

**MINUTES OF THE OPEN HOUSE WITH THE ASSOCIATIONS OF PESTICIDE INDUSTRY
ON 29TH OCTOBER, 2013 AT 11:00 HRS IN THE CONFERENCE HALL,
CENTRAL INSECTICIDES LABORATORY, FARIDABAD**

An Open House with the Associations of Pesticide Industry was organized on October 29, 2013 at 11.00 hours in the Conference Hall of Central Insecticides Laboratory, Faridabad under the Chairmanship of Dr. Gurbachan Singh, Chairman, ASRB & Registration Committee. The list of participants is **annexed**.

At the outset, the Chairman welcomed the participants, representing various Associations of Pesticide Industry, members and experts of the Registration Committee besides officers of the Central Insecticides Laboratory. He lauded the role of the members of pesticides industry and appreciated their keen interest in resolving day-to-day problems with respect to registration of pesticides and allied issues through mutual discussion. He reiterated his commitment to scientific approach in resolving scientific issues, while categorically clarifying that legal aspects were equally important as the law of the land needs to be upheld under all circumstances. He cautioned the members of this Industry about unnecessary complaints, undue in-fighting and unhealthy competition. He emphasized that long term gains weighed far more than myopic benefits. Frequent court cases, appeals, representations and complaints eat away the productive time of technical experts as the cases are of techno-legal cases and the same cannot be handled without the inputs from technical experts. All this has to be done at the cost of scrutiny of the applications of the pesticide industry for registration. He recalled that the common factor for all those present in the system is the Indian farmer who should gain while the Industry carries out its business smoothly. It was followed by a formal introduction of the participants.

The APPA & Secretary (CIB&RC) presented the current scenario of the status of functioning of the Sectt. of CIB & RC. He gave statistics on the number of applications received and certificates of registration issued under various categories during last two years in comparison to previous years without much change in the basic infrastructure. His declaration that export applications are now being dealt on RC-to-RC basis was welcomed with a roar of clapping. He informed that he expected further improvement in view of the fact that now four experts are available in the Medical Toxicological Division. He requested the associations to raise issues of common interest pin-pointedly for detailed deliberations by the house and the issue once raised and deliberated may not be repeatedly raised.

The representatives of Associations of Pesticide Industry unequivocally acknowledged and expressed satisfaction that several issues, raised during previous Open Houses have been resolved by the Registration Committee. They also expressed happiness over the fact that the Committee has been keeping its word of holding the open house every six monthly. The Associations said that there is substantial improvement has since been seen in the functioning of the Sectt. of CIB & RC and that the Certificates of Registration are now being issued expeditiously. Specific issues, raised by the associations, and the decision thereon after detailed deliberation are brought out hereunder:-

S. No.	ISSUES RAISED BY THE ASSOCIATIONS	DECISION OF THE OPEN HOUSE
I. CHEMICAL PESTICIDES		
1	Harmonization of Toxicology studies Protocols with OECD	The job is complete except for exposure of spray operators calculations by using mathematical modules, which will also be completed shortly.
2.	Additional Manufacturing Site(s) of Pesticides in Countries other than the Original Registered Source	RC has already taken a decision on this issue and framed guidelines. A few registrants have obtained endorsements in this regard following the same guidelines. In case, an applicant wants to register more than one manufacturing site at the time of application, itself, he has to undergo the rigours of the same guidelines as in case of endorsement of additional manufacturing site. However, some members feel that this should be done only after one site is registered under section 9(3).
3.	Curbing of illegal imports	The House expressed its serious concerns about illegal imports and emphasized the need to curb it. It accepted the proposal of the industry with modification and decided that a copy of valid registration and manufacturing license of the product be made mandatory alongwith every consignment to ensure that the product is coming from the approved source.
4.	Bio-pesticides laced with chemical pesticides(registered or un-registered)	The Chairman, RC will send a letter to all the APCs/Directors of Agriculture in this regard. Industry on its part would also facilitate exposing illegal trade in bio-pesticides/bio-products, laced with registered or non-registered pesticides.

5.	Data requirement for TIM vs TI u/s 9(3) – Anomaly/Discrepancy in Past and Present Guidelines	It was once again made clear to the industry that whenever a comparison is drawn, establishment of chemical equivalence was necessary. The guidelines under TIM vs TI or TI vs TIM are intermediary guidelines, which are meant to facilitate registration of imported or manufactured products to be registered for manufacture or import, respectively. This way, same chemical composition percolates down the line upto 9(4) category. In case, different chemical composition is claimed, independent guidelines for registration under 9(3) TI or 9(3) TIM are available.
6	Guidelines for registration of combination formulations containing more than two a.i.	It was clarified that if individual active ingredients were non-mutagenic, their combination is also likely to be non-mutagenic. It was decided that cases for such combination formulations mutagenicity data may not be asked at the time of registration.
7.	Sub-acute toxicity in dogs.	It was decided to accept international data in such a case.
8.	Metabolism in livestock	It was decided that data on this requirement may be got generated abroad, if facilities did not exist in India. However, this requirement cannot be exempted. Efforts may be made by some reputed institutions to develop such facilities in India too.
9.	Non availability of on line application facilities for some of the old molecules	The House was informed that necessary measures are being taken for updating informations.
10.	Delay in scrutiny of 9(4) FIM, TI and FIT categories	The House was informed that necessary measures are being taken to expedite the scrutiny of the cases under these categories and about 700 – 800 CRs are being approved by RC in its each meeting. However, due to large number of inflow of applications, this problem is persisting. Industry Associations were requested to reduce submission of application.

