MINUTES OF 49TH MEETING OF THE AGRIULTURAL PESTICIDES TECHNICAL ADVISORY COMMITTEE (APTAC) HELD ON 16.04.2015

The 49th meeting of Agricultural Pesticides Technical Advisory Committee (APTAC) was held in the committee room of the Ministry of National Food Security & Research (MNFS&R) at Islamabad on 16.04.2015 under the Chairmanship of Secretary, MNFS&R (List of participants is attached at **Annexure - D**).

The Plant Protection Adviser & Director General informed the house that some companies tempered the registration / import permission certificate to clear the pesticides consignment from the custom authorities.

After detailed discussion the chairman decided that the companies / importers that are involved in tempering / forged registration certificate's submitted to the custom authorities for clearance will be black listed on completion of formalities.

Item wise discussion and decision are recorded below:

ITEM NO. 1 - CONSIDERATION FOR NEW REGISTRATION / LABEL EXPANSION

New insecticides / fungicides / herbicides and label expansions of already registered insecticides / fungicides / herbicides and locally manufactured pesticides in Pakistan in the attached list as **Annexure-A** were presented before the committee for consideration and discussion.

The representative of PCPA requested to consider all old applications submitted between 2008-2012 on the basis of decisions before the issuance of two SROs and accept the toxicological data already submitted by the applicants from the manufacturer at the time of application. PCPA emphasized that the registration authority in the country of origin already accepted the data from the Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA), China and the protocols for trial of some of the applications were issued much before the issuance of said SROs.

The Director General Agriculture (Ext. & AR), Punjab, Lahore stated that lot of test & trials of the pesticides already conducted by the provincial research institutes as per past practice i.e.,

on evidence of application submitted to the Federal Department of Plant Protection, Karachi but the Department has still not issued lab clearance of the pesticides and should be decided on merit.

Deputy Food Security Commissioner-I, MNFS&R commented that the Department may accept bio-efficacy data of the products as mentioned in the annexure-A and same apply to the pending cases.

The Chairman commented that the products that have lost their efficacy should be re-addressed and mechanism should be derived to withdraw the registration of such products.

After detailed discussion the committee decided that:

1) All products in attached list annexed-A on Form-1 against crop's pests/diseases/weeds may be accepted for toxicological study data as a one time relief and to clear the back lock subject to toxicological study data / other information of the products as pointed out in annex-A should be furnished by the applicant separately from the manufacturer, as submitted by him to the registration authority in the country of origin as per rules & regulations before SRO 1017(I)/2014.
2) This decision at Sr. # 1 will be only applicable on pending cases that are complete in all respect within 90 days after the issuance of APTA Sub-Committee minutes. The DPP would issue the field trial protocols for the products for which application requirements were completed within 90 days and the provincial governments shall consider their cases.
3) The applicant who failed to complete the applications within 90 days, their applications would be rejected and files will be closed.
4) For fresh applications the chairman formulated the committee under the chairmanship of Adviser & Director General, Department of Plant Protection comprising representative from associations, representative from Department of Plant Protection and representation from other related institutes to decide study data as per check list (Form-1) from GLP lab / accredited lab will be acceptable.

5) It should be made mandatory to write the standardized dosages as approved by federal/provincial government institutes of registered product on registration certificate against different crop's pests/weeds/diseases.

6) Maximum Residue Limit data and PHI period of the product should be provided by applicant for label expansion of registered products against crops from the Codex Alimentarius or conducted by the manufacturer.

7) The APTA Sub Committee shall consider Resistance Management of the product at risk. The provincial governments should recommend for those products that have lost their efficacy before APTAC and mechanism will be derived to withdraw the registration of such products.

8) Toxicological, Eco-toxicological, stability, MRL data will be considered from international accredited / GLP certified lab.

ITEM NO. 2 - <u>ENHANCEMENT OF FEE FOR REGISTRATION & RENEWAL OF FORMULATION & REFILLING / REPACKING PLANTS AND STREAM LINING THE SYSTEM OF FORM-18 & FORM-19</u>

The Adviser & Director General, Department of Plant Protection informed the house that registration / renewal fee of formulation and refilling / repackaging plants was Rs. 25000/-, Rs. 10000/- and Rs. 15000/- and Rs. 5000/- respectively and recommendation of the APTA Sub-Committee that:

1) Fresh registration of formulation plant fee should be Rs. 500,000/- and renewal fee to be Rs. 100,000/- for the period of 5 years.

2) Fresh registration of repackaging / refilling plant fee should be Rs. 250,000/ and renewal fee be Rs. 50,000/- for the period of 5 years.

3) Revised application Form-18 & 19 for registration of pesticide formulation plant and repackaging/refilling plant respectively at **Annexure-B** for approval of APTAC.

After detailed discussion, the recommendations were unanimously approved by APTAC.

ITEM NO. 3 - ENHANCEMENT OF FEE FOR DUPLICATE COPY OF REGISTRATION/IPC

After detailed discussion the committee recommended that for issuance of duplicate registration / import permission certificate fee should be Rs. 5000/- instead of prevailing fee of Rs. 20/- only.

