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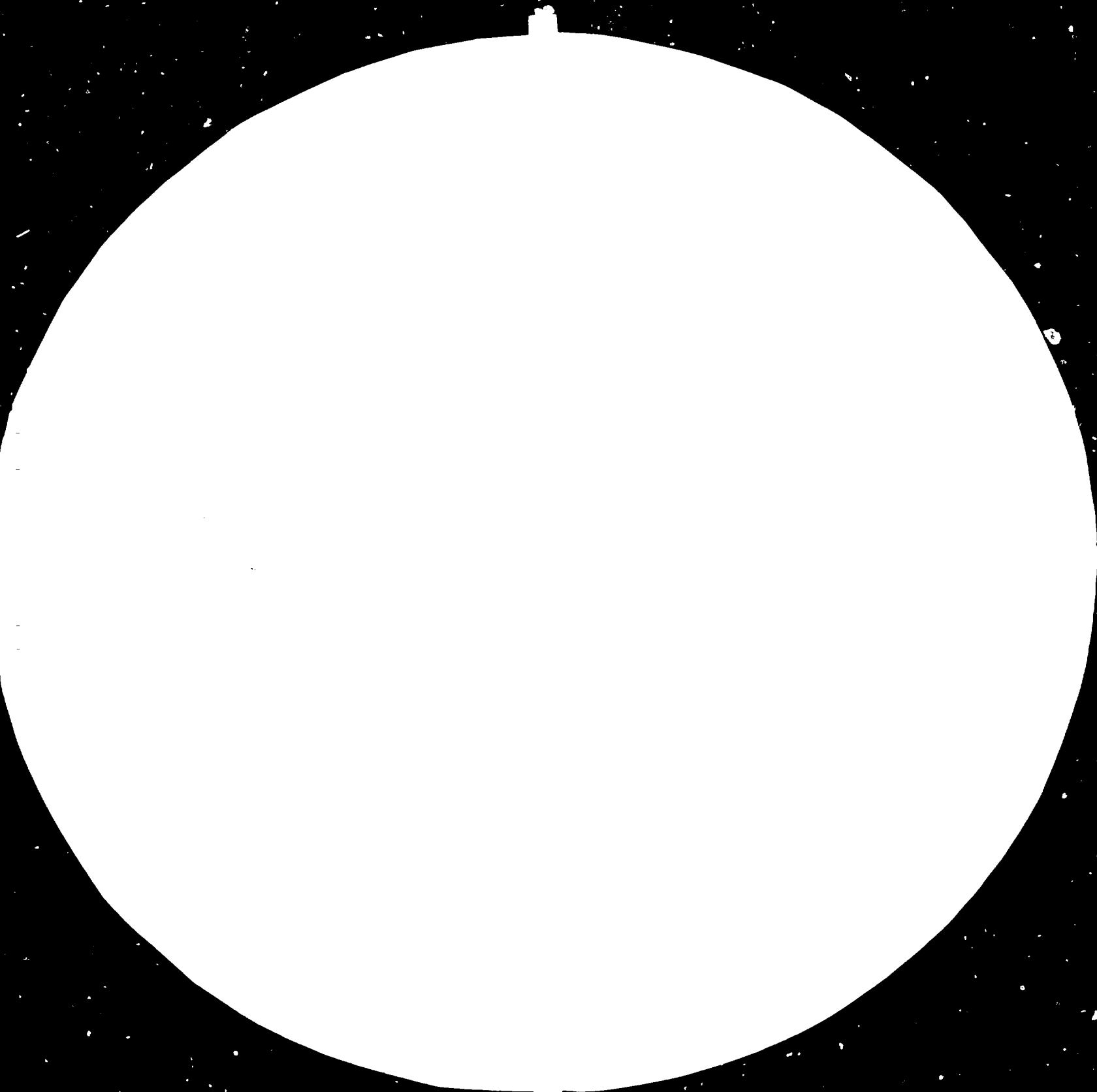