11.	Crop grouping approach of MRL setting	It was clarified that a Committee was constituted by DAC under the Chairmanship of Dr. T.P. Rajendran, ADG (PP), ICAR specifically with respect to fixing MRLs. Implementation of its recommendations has also to be specified. More discussion is needed on this aspect.
12.	Verification of source	It was decided that the existing policy of the RC shall be maintained. CropLife India pointed out that in case of EU countries, individual country may not have registration, which may find difficulty in verification. It was decided that in case of specific problem, it shall be looked into on case-to-case basis.
13.	Issuance of deficiency letters by e-mail	Efforts are being made to implement the decision. However, an appeal was again made that all the applicants may submit their e-mail addresses along with applications for effective implementation.
14.	Analysis of in-process samples for Pre-registration Verification	It was clarified that there is no delay in analysis of in-process samples.
15.	Guidelines on import of samples for Research, Test & Trial purposes	Import permits for Research, Test & Trial shall continue to be issued as in vogue.
16.	Accelerated storage stability test	The existing decision of the RC shall remain in force.
17.	Invoice from manufacturers	The existing decision of the RC has been taken after considering all the factors. Therefore, it shall continue to be in force. In case there is a specific problem for a specific molecule globally, the same shall be brought to the notice of the RC for taking an appropriate decision.
18.	Registration for export	A committee, constituted for the purpose, is seized of the problems on the issue. Its report may be awaited.

19.	Issue of duplicate certificate	The House reiterated RC's decision that no person shall hold two certificates of registration for the same product under the same category and submission of affidavit with every application shall remain in force.
20.	Unique code Number for 9(4) registration	It was informed that introduction of assigning unique code no. for each applicant may not be possible with the existing software system. NISG is looking into the matter. As & when new software is developed, this will be taken care of. Till that time, existing system shall continue.
II BIO-PESTICIDES		
1	Request for fourth extension of validity period of the registration under section 9(3 B)	It was emphasized that there was enough time available from the time of application under Section 9 (3B) to the completion of 3 rd extension to generate complete data for making application under Section 9 (3). However, there seems to lack of will to do so. Therefore, the House did not agree to the request of the association and reiterated the existing decision of the RC in this regard.
2.	Request for fixation of date for organizing workshop on Bio-pesticides.	The House noted that the association(s) failed to rise to the occasion and did not organize the workshop, which was in their own interest. The House decided that the workshop may be organized on priority by the association of biopesticide manufacturers.
3	Mention of 'Biopesticide' in the Certificate of Registration	It was decided to write 'biopesticide' in bracket after name of product (biopesticide) in CR.
4	Once one strain of a biopesticide is registered, then subsequent applications be scrutinized on priority.	Affidavit signed by all the Association of biopesticides to this effect be submitted stating that they have no objection if it is implemented on the cost of other strains.

5	Guidelines for registration of combination of two registered bio-pesticides	The House did not agree on the issue, such combinations are also not registered globally.
6	<p>(a) Resubmission of failed samples of bio-pesticides to CIL for reanalysis</p> <p>(b) Reconsideration of moisture content, pH range and delta-endotoxin as test parameters from the guidelines</p> <p>(c) Relevance of percentage in biopesticides alongwith formulation one CFU is mentioned.</p> <p>(d) Minimum infrastructure facilities.</p>	<p>The House noted that associations had varied views on the issues related to moisture, pH, delta endotoxin contents (Bti and Btk products), etc. in bio-pesticides. Therefore, these should be looked into by an Expert Committee. Accordingly, an Expert Committee has been constituted to look into these issues under the chairmanship of Dr. Mukhopadhyaya, VC, AAU, Jorhat the other members being:-</p> <ol style="list-style-type: none"> 1. Dr.Anupam Verma -Member 2. Dr.Dhinga – Member Biopesticide Assoc. 3. Dr.Gautam Chatterjee, JD(PP), CIL,FBD - Member 4. Sh.D.Bhattacharya, DD(Chem) CIB&RC - Member 5. Dr. V. K. Singh, AD (Ento.), CIB & RC – Member-Secy. <p>The Committee will look after the all issues of bio-pesticides formulation, referred at point No. (a) to (d).</p>

The meeting ended with a vote of thanks to the Chair.

ATTENDENCE LIST OF THE MEETING OF OPEN HOUSE HELD ON 29.10.2013 AT 1100 HRS AT CIL, FARIDABAD.

