made for the products which had been registered in India and it is anticipated that the capabilities to reproduce the same or a better product exists with the firm applying for the endorsement for additional manufacturing site.
3. Sub-Committee also considered some cases where the applications from the firms have been received by the Secretariat CIB&RC requesting to endorse additional site manufacturing more pure technical product having less number or low level of already identified and quantified impurities than the already registered product.
4. It was also recapitulated by the Sub-Committee that some of the countries register the products at nominal value while the same product is either applied for registration at minimal value or is registered at minimal value of purity in India.
5. The Sub-Committee also considered the fact that change in the purity on the already issued certificate of registration may hamper grant of registration under category TIM vs TI and Make in India vision.
6. In view of the above the Sub-Committee made following recommendations :

   a. **The product to be registered for import from the additional manufacturing site should not be of less purity than the product already registered by the firm for use in the country.**

   b. **If the purity of the product to be registered from additional manufacturing site is higher within the limit of 10% than the product already registered by the firm for use in the country, the applicant is then required to submit 5-batch analysis as per the already existing guidelines. Only GLP certified data shall be acceptable from the GLP facilities lab approved under OECD GLP Programme situated in the country of origin or in India.**

   c. **If there is no change in the manufacturing process, Physico-Chemical properties, quality specifications and the impurities are within the limits of already registered product and there is no new / additional impurity then the applicant should submit an affidavit to that extent and the additional manufacturing site may be endorsed with enhanced purity.**

d. If there is change in the manufacturing process or Physico-Chemical properties or quality specifications or the impurities are not within the limits of already registered product or there is any new / additional impurity or active ingredient is higher than the limit of 10% of the product already registered by the firm then the requirement for endorsement or new registration shall be decided by the RC based on the applicable scenario.

e. In addition to the checklist approved in the 325th meeting of RC for Guidelines for endorsement of additional manufacturing site (Guidelines for Endorsements) then an affidavit as indicated at point c above and accordingly revised label /leaflet shall be submitted.

TOR- ii : *Difference in the purity of the already registered product from the same source.*

Sub-Committee deliberated the issue observed following:

1. Many registrations have been granted under various import categories. These registrations were granted with certain chemical composition but subsequently the products have been granted renewed registration in the exporting country with better purity though the chemical profile cited in the CR issued by Sectt.CIB&RC remains at lower purity thus bringing ambiguity.

2. The Sub-Committee opined that such betterment in the product quality may be due to upgradation of existing technology or change in the manufacturing process or change in the raw material quality.

3. Based on the above and the decisions of RC taken in the past the Sub-Committee recommended following for the product to be renewed:

   a) The difference in the purity of the already registered product from the same source /site (within the source country) should not be of less purity than the product already registered by the firm for use in the country.

   b) The application will be considered only when the source is already registered by the firm and the purity is changed at the source. The applicant will be required to submit 5-batch analysis for the product whose purity has been revised in the source country. Only GLP certified data shall be acceptable from the GLP facilities lab approved under OECD GLP Programme situated in the country of origin or in India.

   c) If there is no change in the manufacturing process, Physico-Chemical properties, quality specifications and the impurities are within the limits of already registered product and there is no new additional impurity and the active ingredient is not higher than the limit of 10% of the product already registered by the firm then the applicant should submit an affidavit to that extent and the Certificate of Registration may be endorsed with enhanced purity and accordingly modified impurity profile.

**d) If there is change in the manufacturing process or Physico-Chemical properties or quality specifications or the impurities are not within the limits of already registered product or there is any new / additional impurity or active ingredient is higher than the limit of 10% of the product already registered by the firm then the requirement for endorsement or new registration shall be decided by the RC based on the changes informed by the applicant.**

**e) Accordingly, a public notice shall be issued for all the registrants granted registration u/s 9 for applicability of changed profile as and when endorsed on the Certificate of Registration as indicated at point 3(c) above for compliance.**

**f) The information shall be shared with Customs Authority also for compliance by the registrants.**

*TOR iii : Endorsement of additional approved source having different chemical composition for the same product.*

1. It was brought into the notice of the sub-committee that in the existing state of affairs 9(3) or 9(4) registration certificate holders may get endorsed additional approved source on their certificate having entirely different composition for the same product. Chemical composition of such product endorsed for additional source is not mentioned on the endorsement letter.