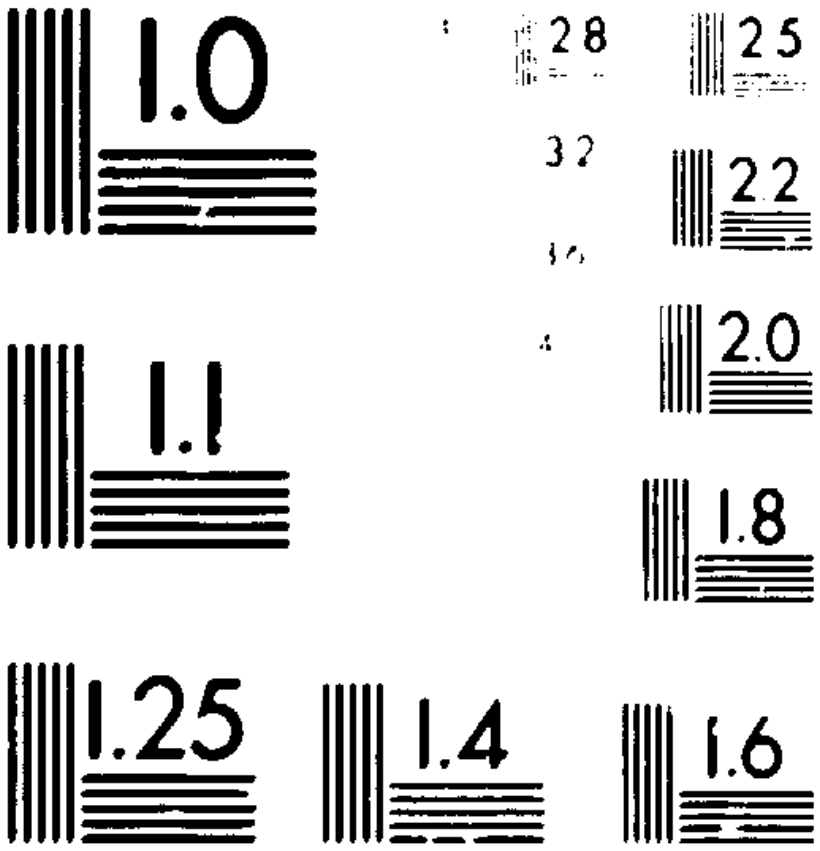

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Regional Network for the Production, Marketing and Control of Pesticides in Asia and the Far East
DP/RAS/82/006

Experts Group meeting on Quality Control of Pesticides*

Dhaka, Bangladesh 13-17 May 1984

REPORT**. (Meeting on quality control of pesticides).

2223

* Organized by the United Nations Industrial Development Organization in cooperation with Food and Agriculture Organization of the United Nations.

**Prepared for the Member Countries of the Network and other participating countries of the Region. This document has been reproduced without formal editing.

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# CONTENTS

## INTRODUCTION

1. The Experts Group Meeting on Quality Control of Pesticides organized by the United Nations Industrial Development Organization in cooperation with the Food and Agriculture Organization of the United Nations and the Ministry of Agriculture, Government of the People's Republic of Bangladesh, was convened at Sonargaon Hotel, Dhaka, Bangladesh, from 13 to 17 May, 1984.

2. The Meeting was organized as an implementation of one of the activities under the work programme approved by the Technical Advisory Committee (TAC) of the Regional Network project. The Experts Group Meeting has the following objectives:

   2.1. To exchange experience in quality control methodologies and practices generally applied in the region with emphasis on identified needs for introducing new techniques if necessary;

   2.2. To identify specific areas of pesticide quality control measures, which call for joint efforts and initiation of developmental work in the region based on co-operative arrangements in this field among countries;

   2.3. To identify facilities and expertise existing in the region suitable for undertaking studies on new quality control methodologies and techniques, with the aim of establishing a regional collaborative system which would warrant steady and coordinated development in the future, taking into account related work conducted by other professional and international organizations;

   2.4. To identify specific pesticides of key importance, widely used in the region, and to compare their specifications as well as currently used analytical methods, with the ultimate aim of promoting standardization of quality control parameters and adopting common specifications;

   2.5. To plan specific activities in the field of quality control of pesticides to be pursued on a regional cooperative basis which may need strengthening through support by and liaison to be maintained with relevant international organizations and institutions.

