MINUTES OF 406thMEETING OF REGISTRATION COMMITTEE HELD ON 23.07.2019 IN THE CHAMBER OFDR. S. K. MALHOTRA, ROOM NO. 231, KRISHI BHAWAN, NEW DELHI.

The 406thMeeting of Registration Committee (RC) was held under the Chairmanship of Dr. S. K. Malhotra, Agriculture Commissioner on 23.07.2019 at 10:00 AM in Room No. 231, Krishi Bhawan, New Delhi. Sh. Rajesh Malik (Member), Plant Protection Advisor, Directorate of PPQ&S, Faridabad; Dr. S. P. Shani (representative of DCGI), New Delhi (Member); Dr. Harmeet Singh Rehan, Professor and Head, Department of Pharmacology, Lady Harding Medical College, New Delhi; Sh. Madhab Chakarborty, Joint Director & Regional Head, Indian Institute of Packaging, New Delhi and Dr. Sushil K. Khurana (Member Secretary), CIB&RC, attended the meeting. Following officers from the Secretariat of CIB&RC also attended the meeting to present their agenda and advises as and when required/or volunteered to provide the information during the deliberations.

1. Dr. Sandhya Kulshrestha, Consultant (Pharma)
2. Dr. Sarita Bhalla, Consultant (Pharma)
3. Dr. Archana Singha, JD (Chem)
4. Dr. Vandana Seth, JD (Chem) CIL (special invite)
5. Sh. HariomMiglani, Sr. Law Officer
6. Sh. Vivek Naryan, Sr. AO
7. Sh. Kiran W. Deshkar, DD (E)
8. Sh. A. K. Reddy, DD(WS)
9. Sh. Niraj Kulshreshtha, Law Officer
10. Sh. AvnishTomar, AD (Chem.)
11. Dr. Vandana Pandey, AD (PP)

At the outset, Chairman welcomed the members & experts and asked Secretary, CIB&RC to take up the agenda for deliberations. The decisions taken by the RC are as under: -

Agenda item No.	**Particulars of Agenda**
1.1	**404 RC minutes, agenda item no.10.17, registration of Renofluthrin 5% MUP**
	RC perused the representation received from M/s Shogun Organics Ltd. and also the parawise comments of Secretariat of CIB&RC. RC reiterated its decision taken in 404th meeting for generation of complete data as per guidelines of RC. RC also directed Sectt. CIB&RC to communicate comments to DAC&FW and the applicant and if needed may be called for clarification before RC.

	RC further directed Secretariat CIB&RC to discuss separately in Other issues regarding GLP/Non-GLP data requirement in light of decisions in 344, 351, 371, 375, 376, 381, 397, 398, 404th RC meetings.
1.2	**Consideration of application of M/S Tropical Agrosystem (India) Pvt. Ltd for grant of Registration for Import of 1-MCP 3.3% VP u/s 9(3).**
	RC discussed the agenda in light of 405th RC deliberations as well as presentation made by applicant and the observation of the RC are hereunder :- 1. Considering the facts and to address the safety concerns, restricting transport of the pure 1-MCP gas to CRO/test facilities, the required toxicological studies on stable technical powder MUP-HAIP with nominal content of 4.5% 1-methylcyclopropene (certified limits 4.1 to 4.9% w/w) were acceptable by the RC. 2. The requirement is for two mammalian studies one is on rodent and another in non-rodent where in rabbit is found most suitable animal and adequately mentioned in the Guidelines framed by RC. But as stated above by the applicant that attempts proved difficult and unfeasible to dose rabbit. The RC referred & deliberated the report [Waiver for a second species (non-rodent) OECD 414 and found that rabbit cannot be satisfactorily dosed orally with MUP-HAIP (1-MCP) via gavage/capsule/dietary because of vehicle stability and tolerability issues. It was also noted from report that 1-MCP gas cannot be produced safely or insufficient quantities at test sites for a rabbit studies and exposure via aerosol to with MUP-HAIP (1-MCP). Regulators across globe (EPA, EU, Canada, Japan, Australia etc) have accepted the waiver and granted registration based on available and submitted animal data. Considering OECD 414 report, the report of Exponent International Limited, (2017) and also Murthy committee recommendations, RC is not inclined to accept the waiver request for teratogenicity rabbit and carcinogenicity studies and these studies are indispensable and are to be carried out by the applicant. 3. On referring the peer review of pesticides risk assessment of the active substance 1-methylecyclopropene RC noticed that assuming the highest non-dietary exposure at the acceptable operator exposure level (AOEL) of 1-MCP, the margins of exposure for 1-CMP and 3-CMP with the presence of these two impurities at 0.2 gm per kg in the technical specification does not pose any safety concern. Further, the batches used for further toxicological studies support the proposed renewal specification but not the original reference specification. The RC was informed by the Secretariat that they have applied with the specification of active ingredient 96% with higher level of impurities in the statutory Form-1 (Application for registration of an insecticide) however they are now claiming the active ingredient at 98% with presence of these two impurities at 0.2 gm per kg. RC decided to take a precautionary steps during generation of ATR and the product will be kept under strict surveillance.Analytical Method to test 1-MCP 3.3%VP is required to be adequately addressed by CIL a statutory laboratory constituted under section 16 of the Insecticides Act, 1968. RC further observed that there are ambiguity in the test chromatograms generated in 5-batch analysis and the

