

F. No. 26-03/2021-CIR-I 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 केंद्रीय कीटनाशी बोर्ड एवं पंजीकरण समिति Central Insecticides Board and Registration Committee एन. एच. 4, फरीदाबाद (हरियाणा)-121001 N.H. IV, FARIDABAD (HARYANA)-121001

Dated: 16 July, 2021

PUBLIC NOTICE

Subject: Draft Memorandum of Agreement prepared in consultation with CSIR-IITR, Lucknow- Inviting comments of stakeholders-reg.

Reference the decision taken by the Registration Committee at Agenda Item No. 11.4 in the 429th RC meeting held on 24.06.2021, 28.06.2021 and 30.06.2021.

Accordingly, the draft Memorandum of Agreement prepared in consultation with CSIR-IITR, Lucknow is enclosed at Annexure for inviting comments of the stakeholders.

All stakeholders are requested to submit their comments, if any, on the draft MoA within 15 days of hoisting of this Public Notice on the website of Dte. Of PPQ&S through email at cibsecy@nic.in and socir1.ppqs-agri@gov.in.

This has the approval of APPA & Secretary (CIB&RC).

Encl: As above.

you

(Suman Jakhar) Section Officer

Copy to:
(i) All Pesticide Associations
(ii) Chairman, Registration Committee
(iii) PPS to JS(PP)/ PPS to PPA/PPS to APPA & Secretary (CIB&RC)
(iv) IT Cell, Hq. Faridabad for uploading the same on the official website.

Memorandum of Agreement

This Memorandum of Agreement (MoA) is signed at.....on this day of June..., 2021, between the **Registration Committee** (herein referred as the "**RC**") through its **Secretary, Central Insecticides Board and Registration Committee** (**CIB&RC**), situated at Directorate of Plant Protection Quarantine & Storage, Old CGO Complex, NH-IV, Faridabad-121001, Haryana (hereinafter referred to as the "**CIB&RC**" the first party) and **CSIR-Indian Institute of Toxicology Research** (**CSIR-IITR**), a constituent laboratory of Council of Scientific & Industrial Research, situated at Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001, UP (hereinafter referred to as "**CSIR-IITR**" the second party). Party shall mean CSIR-IITR or RC as the context dictates, when used in plural shall mean CSIR-IITR and RC.

WHEREAS the Central Government has constituted the 'Registration Committee' under Section 5 of the Insecticides Act, 1968 (the "Act"), which performs the functions, inter-alia, registering insecticides after scrutinizing their formulae and verifying claims made by the importer or the manufacturer, as the case may be (hereinafter "Applicant" or "Applicants"), as regards their efficacy and safety to human beings and animals;

WHEREAS the First Party is desirous of empaneling experts ("**Empanelment**") for the purpose of assisting the Registration Committee in verifying claims made by the Applicants, by studying the data submitted by the Applicants under various heads such as chemistry, toxicology, bio-efficacy, packaging, etc. along with their applications made for registration of insecticides under the Act and the Insecticides Rules, 1971 (the "**Rules**");

AND WHEREAS the CSIR-IITR has represented that they have requisite skill, expertise and experience required to assist in evaluation of the data in the field of Toxicology, submitted by Applicants along with their application for registration of insecticides. A copy of the Profile/ Curriculum Vitae of the Experts Toxicologists involved by the CSIR-IITR as subject-matter experts is annexed hereto as Annexure-I;

AND WHEREAS the First Party, relying on the CSIR-IITR representations made in their profile/ curriculum vitae and supporting documents as regards its qualifications, wherewithal, infrastructure, accreditations, certifications etc. and other documents submitted by CSIR-IITR through its Director, decided to empanel the CSIR-IITR for the purpose of assisting the Registration Committee in evaluating the toxicological data /information submitted by Applicants seeking registration of insecticides, in the manner and on the terms appearing hereinafter;

Therefore, the parties hereinafter agree as follows:

1. <u>EMPANELMENT:</u>

The Empanelment of the CSIR-IITR will be for a period of **three years**, unless terminated earlier in accordance with this Agreement.

2. <u>SCOPE OF WORK:</u>

RC has agreed upon to seek services of the experts of CSIR-IITR to get scrutinized toxicity folders of the applications received under section 9(3) of the IA 1968. During the term of Empanelment, the RC would give Assignments (defined below) to the CSIR-IITR from time to time for the purposes of evaluating the safety of any Insecticide covered under the schedule to the Act.