3. The Meeting was attended by 11 delegates representing their respective governments, 2 representatives from UNIDO, Dhaka, 2 representatives from international organizations, CIPAC and GIFAP, 1 from the Regional Coordination Unit, and 28 observers from trade, industry, research organizations and affiliated Bangladesh Government departments. No participants attended from Indonesia, Sri Lanka and Afghanistan. The list of participants is attached as Appendix I.

4. The proceedings of the Meeting are summarized below.

OPENING OF THE MEETING

5. The Meeting was inaugurated by the Honourable A.Z.M. Obaidullah Khan, Minister of Agriculture, who emphasized the need for continuous review of the quality of pesticides in order to ensure their efficacy and safety to the users. He stressed the fact that although pesticides are needed for crop protection, they are not without harmful effects. It is therefore essential that the quality of such products be thoroughly checked in order to minimize possible health hazards. He advised the participants to deliberate on problems related to quality control and wished them a successful Meeting.

6. Mr. S.A. Mahmood, Director General, Department of Agricultural Extenstion, in his address, extended a warm welcome to the delegates while he stressed the importance of quality control of pesticide products. He expressed confidence that through the meeting the countries in the would benefit through exchange of experiences in quality control methodologies and practices in the field of pesticides as well as through expert evaluation of the latest techniques developed in the more advanced countries.

7. Mr. A. M. Anisuzzaman, Secretary of Agriculture and Forest Division, in his address, expressed his personal concern on the subject of quality control of pesticides. The Ministry of Agriculture is often beset by complaints from farmers, extension staff, politicians and the media on adulteration of pesticides and other problems related to their efficacy and quality. He advised the Meeting that quality control should not be considered in isolation but rather in its physical, social and economic setting. Effective quality control must be seen throughout the plant protection system, from pesticide manufacture, purchasing, distribution and storage, through an efficient plant protection service for farmers. He cautioned the Meeting that during the deliverations, the participants should not become over-absorbed in abstruse theory and high technology but to bear in mind the small farmers who use the end-product of such technology. The farmer needs pesticides that are fool-proof at his end; he needs a service that can identify when pesticides have been tampered with, or have lost their potency for other reasons, so that eventually he may be satisfied with the reliability of the product he buys.

8. Mr. V. C. Lavides, UNIDO Senior Industrial Development Field Adviser, in his statement, emphasized the support of UNIDO and UNDP to the Regional Network project and stressed the importance of quality control of pesticides in this region which is basically dependent on agriculture. He expressed appreciation to the Host Government in organizing this activity and wished for a successful conclusion of the Meeting.

9. Mrs. Cecilia P. Gaston, Regional Co-ordinator of the Network briefed the Meeting on the importance of the activity on quality control of pesticides and congratulated the Government of Bangladesh for having successfully implemented an effective system of quality assurance of pesticide products.

She welcomed the delegates for a fruitful meeting and urged them to carry out the recommendations arrived at during the deliverations so that in the next few years standardized methodologies can be adopted by all member countries of the network.

10. Mr. D. U. Khan, Director, Plant Protection Wing, Department of Agricultural Extension proposed vote of thanks on behalf of the organizers.

ELECTION OF OFFICERS

11. Mr. Dalil Uddin Khan (Bangladesh) was elected Chairman, Mr. M. M. H. Baig and Dr. N. K. Pillai (India), Rapporteur for the Meeting.