	test chromatograms generated by Ross Lifescience Laboratory and as submitted by the applicant. RC was apprised that CIL presently does not have the instrument to detect the same. It was accordingly decided that the CIL may takeup the issue of conducting analysis at ICAR-NRC Grapes laboratory. 4. RC also noted that presence of these two impurities at 0.2g/kg in the technical specification results in margins of exposure of 150,000 and 3,200,000 for 1-CMP and 3-CMP respectively, which are unlikely to be of safety concern for consumers. 5. RC observed that the applicant has submitted 1-MCP 3.3% formulation to CIL on 19.6.19. The copy of testing protocol submitted to CIL has been submitted to CIB&RC on 15.7.19. However, the sample of MUP-HAIP (1-MCP) is yet to be submitted by the applicant. 6. RC was satisfied with bioefficacy and persistence data. The technical comments on 1-MCP 3.3% VP are awaited from ICAR in order to satisfy itself regarding the Bioefficacy of the product. 7. RC also noted that the product is registered in 40 countries including US, UK, Australia, Japan, Canada and many European and Latin American countries etc. 8. It was also noted by RC that 1-MCP is for the intended use as post-harvest plant growth regulator. 9. In view of the above discussions the RC is of the considered view that the applicant is required to submit the following information/documents as mentioned herein below as per the applicable guidelines of the RC: i. Fresh Form-1 indicating the revised chemical composition of counterpart technical of 1-MCP 3.3%VP along with revised label and leaflets. ii. Duly filled MRL Performa with suggested ADI so that it can be submitted to FSSAI for fixation of MRL. iii. Analytical Method to test 1-MCP 3.3%VP as required to be validated by CIL as there are ambiguity in the test chromatograms generated in 5-batch analysis and the test chromatograms generated by Ross Lifescience Laboratory and submitted by the applicant. iv. The applicant has submitted accelerated storage stability test (ASS) which has ambiguity as indicated at point iii. The applicant has submitted the conventional shelf life data on 19.07.2019 after their presentation in 405th RC meeting which is also required to be examined at the level of Secretariat of CIB&RC. v. As the application of registration is under the category of formulation import (without registering technical) the applicant should submit the sample of 4.5% MUP –HAIP also to CIL for analysis purposes immediately in view of the order Hon'ble High Court of Gujarat. A condition to this effect shall be incorporated in the CR. vi. The above product is to be used through the recognized Pest Control Operators (PCOs) only.

	In view of the above discussion and observations and in view of the fact that the molecule is being introduced for the first time in the country further the above matter is pending enquiry before the RC. Therefore, at this stage RC decided to accords it approval for the product under section 9(3B) of the Insecticides Act, 1968 along with subject to fixation of MRL by FSSAI, receipt of satisfactory ICAR comments and the satisfactory analytical test report as received by the Secretariat of CIB&RC. RC further decided that the applicant has to comply with the above requirements as per the observations of the RC and the same shall be submitted within a reasonable time to the Secretariat of CIB&RC for considering their application under section 9(3) of the Insecticides Act, 1968. Besides, adhering to the applicable provisions of the Insecticides Act, 1968 and Rules, 1971. The applicant may request DAC&FW being the competent authority for the grant of commercialization if he so desires. The conditions as discussed above shall be incorporated in the CR.	
2.0	**<u>Any other Item</u>**	
2.1	**Issue of certificate of registration to M/s Coromandel International Ltd. for Pymetrozine technical approved in 401st meeting.**	
	The committee discussed the representation of the applicant dt 16.7.19 regarding issue of certificate of registration as per the decision in 401st meeting. The committee decided that the certificate may be issued as per the decision taken in the 404th meeting.	
2.2	**Expert Committee under the Chairmanship of Dr KK Sharma, Network Coordinator, ICAR-AINP on Pesticide Residue, New Delhi,**	
	The RC reconstituted the committee formed on the "Persistence Studies in Plant" in its 380th meeting held on 20-11-2017 replacing Dr. Subhash Kumar, DD (WS), Member Secretary with Sh. A.K. Reddy, DD(WS).	
2.3	**The objective of agenda is the request letters from pesticide industry to extend date of submission of experimental data as per the recommendation in 361st RC from December, 2017 to December, 2019.**	
	In view of light of new facts regarding submission of data on studies by December, 2017 it was compliance on part of CIB&RC as a follow up action of the Dr. Anupam Verma committee recommendations. The RC withdrew the decision taken in 399th RC agenda 9.2 regarding extension of submission of experimental data as it is to be decided by DAC&FW.	
2.4	**Fall Army Worm (FAW) ad-hoc recommendation**	
	In addition to earlier decisions RC also considered and approved as under- a. Seed treatment with Cyantraniliprole 19.8% + Thiamethoxam 19.8% FS @ 6 ml/kg of seed. (Approval only upto 31st December, 2019).	
	b. Bio-pesticide as below- *Metarhizium anisopliae* *Metarhizium rileyi (Nomuraea rileyi)* *Beauveria bassiana* *Verticilium lecani*	1×10^8cfu/g) @ 5g/litre whorl application. Repeat after 10 days if required.
	Bacillus thuringiensis v. *kurstaki* NPV	@ 2g/l (or) 400g/acre.