After detailed discussion, the recommendations were unanimously approved by APTAC.

ITEM NO. 4 - STREAMLINING THE SYSTEM OF ALREADY REGISTERED PESTICIDES ON FORM-1 FROM THE MANUFACTURERS ABROAD AND TRANSFER STATUS OF THE PRODUCT AS LOCAL MANUFACTURERS

The Department of Plant Protection informed the house that the product already registered on Form-1 directly from the manufacturers abroad and had no registration of formulated product in the country of origin in favour of manufacturers and the registered importers have shown their desire to get status of local manufacturers of the formulated product and recommendation of the APTA Sub-Committee that:.

1) If product recipe and technical source is the same then the same should be given the status of local manufacturing of the formulated product without any toxicological study data from international accredited lab / GLP certified lab.

2) If product recipe is different, then toxicological study data of formulated product from international accredited lab / GLP certified lab should be mandatory.

After detailed discussion, the recommendations were unanimously approved by APTAC.

ITEM NO. 5 - STREAMLINING THE SYSTEM OF REGISTRATION OF GRANULES PESTICIDES, REGISTERED ON FORM-16

The Plant Protection Adviser & Director General submitted the recommendation of the sub committee that harmonized recipe of granules would be i.e, Monomehypo 5% G, Dimehypo 4% G, Cartap Hydrochlride 4% G, Carbofuran 3% G & Fipronil 0.4% G, the said product sample with harmonized recipe should be provided by the applicant to DPP for testing by PARC and PCSIR or any other accredited lab and after satisfactory analysis report, DPP would register the same formulation from registered applicant on the basis of registration of

technical grade material issued in favour of the manufacturer. After detailed discussion, the committee unanimously approved the recommendations of the committee. The harmonized recipe of the said products are enclosed at **Annex- C**).

ITEM NO. 6 - **DEVELOPMENT OF PROCEDURE FOR RENEWAL CASES OF ALREADY REGISTERED PRODUCTS (FORM-1) MANUFACTURED LOCALLY**

The Adviser & Director General, Department of Plant Protection informed the house about recommendation of the sub-committee that:

1) Tenikil 100% EC (Petkolin) being petrochlorine product should be reviewed for concerns related to its use in agrochemicals and more information would be gathered.

2) For the renewal of the Ragto-AP 56% Tablets (Aluminium Phosphide) the case would be considered after fulfilling mandatory requirements as per existing law / rules and registration of formulation plant by the registrants.

After detailed discussion, the recommendations were unanimously approved by APTAC.

ITEM NO. 7 - **REVIEW OF 36TH APTAC DECISION**

The Adviser & Director General, Department of Plant Protection informed the house about recommendation of the sub-committee that:
"After detailed discussion the Sub committee recommended that fresh toxicological study data of the formulated product will be required for multiple / higher concentration formulation from international accredited lab".

The committee discussed the subject matter in detailed and approved the recommendation of the APTA Sub Committee and also decided that the applicant should inform about carry over stock of the product with supporting documents and then be decided in the next meeting.

ITEM NO. 8 - DEVELOPMENT OF PROCEDURE FOR FORWARDING SAMPLE TO THE PROVINCIAL RESEARCH INSTITUTES ACCORDING TO RULE 4 OF APR, 1973

The Adviser & Director General, Department of Plant Protection informed the house about recommendation of the sub-committee that:

1) Two crop seasons official trial data from two agencies was mandatory for old chemistry products with new brand names as per rules 4(3) of APR, 1973.

2) The Department of Plant Protection would ensure issuance of field trial protocol within 60 days of the receipt of the sample on submission of complete application.

3) Formulated product samples for field trial would also be submitted to DPP alongwith file for registration and DPP may forward sample to provincial & federal research institutes for conducting field trials as required under Agricultural Pesticides Rules, 1973.

After detailed discussion, the recommendations were unanimously approved by APTAC.

ITEM NO. 9 - ANY OTHER ITEMS WITH THE PERMISSION OF THE CHAIR

Review of 44th APTAC decision

The Director General (Pest Warning & Quality Control of Pesticides) commented that the 44th APTAC decision is against the basic law of Section 15 & 16 of PAO 1971 & (Amendment) Act 1992 & 1997 and APTAC is not the authority to change the law.

After detailed discussion the committee decided that:

1) The committee withdraws 44th APTAC decision.
2) All the pesticide formulation and refilling/repackaging plants holders and registered importers of pesticides shall provide report regarding import and locally formulated pesticides within 15 days, otherwise Department of Plant Protection will not issue NOC. The importers will provide import data regularly by email and followed by hard copy to Department of Plant Protection. In addition the custom will be approached for providing actual export data from Chinese government.

3) It was also proposed that CropLife & PCPA develop a proposal to establish an accredited lab in the country and this lab may work under independent governing board and 25% fee of lab analysis may be granted to the Department of Plant Protection for laboratory development.
4) The Adviser & Director General, Department of Plant Protection agreed to the request by association to prefer dispose-off applications for registration against cotton, rice & wheat crops.