2. Sub-committee felt that there are two ongoing mechanisms running parallely to get such registrations / endorsements.

   In view of the indistinctness arising from the above situation Sub-Committee recommended following:

   a) **The applicants shall apply for grant of registration u/s 9(4) TI category for the product having different chemical compositions.**

   b) **The Certificate of Registration may be endorsed with the already approved source if the chemical composition of the registered source applied for endorsement is identical to the product registered in favour of the applicant. The requirement as per the existing Checklist approved in 266$^{th}$ RC shall be applicable.**

*TOR iv: Implementation of change in name of source and supplier (if applicable) uniformly to all registrants*

Sub-Committee considered imprecision arising due to endorsements w.r.t. change in the name of source or supplier by only one or two applicants thus bringing non-uniformity in other issued certificate of registration having same source or supplier.

In view of the above situation Sub-Committee recommended following:

1. **Guidelines / Checklist shall be revised.**
2. **The information regarding any application received by the Secretariat for change either in the name of source or supplier in the certificate of registration shall be displayed for one month on the website as public notice for comments of stakeholders. After which the comments shall be compiled and put up to RC for finalization.**
3. **After approval by the RC for change in name of source or supplier, a public notice shall be issued for all the registrants granted registration u/s 9 for applicability of changed name of source or supplier as endorsed on the Certificate of Registration as indicated at point 2 above for compliance.**
4. **The information shall be shared with Customs Authority also for compliance by the registrants.**
5. **Checklist 17 and 23 have been revised accordingly only with reference to change of name of source of import (and not for change of manufacturing premises in the country of origin) (Annexure I)**

Checklist 17.

## CHECK LIST FOR CHANGE OF NAME OF SOURCE OF IMPORT OR CHANGE OF MANUFACTURING PREMISES IN THE COUNTRY OF ORIGIN

**NAME OF THE APPLICANT**: M/s.....

**Name of the Product**.....

**Administration/Legal**

1. Index
2. Page numbering
3. Notarized copy of BOD Resolution/Affidavit/Partnership Deed
4. Authentication of pages by authorized signatory.
5. Affidavit duly notarized regarding endorsement made earlier in respect of Certificate for which the present request is being made
6. Documentary proof of change of name applicable in respect of country duly authenticated by Consulate/Embassy/High Commission

OR

Documentary proof as per change of manufacturing premises duly authenticated by Consulate/Embassy/High Commission.

7. Copy of certificate of Registration along with label / leaflet

**CHEMISTRY**

1. Reason/justification for the change in name clarifying whether it is a case of merger/taking over of company/internal rearrangement/shifting of manufacturing unit.
2. Analytical test report from the new premises alongwith undertaking w.r.t. quality specification and process of manufacture
3. Supportive document from the designated National Authority/Registration Document
4. Letter of consent, duly legalized from Indian Embassy/High Commission /Consulate in the country of origin

5. Any other additional relevant document/information.

**Checklist 23.**

**Check List for Endorsement of name of supplier of already approved source of import in the Certificate of Registration.**

1. Index
2. Page numbering
3. Notarized copy of BOD Resolution/Affidavit/Partnership Deed
4. Authentication of pages by authorized signatory.
5. Affidavit duly notarized regarding endorsement made earlier in respect of Certificate for which the present request is being made
6. Letter of consent, from approved source of import duly legalized from Indian Embassy/High Commission/ Consulate in the Country of origin in favour of proposed supplier
7. Reference of Registration Committee meeting in which additional source of Import is approved.

    1. Copy of Registration Certificates along with label/leaflets.