

**MINUTES OF THE 433<sup>rd</sup> REGISTRATION COMMITTEE (SPECIAL) MEETING HELD ON 05.10.2021**

The 433<sup>rd</sup> meeting of the (special) Registration Committee (RC) was held under the Chairmanship of Dr. S. K. Malhotra, Agriculture Commissioner & Chairman, Registration Committee on 05.10.2021 at 14:30 hrs onwards in the PPA Secretariat. Dr. Ravi Prakash, PPA, DPPQ&S, Faridabad; Dr. S. C. Dubey, ADG (PP) ICAR, Krishi Bhawan, New Delhi; Dr. Rajesh Verma, Assistant Drug Controller, (Representative of Drug Controller General of India) New Delhi and Dr. J. P. Singh, APPA & Secretary, CIB&RC attended the meeting.

Experts/Officers from the Secretariat of CIB&RC participated for assisting to the RC and during the deliberations Dr. Sushil K. Khurana, Consultant (Pathology); Dr. Sandhya Kulshrestha, Pr. Consultant (Pharma.); Dr. Vandana Seth, JD(Chem); Sh. Subhash Chand DD (Chem.); Sh. A. K. Reddy, DD(WS); Sh. Kiran W. Deshkar, DD (E); Dr. K.L. Gurjar DD (PP); Dr. Sneha Potdar, DD (Chem); Dr. Brijesh Tripathi, DD (Chem.); Sh. Niraj Kulshrestha, LO; Sh. A.D. Bhatt, PPO (Chem); Dr. S. K. Jain Consultant (Medical Tox) and Dr. Sameya Anjum, Consultant (Medical Tox) were present.

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

<b><u>Agenda item No.</u></b>	<b><u>Particulars of Agenda</u></b>
<b>1.1</b>	<b>Follow up action of the decision made in 429<sup>th</sup> RC meeting regarding draft guidelines recommended in the report of the sub-committee to review guidelines for registration of pesticides u/s 9(3b), 9(3) and 9(4)</b>
	RC deliberated the report and deferred for the detailed discussion in the forthcoming RC meeting.
<b>1.2</b>	<b>Follow up agenda on comments/suggestions of stake holders on the draft memorandum of agreement prepared in consultation with Indian Institute of Toxicological Research (IITR-CSIR), Lucknow for outsourcing scrutiny of toxicology data circulated vide public notice dated 16.07.2021</b>
	The RC deliberated the agenda and accepted the report of the sub-committee and in the light of the sub-committee report asked the Secretariat of CIB&RC to communicate observations/recommendations to DA&FW. RC recommended that following may be considered while signing the MOA between IITR and Secretariat of CIB&RC or DA&FW: - <ol style="list-style-type: none"> <li>a. MOA (Memorandum of Agreement) should be in between the Indian Institute of Toxicological Research (IITR) and the Secretariat of CIB&amp;RC, Dte PPQ&amp;S or PP Division, Department of Agriculture and Farmers Welfare (DA&amp;FW).</li> <li>b. Since the registration fees is charged at the time of application filed for registration to CIB&amp;RC, the payment for scrutiny of toxicology folder to be made to IITR by the Directorate/CIB&amp;RC. Accordingly, a mechanism to be developed for payment of fees accordingly. No additional/separate fee should be charged for scrutiny of toxicology folder by IITR as this will be one of the arrangements to facilitate</li> </ol>

	<p>registration process.</p> <ul style="list-style-type: none"> <li>c. In order to support timely scrutiny, only those folders to be sent for toxicology scrutiny (first in first out (FIFO) basis) to IITR which are lacking behind than other units (bio-efficacy/chemistry/ packaging) due to shortage of experts in toxicology.</li> <li>d. IITR should be assigned complete responsibility of processing the toxicology file from scrutiny, agenda preparation, present the agenda in the RC meetings and associated authentication work of label and leaflets. Post registration support for providing inputs/ clarification (court case, parliament question etc. on need basis) should also be the responsibility of IITR i.r.o. toxicology files scrutinised by them.</li> <li>e. IITR will maintain all confidentiality of data and make sure that no conflict of interest is involved.</li> <li>f. IITR should communicate list of experts to Sectt. of CIB&amp;RC who will be involved in the scrutiny of the files.</li> <li>g. IITR to complete all online requirements of registration process through CROP portal as being done by the existing toxicology experts.</li> </ul>
<p><b>1.3</b></p>	<p><b>Follow up agenda on compiled comments/suggestions of stake holders on the draft SOP for use of drone application of pesticide for crop protection (small marginal and organized sector) in agriculture, forestry, non-copped area.</b></p>
	<p>The RC deliberated the agenda in detail and observed that in lieu of SOP, the term guidelines for use of drone for Registration requirements of pesticides should be used as this mainly covers guidance on drone related operational aspects and the technical data requirements for considering the registration of pesticides using drone in agriculture, forestry and non-cropped areas. It is further observed that use of drone based pesticide application for locust control, public health and plantation crop was discussed and finalized in the 58<sup>th</sup> CIB meeting held on 22.05.2020. On the operational part, the RC observed that under the “Provision of the Insecticides Rules 1971, envisaged under the Insecticides Act, 1968” one of functions of the Board (Central Insecticides Board) constituted under Section 4 of the Act, is to specify the uses of the classification of insecticides on the basis of their toxicity as well as their being suitable for aerial application [Rule 3 (b)]”. So, the procedure to be adopted for deciding the suitability of pesticides for aerial application keeping in view the Insecticide Rules 1971, Chapter VIII, Rule 43, on Aerial Spraying Operations may be approved by the CIB. For this it was suggested that a technical committee under the Chairmanship of PPA, DPPQ&amp;S may be constituted, to examine the proposal submitted by the applicants as per the approved guidelines for using approved pesticides with Drone and to apprise the findings to the Board for its consideration /approval.</p> <p>Further, on the technical part of the guidelines which is related to data requirement for registration of insecticides, the RC deliberated in detail and suggested some modifications in the proposed model study protocol of bio-efficacy data generation as well as data requirement in the guidelines and also in the Spray Monitoring Form (<b>Appendix</b>) herein: RC decided to approve the following Guidelines for Registration requirements of pesticides</p>

