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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

केंद्रीय कीटनाशी बोर्ड एवम पंजीकरण समिति

Secretariat of Central Insecticides Board and Registration Committee

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Date: April 21st, 2017

PUBLIC NOTICE

Sub: Recommendations of various Commitees constituted by RC-reg

As you all are well aware that Registration Committee constituted u/s 5 to the Insecticides Act, 1968 is empowered to constitute Comittees on the technical matters for transecting its business smooth and transparently. Accordingly an Expert-Committee was constituted by RC in its 356th meeting under the chairmanship of Dr. K.K. Sharma, Project Coordinator & Co-opted Member RC on *"Chemical equivalence & five batch analysis for 9(3)TI and TIM & 9(4) TIM category"* and *"Policy/guidelines on the shelf-life period of formulation prepared from the technical material near the date of expiry of the shelf life"*.

The recommendations of the Expert-Committee was approved by the RC in its 360th meeting vide agenda item No. 3.2. The report of the committee is attached as Annexure-I.

Thanking you

Yoursfaithfully

(D.D.K. Sharma)
APPA & Secretary (CIB&RC)

Minutes of meeting of "Expert Committee" constituted by RC in its 356th meeting on "Establishing of Chemical Equivalence under section 9(3) TI/TIM and 9(4) TIM" and "Policy/guidelines on the shelf life of formulation prepared from technical grade material near the date of expiry of shelf life"-reg

The Registration Committee in its 356th meeting constituted an "Expert Committee" under the chairmanship of Dr. K.K. Sharma, Project Coordinator on the above matter. The committee meets twice to arrive at the recommendations. The first meeting of the "Expert Committee" (EC) was held under the Chairmanship of Dr. K.K. Sharma, Project Coordinator, MPRNL on 04.09.2015 at 14.30 hrs in the R. No. 203, LBS Building, IARI, Pusa, New Delhi. The list of participants is annexed as -**Annexure –A.**

At the outset the Hon'ble Chairman of the Committee welcomed all the participants. Hon'ble Chairman requested all the participants to give brief self introduction to make the discussion in a fortiori manner to help the committee in arriving at a consensus decision. The Chairman asked the Member Secretary to present the agenda and terms of reference to the committee. The Member Secretary presented the TOR of the committee which is as under:

1. **Establishing of Chemical Equivalence under section 9(3) TI/TIM and 9(4) TIM.**

2. **Policy/guidelines on the shelf life of formulation prepared from technical grade material near the date of expiry of shelf life.**

It was stressed by the Hon'ble Chairman that first of all, we shall share the information and universal/global requirement\guidelines on the subject in Indian scenario and prepare thoroughly before arriving at any conclusion. The members took active part in the discussion. All the members presented their views on the subject one by one. Representatives of Crop Life India elaborated the worldwide scenario and European Union status on the five batch analysis for establishing the Chemical equivalence of Technical grade pesticides. They elaborated in detail about the procedure adopted in the European Union on the baseline of FAO/WHO guidelines. It was also elaborated that for implementation of five batch analysis certain basic infrastructure is also mandatorily required. It was also discussed that the FAO/WHO five batch guidelines on establishment of chemical equivalence cannot be implemented in piece meal.

All the guidelines have to be implemented without any consideration of TI or TIM category or without any impartiality/favor. The members pointed out that the PRV sample of Technical Import is not drawn, hence the import source is also not verified physically, which sometimes may leads to the registration of false source of import and ultimately leads to illegal import in to India. The members of PMFAI discussed that there should not be any reference to the FAO/WHO guidelines for taking any inspiration or what so ever may be, as we are having very robust system for registering the pesticides in India, in comparison to other countries of the world. They further elaborated that at present our registration system and its guidelines are in consonance with science/latest technology with minimum interference from the Govt. and is not observed ever. They further stressed that there is no need for shifting to the five batch analysis for establishing the chemical equivalence as the

same is being been done since last about twenty years by drawl of in-process sample from the laboratory/manufacturing site and PRV analysis at Central Insecticides Laboratory established under the Insecticides Act, 1968.

Representatives of CCFI shred the light on the current scenario of pesticides registration in most developing/Asian countries and argued that the conditions and infrastructure is totally different in our country from the developed countries. They informed that the science and present condition of the country does not demand departure from the current guidelines in force. They informed that effective implementation of current guidelines of registration of pesticides is the best in the world and simultaneously encourage domestic manufacturer which is also a mandate of our statute in the form of 9(4) to address the make in India concept. These guidelines are the catalyst for achieving the target of high quality of pesticides and gaining of foreign currency under export category. As on date India is among top five countries of the world in export of pesticides. Dr. A.K. Dixit emphasized on the need of the hour i.e. promote the "Make in India" program and registration of pesticides under TIM category and bring the newer and safer molecules in to India to increase the production of crops, while providing the good quality of the pesticides at cheaper rates to the farmers.