I. Assignment:

- a. The Registration Committee would request the CSIR-IITR to conduct evaluation of relevant data submitted to the Registration Committee by an Applicant in the field of Toxicology along with such Applicant's application for registration of insecticide under the provision of the section 9(3) of the act (Toxicity folder).
- b. CSIR-IITR will nominate a Nodal Expert (Toxicologist) duly approved by the Director, CSIR-IITR for access of Applicant's folder (Offline/ Online) handed over by the CIB&RC. Access of online folder can be done by using CROP PORTAL for which USER ID and PASSWORD shall be shared to the Nodal Expert for evaluation of the data/ information submitted by the Applicants.
- c. The CSIR-IITR shall make such evaluation with regard to the safety of the product, and with highest degree of professionalism, and the risk assessment strictly is to be undertaken based on the data submitted by the Applicant as per the applicable extant guidelines and data requirements approved by the Registration Committee from time to time (available on the website of CIB&RC, i.e., ppqs.gov.in) and the information available in the public domain.
- d. Any addition or deletion of the scope of work will be decided by mutual agreement of the parties.
- e. In case of legal dispute, CSIR-IITR will provide all the technical support to the officers appointed by Central Government Counsels of the first party to settle the issues.
- II. Evaluation Report: CSIR-IITR shall submit its reports on the evaluation of

data strictly in the format(s) that are approved and provided by the Registration Committee to the Institute from time to time and containing all heads of information stipulated in such approved format as per approved guidelines. The Institute may also provide any additional specific observations/ comments that help in the evaluation of the safety of the product. The outcome of scrutiny along with comments or requirement for any clarification/ additional data/ information for performing risk assessment is to be recorded in detail for communicating to the applicant for presentation of results of scrutiny and risk-assessment to the RC. Any clarification/ additional data or information received from the applicant based on the requirement communicated to them should also be scrutinized and comprehensive safety analysis is to be presented to the RC. It will be a responsibility of the Nodal Expert to present the facts in the form of a self-contained Agenda as well as to remain available through VC/ in person for clarification, if any sought by the RC during its meeting.

III. Timeline:

- a. The CSIR-IITR shall submit its evaluation report through the Nodal Expert strictly within a period of three months from the date of acceptance of the documents by CSIR-IITR.
- b. In case of any queries or deficiencies or requests for information by the CSIR-IITR to the Applicant, the period commencing from the date on which such queries or deficiencies or requests are raised and ending on the date of response to the same by the Applicant, shall be excluded from the timeline within which the evaluation report has to be furnished by the CSIR-IITR.
- c. Communication with Applicant during evaluation: Any communication between the Expert of the CSIR-IITR with the Applicant shall only be:
- i. need-based through CROP PORTAL;
- ii. with the knowledge of the First Party; and

iii. duly recorded in Minutes signed by all attendees where the communication is done during a meeting/ concall/ virtual meeting.

3. <u>CONFIDENTIALITY</u>:

(i) CSIR-IITR will keep all INFORMATION that may be shared by CIB&RC or generated from the work undertaken as a consequence of this agreement confidential and will not be divulged to any person without prior permission of CIB&RC.

(ii) CSIR-IITR shall not use the INFORMATION for any purpose other than the required work.

(iii) CSIR-IITR shall not file any application for seeking intellectual property rights in its own name or in the name of its associates or any other person on any matter relating to the information generated regarding work for CIB&RC.

4. <u>PAYMENT</u>:

Payment(s) shall be made to CSIR-IITR by as per GFR-2017 in INR, including taxes of any kind, as follows: Payment of 40% of the contract value shall be paid to CSIR-IITR in advance as per rule 172 (1)(ii)(b) of GFR-2017.
 Fee: Rs 5 Lakh per application/- (plus GST as per the rules of Government of India, at present it is @ 18%) either directly by the Applicant or by Accounts

Officer, DPPQS, Faridabad through e-payment (NEFT/RTGS). Modalities of the payment to be mutually agreed to the CSIR & DPPQS.

b. The final amount will be paid to CSIR-IITR after the evaluation report is duly submitted in the format containing all requisite heads of information, and subject to compliance of all terms and conditions of this Agreement by the CSIR-IITR, and further which shall be done within 45 days of the submission of the evaluation report.

5. Data Access:

- (i) Save as expressly provided for in this Agreement, CSIR-IITR shall only access the data to be evaluated, remotely, via a secure web portal to be set up by the CSIR-IITR, and shall not in any manner save or store this data on any device. CSIR-IITR shall not save, copy, print, modify, distribute, transmit, display, reproduce, publish, or otherwise use any data for any other purpose other than for performance of duties under this Agreement.
- (ii) The CSIR-IITR may save or print any data if specifically permitted to do so in writing by the First Party with the prior written consent of the RC by giving reason and shall ensure that confidentiality is strictly maintained in respect of such data.
- (iii) CSIR-IITR shall at all times, at its own expense, maintain high speed Internet communication capability.
- (iv) CSIR-IITR shall install all data security, encryption and other related softwares and take all security measures that are required to ensure confidentiality of data.