for drone application and asked the Sectt. Of CIB&RC to issue a **public notice** for information of the applicants/stakeholders for initiation of the data generation for registration of pesticides or for label expansion as per below mentioned guidelines (as per Annexure):

The applicant may apply for seeking registration for drone-based application of pesticides and the endorsement (label expansion) related approvals under the relevant provisions/category to the secretariat of the CIB&RC. For various categories of applications, the RC recommended the following requirements:-

**A. Products with existing label claim in a crop recommended for spray with conventional sprayers and to endorse the use of Drones as alternate/additional spraying equipment.**

**Requirement:**

- a) If critical Good Agriculture Practices (GAP) e.g. AI dose/ha, Pre harvest Interval (PHI) and number of applications is within a recommended range of conventional spray then; Data on phyto-toxicity on the approved crop-pest combination for one season four different agro-climatic conditions, where the target crop is cultivated, to be generated as per protocol (given at Annexure) and also in the Spray Monitoring Form (given at Appendix) from the Institutes approved by the RC.
- b) If critical GAP e.g. AI dose/ha, PHI and number of applications is not within a recommended range of conventional spray then; Data on bio-efficacy, phyto-toxicity and residue may be generated as per approved guidelines alongwith protocol (given at Annexure) and details shall also be submitted in the Spray Monitoring Form (given at Appendix) from the Institutes approved by the RC.

No data requirement for chemistry/ Toxicology/Packaging/ Legal.

**B. New product/Insecticide / new endorsement (label expansion) registration with use of conventional sprayers or Drones as spraying equipment or use of both as spraying equipment.**

**Requirement:**

Data requirement on bio-efficacy, chemistry, toxicity, packaging and legal as per approved guidelines under respective category alongwith protocol (given at Annexure) and details shall also be submitted in the Spray Monitoring Form (given at Appendix) from the Institutes approved by the RC.

RC further decided that, each applicant wish to generate data for seeking registration for drone-based application of pesticides and their endorsement (label expansion) shall intimate about proposed data generation to the Sectt. of CIB&RC in advance.

**Model study protocol of bio-efficacy data generation**

For bio-efficacy data generation using Drone for application of pesticides, the study protocol may include data on following:

**A. Trial conditions details**

1. **Name of Crop and Variety of Crop**
2. **Cultivation Details**
3. **Weather conditions**

**B. Trial design and arrangement details**

1. **Name of pesticide**
2. **Control pesticide**
3. **Trial plot arrangement (Design/ No. of replicates/Layout etc.)**

**C. Pesticide application details**

1. **Application method:** The pesticide application method, time, frequency and dose should be in compliance with the agreement or label instructions. The pesticide application should be in line with the local agricultural practices. The amount of the active ingredients in the pesticide is usually expressed as (g/ha).

**D. Application equipment details**

1. **Crop protection Remotely Piloted Aircraft System (RPAS) or Drones**
2. **Control pesticide application equipment (if applicable)**

**E. Details of License Pilot/ operator, registration of UAV details, training etc.**

1. **Declaration of Details about the intended pesticide use:** If any other pesticide is to be used, the pesticide should have no effect on the trial pesticide and the trial subject, and be applied evenly to all trial plots. The pesticide should be used separately from the trial pesticide and the control pesticide, to minimize their mutual interference. Accurate data about such pesticide, such as the name, application time and application dose, should be recorded.

**G. Droplet distribution determination details (size of droplet and related information)****H. Data, recording and measurement methods details****I. Meteorological and soil data details**

1. **Weather conditions:** The precipitation (mm), temperature (daily average temperature, maximum temperature and minimum temperature, °C), relative humidity (%), wind force (m/s) and wind direction during the trial period should be recorded. Adverse climatic factors if any, that will affect the trial results throughout the trial period, such as severe or prolonged droughts, heavy rains and hail, must be recorded.
2. **Soil data:** The soil type, soil fertility, irrigation and drainage, algae growth and weeds, among others, should be recorded.