S.No.	Name and Designation	Address of Office
1.	Dr. Gurbachan Singh, Chairman ASRB & RC	ASRB, Pusa, New Delhi.
2.	Dr. B.S. Phogat, APPA&Secretary (CIB&RC)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
3.	Dr. (Ms.) Shalini Chawla, Prof. MAMC (MOH & FW)	Maulana Azad Medical College, New Delhi.
4.	DR. Sarita Bhalla, Sp. Gr. I, CIB&RC	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
5.	Dr. Sushil K. Khurana, Consultant (Path)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
6.	Dr. S. Kulshrestha, Consultant (Pharma)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
7.	Mr. Vipin Bhatnagar, JD (Chem.)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
8.	Mr. R.V Singh, JD (Chem)	CIL, Chem division Dte. of PPQ&S, Faridabad
9.	Dr. Vandana Seth, Dy Director (Chemistry)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
10.	Mr. R. Murali, DD (PP)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
11.	Mr. A. N. Singh, DD(WS)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
12.	Mr. S.K Verma, DD (PP)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
13.	Mr. D. Bhattacharya, DD (Chem.)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
14.	Mr. Hariom Miglani, Sr. Law Officer	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
15.	Mr. D.K Mittal, A.D Chem	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
16.	Mr. K.V Singh, A.D Chem	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
17.	Dr. V.K Singh, AD (Ento)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
18.	Mr. Subhash Chaudhary, AD (Chem.)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
19.	Dr. P.S Maui	CIL, Dte. of PPQ&S, NH-IV, Faridabad
20.	Mr. Sher Singh, Section Officer	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
21.	Md. Mahfooz Alam, PA to Secretary (CIB&RC)	Sectt. of CIB&RC, Dte. of PPQ&S, NH-IV, Faridabad
22.	Dr. T. Basu, Dy. Mgr. (Product Dir.)	Hindustan Insecticides Ltd., Core-6, Scope Complex-7, Lodhi Road, N.D
23.	Mr. Raju Shroff, CCFI	CCFI, Delhi
24.	Mr. Nirmala Pathnawal	Head CCFI, Delhi
25.	Dr. JC Majumdar	Sr. Advisor, CCFI
26.	Mr. S.S Manhans	Syngenta India Ltd.
27.	Mr. R.G Aggarwal, Dhanuka Agritech	Bldg. No. 5, DLF Phase-III, GGN
28.	Dr. Shiv Mani Pathak Registration Manager- South Asia	Chemtura Chemicals India Ltd.

29.	Dr. Shekhar Varshney	Crop Life India
30.	Mr. Amrban Yangopadhyaya	E.I Dupont Pvt. Ltd.
31.	Mr. Manoj Lingani	Crop Life India
32.	Dr. Abraham Mathew	E.I Dupont India Pvt. Ltd. Ref. Crop Life India
33.	Dr. JC Majumdar	Sr. Advisor CCFI
34.	Mr. Raj Kumar Singh	PMFAI
35.	Mr. Samir Davl	PMFAI
36.	Mr. Ketan Mehta	PMFAI
37.	Mr. N.N Mishra	MGR Ind. Association, Delhi
38.	Mr. Kusta Vaingankar	FMC India/CCI
39.	Mr. K.Sumeswara	HPM Chemicals& Fertilizers, Delhi
40.	Mr. Rajiv Kumar	ABMA, HYD
41.	Mr. Sushil Misra	Crystal Crop Protection Pvt. Ltd.
42.	Dr. Rajeev Goel	Crystal Crop Protection Pvt. LTd.
43.	Dr. V.K Dhingra	ABMA
44.	Mr. Anand V Kulkarni	Nagarjuna Agrichem Ltd. HYD
45.	Dr. S.S Bhatnagar	Bio Input Manufacturer Association, HYD
46.	Mr. S. M Ahsan	P.I Ind. Ltd. GGN
47.	Mr. Ramdas J Patil President MBMA NASHIK	R.B Herbal Agro, Nashik
48.	Mr. B.S Thakur MBMA, NASHIK	Ruchi Group, Gondia
49.	Mr. Yogesh Kumar Sr. G.M (Regulatory Affairs)	Cheminova India Ltd., BLR
50.	Mr. Vijay Jha, Rallis India Ltd. (Manager Registration)	Rallis India Delhi
51.	Mr. Anand Jha UPL	UPL, Delhi
52.	Dr. Arvind Patel Dhanuka Agritech Ltd.	Dhanuka Agritech Ltd., N.D
53.	Dr. S.N Rai	Dhanuka Agritech Ltd., New Delhi
54.	Dr. R.K Singh Manager (Regulatory Affairs)	Meghmani Organics Ltd., AMD
55.	Mr. Rajat Srivastava AGM-Regulatory Affairs	Willwood Chemical Ltd., N.D
56.	Mr. Anil Kumar	Willwood Chemical Ltd., N.D

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