Dr. Patanjali explained the global scenario on the shelf life of the formulated pesticides product prepared from the technical grade pesticides near its expiry. All other expert also provided their valuable comments/information on the subject. Thereafter due to paucity of time unanimously it was decided that another meeting shall be required to arrive at a conclusive recommendations, the Chairman happily agreed. Therefore it was decided to convene 02nd meeting of the "Expert Committee" on 01st October 2015 at 11.30 hrs at the same venue.

The 02nd meeting of the committee was convened as per Schedule at the same venue under the Chairmanship of Dr. K.K. Sharma, Project Coordinator, MPRNL. List of the participants is annexed as-Annexure-B.

The Hon'ble Chairman gave a warm welcome to the participants and requested all the participants to give their self brief introduction. After that, the Chairman asked the Member Secretary to brief the committee about the outcome of the last meeting and refresh the points discussed in the last meeting. The Member Secretary informed the members about the formal discussion and information shared by the members with the committee in the earlier meeting on both the points. The Hon'ble Chairman asked the Member Secretary to take up the agenda point wise as per TOR of the committee. The discussion took place in a very conducive and vibrant atmosphere. The following decisions were taken:

Agenda Item No.1:	**"Chemical equivalence and five batch analysis for 9(3) TI and TIM & 9(4) TIM category"**

It was discussed during the meeting that FAO/WHO guidelines are not binding/mandatory to any country. These guidelines are the base frame work which may or

may not be adopted or improved by the countries. It was also pointed out by the participants that the guidelines of WHO/FAO have already been opposed by the generic manufacture as these guidelines will create monopoly rather than technology open to all. Plea of generic manufacturer in Europe has been under consideration in the European Commission. The representatives of CCFI again stressed that the present guidelines are the best one in the world and new guidelines will create confusion and hindrance to growth of the Indian pesticides industry and generic manufacturer will suffer badly.

Representative of PMFAI again mentioned that there is no need of any change in the present guidelines of pesticides registration and five batch analysis. He stated that the present guidelines ensures the establishment of Chemical Equivalence in more scientific way and at the same time ensures the technical competency, qualified man power and basic infrastructure of the applicant. At present the applicant provide one batch analysis at the time of application after enough R&D in the own laboratory and then In-process sample is drawn by the team of Expert from the Directorate, doing so, two batch analysis is already in the guidelines.

Representative of Crop Life India again stressed upon the need of implementation of five batch analysis for establishing the chemical equivalence in the pesticides. Dr. A.k. Dixit stated that as per the information available in the public domain it seems that our registration system for Establishing of Chemical Equivalence is robust and transparent provides ample opportunity to generic manufacturer as well as original inventor of the molecule.

Dr. Patanjali was also of the view that present guidelines on establishing of chemical equivalence does not need any change and five batch analysis guidelines of FAO/WHO will create monopoly. Dr. Irani Mukerjee asked about the relevance of new impurities if any found and its relevance in the chemical composition, which was clarified by the Hon'ble Chairman. Dr. S. Bhalla, spl-Gr-I stressed upon the requirement and importance of AMES test and emphasized that in case the five batch analysis is not taken in order to establish safety of the product because of the presence of impurities in addition to acute test-AMES test as recommended by WHO/FAO guidelines should also be asked for. however the members objected stating that if other studies like Medical data, Acute dermal, Primary skin irritation, Irritation to mucous membrane, Acute oral in rat & mice are being provided by the applicant, hence no AIMES studies is required.

Recommendation:

(I). Therefore after detailed deliberations on the issues it was decided that the present guidelines of establishing of chemical equivalence under section 9(3) TI/TIM & 9(4) TIM are very pragmatic, transparence, simple yet robust and are in the agreement of evolution, hence do not need any change, these guidelines works as a balance of cloth between generic manufacturer and inventor. It was further decided that the data generation may be taken up from the institution/laboratory accredited by the NABL/GLP.

(II). Physical Pre Registration Verification of the source of import has also to be under taken mandatorily as they are already manufacturing the pesticides or registered for manufacturing and it is strongly recommended that the verification of manufacturing site and pre-registration verification (PRV) of applicant under section 9(3) TI and FI categories may be

made mandatory, which shall help in curbing the illegal import.