**J. Efficacy calculation method details****K. Direct effect on crops (Phytotoxicity Data)****L. Effect on other organisms****M. Effect on other pests and diseases****N. Effect on other non-target organisms**

**O. Product yield and quality:**

For herbicides and plant growth regulators, determination of the product yield is generally required. The yield per plot should be recorded and expressed in (kg/ha).

**P. Information on Liquid preparation drifting, droplet size and distribution etc.**

**Note:** The proposed model study protocol of bio-efficacy data generation in the SOP/ Guidelines may be aligned with the requirement of existing data generation protocol in National Agriculture Research System Institutions for Bio-efficacy protocol may also be adhered to by the applicants.

**Appendix**

**SPRAY MONITORING FORM**

<b>1</b>	<b>LOCATION of Trial Details</b>	1		2		3		4		5		6	
1-1	Date												
1-2	Name												
<b>2</b>	<b>VEGETATION DATA</b>												
2-1	vegetation type (Crop, Grass, Bushes, Trees,)	GBTC		GBTC		GBTC		GBTC		GBTC		GBTC	
2-2	Height from ground/Crop Canopy (m)												
2-3	Crop names and pest/disease/weed infection/infestation/intensity (%)												
<b>3</b>	<b>PESTICIDE DATA</b>												
3-1	Trade name & Common name												
3-2	concentration (g a.i./l or %)												
3-3	Formulation (EC, ULV, Dust)	EUD		EUD		EUD		EUD		EUD		EUD	
3-4	Expiry date												
3-5	is insecticide mixed with water or solvent?	YN		YN		YN		YN		YN		YN	
3-6	if yes, what solvent and mixing ratio details												
<b>4</b>	<b>WEATHER CONDITIONS</b>												
	Start and end of control operations	Start	End	Start	End	Start	End	Start	End	Start	End	Start	End
4-1	Date & time												
4-2	temperature (°C)												
4-3	relative humidity (%)												
4-4	wind speed (m/s)												
4-5	wind direction (degrees from N)												
4-6	spray direction (degrees from N)												
<b>5</b>	<b>SPRAY APPLICATION</b>												
5-1	Sprayer type (Rotary, Airblast, ENS, Hydraulic, Other)	RAEHO		RAEHO		RAEHO		RAEHO		RAEHO		RAEHO	
5-2	sprayer operator (Pilot, Driver, Hired, Other)	PDLHO		PDLHO		PDLHO		PDLHO		PDLHO		PDLHO	
5-3	sprayer manufacturer												
5-4	sprayer model												
5-5	sprayer platform (Aerial, Vehicle, Handheld)	AVH		AVH		AVH		AVH		AVH		AVH	
5-6	date of last calibration												
5-7	atomizer height above ground (m)												
5-8	ROTARY SPRAYERS: speed setting (blade angle, pulley setting, no. batteries)												
5-9	speed of atomizer (rpm)												
5-10	flow rate setting (which nozzle or restrictor used)												
5-11	flow rate/atomizer (l/min)												
5-12	number of atomizers												
5-13	track spacing (m)												
5-14	BARRIERS ONLY: width and spacing (m)												
5-15	forward speed (km/h)												
5-16	AERIAL SPRAYING: support supplied	GP = ground party available RC = radio communication with dronet TG = DGPS track guidance											
		GP RC TG		GP RC TG		GP RC TG		GP RC TG		GP RC TG		GP RC TG	
5-17	ground marking (GPS, Flag, Mirror, Smoke, Vehicle, None)	GFMSV N		GFMSV N		GFMSV N		GFMSV N		GFMSV N		GFMSV N	
<b>6</b>	<b>CONTROL EFFICACY</b>												
6-1	Effectiveness/mortality (%)												
6-2	Days after treatment/ time after treatment (hours)												
6-3	Yield of Crop/method of Effectiveness /mortality estimation (Quadrats, Target size, Visual, Cages, Other)	QTVCO		QTVCO		QTVCO		QTVCO		QTVCO		QTVCO	
<b>7</b>	<b>SAFETY AND ENVIRONMENT</b>												

Minutes of 433<sup>rd</sup> RC (special) meeting held on 05.10.2021

7-1	protective clothing:what did the operator wear?	G = goggles M = mask L = gloves O = overalls B = boots					
		GMLOB	GMLOB	GMLOB	GMLOB	GMLOB	GMLOB
7-2	was soap and water available?	Y N	Y N	Y N	Y N	Y N	Y N
7-3	who was informed of spraying? (Farmer, Nomad, Villager, Official, Beekeeper, others etc.) with date and time	F N V O B	F N V O B	F N V O B	F N V O B	F N V O B	F N V O B
7-4	effect on non-target organisms	Y N	Y N	Y N	Y N	Y N	Y N
7-5	if yes, what						
7-6	details of anyone who felt unwell or if other problems were encountered						
7-7	Details about nearby water-bodies and water channels, etc.						

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