6. **PROFESSIONAL CONDUCT AND CONFLICT OF INTEREST:**

- (i) CSIR-IITR acknowledges and agrees that:
 - a. the highest level of integrity on part of the Institution and its personnel;
 - b. the Institution and its personnel shall work with the highest degree of professionalism, independence and impartiality, and shall not allow any external or internal factors at the Institution to interfere or influence their work under this Agreement in any manner; and
 - c. strictly ensure at all times that the Institution and its personnel have no conflict of interest, whether personal or professional or otherwise (e.g. If

the Institution or its personnel: (a) is related to a promoter or senior managerial personnel of an Applicant or group concern; or (b) is retained as an advisor to the Applicant company or its group concern; or (c) has worked for or advised the Applicant or its group concern on the specific insecticide) which in their reasonable opinion is likely to influence or adversely affect the independent, impartial, unbiased performance of their duties under this Agreement.

- (ii) Whenever an Assignment is given to the CSIR-IITR for evaluation, the Institution shall first ascertain and give a declaration to the effect that the Institution and its concerned personnel have no conflict of interest in taking up the Assignment.
- (iii) If the Institution is unsure of whether or not a particular circumstance would lead to conflict of interest, the CSIR-IITR shall immediately inform the First Party of such circumstance. The opinion of the First Party as to whether or not there is a conflict of interest, as communicated in writing to the Institution, shall be final.
- (iv) If at any time after being given an Assignment, the Institution finds that there are any conflict of interest concerns, the CSIR-IITR shall forthwith cease work on the Assignment, refrain from accessing the data and inform the First Party in writing as regards the conflict of interest concern. The opinion of the First Party as to whether or not there is a conflict of interest, as communicated in writing to the CSIR-IITR, shall be final.

7. <u>Representations of the CSIR-IITR:</u>

CSIR-IITR hereby represents as under:

- CSIR-IITR is duly organized and validly existing under the laws of India, and has full power and authority to execute and perform its obligations under this Agreement and to carry out the transactions contemplated hereby;
- (ii) CSIR-IITR has taken all necessary corporate and other actions under Applicable Laws to authorize the execution and delivery of this Agreement and to validly exercise its rights and perform its obligations under this Agreement;
- (iii) This Agreement has been duly executed by the CSIR-IITR and constitutes their legal, valid and binding obligation, enforceable against them in accordance with the terms hereof, and the Institution's obligations under this Agreement shall be legally valid, binding and enforceable obligations against it in accordance with the terms hereof;
- (iv) The execution, delivery and performance of this Agreement shall not conflict with, result in the breach of, constitute a default under, the terms of its Memorandum and Articles of Association or any Applicable Laws or any covenant, contract, agreement, arrangement,

understanding, decree or order to which it is a party or by which it or any of its properties or assets is bound or affected;

(v) CSIR-IITR and its personnel have the requisite skill and experience to evaluate the data relating to Toxicity evaluation of the Scheduled Insecticide usually submitted by applicants along with their applications for registration of insecticides under the Act and Rules, and to perform all of its obligations under this Agreement.

8. FORCE MAJEURE:

Neither party shall be held responsible for the indemnification of their respective obligations under this MoA due to the exigency of one or more of the force majeure events such as but not limited to acts of God, War, Flood, Earthquakes, Strikes, Lockouts beyond the control of the party claiming force majeure, Epidemics, Pandemics, Riots, Civil Commotions etc., provided on the occurrence and cessation of any such event the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continue beyond six months, the parties shall jointly decide about the future course of action.

9. DISPUTE RESOLUTION, GOVERNING LAW AND JURISDICTION:

Any disputes arising out of or in connection with this agreement shall be referred to Delhi International Arbitration Centre (DIAC), Delhi High Court, New Delhi.

10. <u>WAIVER.</u>

No provision of this MoA will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by both Parties. No waiver by either party of any breach of, or of compliance with, any condition or provision of this MoA by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

Authorized Signatory

Authorized Signatory

Party 1:

Party 2:

Secretary, Central Insecticides Board and Registration Committee (CIB&RC)					•
(On behalf of the RC)					Vishvigyan Bhawan,
Directorate	of	Plant	Protection		31, Mahatma Gandhi Marg,
Quarantine	&	Storage,	Old	CGO	Lucknow, Uttar Pradesh 226001

DRAFT

Complex, NH-IV, Faridabad-121001, Haryana

Witness:

1. 1.

2.

2.