Agenda Item No.2:	"Policy/guidelines on the shelf life of formulation prepared from technical grade material near the date of expiry of shelf life"

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the participants expressed their views and shared the knowledge with the committee on the topic. Dr. A.K. Dixit explained that how long a pesticide remains effective depends on the pesticide formulation, length of storage and conditions during storage. The biological efficacy of pesticides gradually decreases with time. The pesticide shelf-life is the period of time that a pesticide can be stored before it deteriorates. Nearly all pesticides have a limited shelf-life. As part of modern pesticide formulation technology, packing methods and storage practice aim to prolong shelf-life as much as possible. Representative of CCFI informed that manufacturers indicate the shelf-life of the pesticide on the container, but many pesticides may still be usable long after the indicated shelf-life has expired. Most pesticides have an indicated shelf-life of at least two years from the time of manufacture, but shelf-life will be shortened if pesticides are not stored properly (e.g. if they are stored at high temperatures). Stock turnover organization needs to take into account the time that pesticides may have been in transit between manufacture and reaching the store. Pesticides in sealed containers may change over the time after expiry of shelf-life in two main ways:

- The active ingredient may change chemically and break down into products that may no longer have pesticidal properties, thus decreasing the concentration of the original active ingredient.
- The formulation of the pesticide may break down and a precipitate of flakes, crystals or sludges may form, making it impossible to mix or use in sprayers.

An organochlorine such as endosulfan, carbandazim, COC, Mancozeb etc is chemically very stable, but some formulations may break down more rapidly. Organophosphates like Diamethoate, Malathion, Monocrophos, Phorate etc is less stable and therefore generally have a shorter shelf-life. Dust and wettable powder formulations tend to break down and cake together, as a result of high temperature, high humidity, strong sunlight or compaction under pressure, more than liquids in sealed containers.

The Hon'ble Chairman Dr. K.K. Sharma, Project Coordinator stated that Pesticides vary in their stability and response to storage conditions, he further stressed upon the legality of matter and clarified that the legality is the backbone of Science. Representatives of PMFAI informed that under proper storage conditions most pesticides can be used even after expiry of storage as the data generated is about six months more than the S/L granted. Pesticides in general are manufactured, formulated and packaged to specific standards. However, when stored improperly, they can break down in storage, especially under conditions of high temperature and humidity. Some pesticides can lose their activity through chemical decomposition or volatilization. Dry formulations such as wettable powders (WP) or granular (G) can become caked and compacted; emulsifiable concentrates (EC) can lose their ability to form emulsions. Some pesticides can actually become more toxic, flammable, or explosive as they break down. Dr. Irani Mukherjee added that Pesticide containers (including fiber and metal drums, pails, cans, bottles, bags, boxes, overpacks and liners)

have an important effect on storage and shelf life. If stored for long periods, these containers may eventually corrode, crack, break, tear, or fail to seal properly. Also the label may become illegible.

Dr. P.K. Patanjali, scientist (H) IPFT, Gurgaon informed the committee that as such there is no data on the topic to say something concurrently. Some pesticides are stable and some not. He stressed upon the need of a mechanism to prove topic either of the way. He further stated that as on date as per Insecticides Act, 1968, if any manufacture formulate a formulation of the pesticides from a technical grade pesticides just minute before its expiry, which shall be called legal.

Recommendation:

(I) Unanimously it was decided that a proper study has to be undertaken/conducted on different Technicals from the zero day of manufacturing technical which is subsequently converted in to the formulation and then 03 months, 06 months, 09 months, 12 months, 15 months, 18 months, 21 months, one day before of 24 months and formulation study of thirty months on each formulation on the basis of different class of pesticides as under:

A. Stable compound/pesticides like organochlorine etc.

B. Un-stable compounds/pesticides like Organophosphates etc.

(II) Till (I) is complete the formulators be advised to get the technical tested mandatorily before making it into formulation & should keep complete record for verification by the regulators.

The meeting ended with the vote of thanks to the chair.

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Annexure-I

List of participants in the meeting held on 04.09.2015 at 14.30 hrs in the R. No. 203, LBS Building, IARI, Pusa, New Delhi

1. Dr. K.K. Sharma, Project Coordinator & Co-opted member RC, - Chairman
2. Dr. A.K. Dixit, Professor & Head (Retired), Agricultural Chemical Division, IARI, New Delhi - Member
3. Dr. P. K. Patanjali, Scientist (H), IPFT, Gurgaon - Member
4. Dr. Sarita Bhalla, Spl-Grade-I, Sectt. of CIB&RC - Member
5. Shri Dipankar Bhattacharya, Deputy Director (Chem), Sectt. of CIB&RC - Member
6. Dr. Samir Dave, PMFAI - Member
7. Dr. K.N. Singh, PMFAI -

Representative

8. Dr. Yogesh Kumar, Crop Life India (CLI) -Member
9. Dr. Ajit Kumar, CCFI - Member
10. Sh. Vipin Saini, Executive Director, Crop Life India (CLI) - Member
11. Dr. Ananad Jha, CCFI -

Representative

12. Subhash Chand-Deputy Director (Chem), Sectt. of CIB&RC -Member Secretary