ADOPTION OF AGENDA

12. The Meeting adopted the agenda as presented in Appendix 2.

PRESENTATION OF COUNTRY PAPERS

13. Delegates from 7 participating countries presented papers on the status of quality control measures and methodologies in their respective countries together with their proposals for inter-country regional cooperation in this field. The papers included descriptions of quality control practices applied at production site and distribution chain; equipment and adoption of specifications; methods of analysis, training of personnel; problems and proposals for inter-country cooperation. A summary of each paper is attached as Appendix 3.

STATUS OF QUALITY CONTROL MEASURES AMONG MEMBER COUNTRIES OF THE NETWORK

14. Dr. N. K. Pillai (India), one of the resource speakers presented his observations on quality control measures in 7 of the member countries which he visited as a recipient of the study tour grant from the Network. Mr. Ruhul Amin (Bangladesh) added his views on the situation in Sri Lanka and Afghanistan, where he was a consultant under the auspices of the Network. In general, their findings concur with those reported by the delegates.

15. Bangladesh has the most rigid quality control practices with enforcement done by the government at the point of entry, during production and in the distribution chain. The Bangladesh Standards Institution has adopted with some modifications FAO/WHO specifications utilize CIPAC and AOAC methods of analysis. Korea relies heavily on the self-inspection system imposed by manufacturers and the NAMIO which sets standards specifications using basically FAO guidelines. The Indian Standards Institution has adopted specifications for

pesticides which are more or less similar to that of FAO. Monitoring of quality control is done by the Government with the Central Insecticide laboratory providing advice in cases of dispute. Pakistan has started to adopt national standards. The rest of the countries, Philippines, Thailand, Nepal - currently have no national standards. However, all are contemplating on adopting FAO/WHO specifications. All, except Nepal monitor quality control in both pre and post distribution stages. Summaries of the reports of Dr. N. K. Pillai and Mr. Ruhul Amin are attached as Appendix 4.

## LIAISON WITH INTERNATIONAL ORGANIZATIONS

16. Dr. J. Henriet, CIPAC Chairman and resource speaker for the Meeting, presented a paper providing basic information on the work of CIPAC, FAO, WHO in the field of pesticide specifications and methods of analysis. He expressed interest in the activities of the Network in this field and invited member countries to join in CIPAC collaborative laboratory trials. He also encouraged member countries of the Network to bring to the attention of FAO WHO and CIPAC specific requests and problems for pesticides extensively used in this region which have no FAO or WHO specifications and where CIPAC or AOAC methods are not available. A copy of Dr. Henriet's paper is attached as Appendix 5.

17. Mr. Roger J. Parker, (GIFAP), discussed the views of GIFAP on quality control of pesticides and presented excerpts from a proposed publication of GIFAP entitled "Guidelines on Pesticide Quality Control."

18. In this document emphasis is placed on two aspects of Quality Control which are important from both the industrial and regulatory viewpoints. The provision of defined manufacturing systems and procedures is of paramount importance together with effective analytical testing programmes in the laboratory.

Manufacturing systems described cover, organization, training design of plant and documentation. In the laboratory, emphasis is placed on the design and layout, organization, working systems and documentation. GIFAP recommends that the FAO guidelines be used for drafting specifications. It is essential that the specifications tests should be realistically applied however. For chemical analysis, chromotographic methods are favoured and in particular the advantages of HPLC methods in terms of flexibility and range of application is stressed.

## QUALITY CONTROL PRACTICES AND METHODOLOGIES

### A. SCOPE

19. A technical product of a pesticide active ingredient is rarely suitable to be used as such in the field. It has to be formulated. Formulation involves at a set of processes consisting mainly of converting an active ingredient into

a form which enhanced maximum biological efficacy in a given application technique, while remaining in acceptable economical limits. Formulation is an art and this explains why different commercial products based on the same active ingredient content behave differently in the field. The aim of quality control therefore is to ensure that the physical and chemical characteristics of a commercial product would satisfactorily be effective in the field and safe for end-users to apply. Quality control must be based on two aspects: a) the chemical aspect, consisting of checking the active ingredient content and harmful impurities; and b) the physical aspect, consisting of checking conformity of physico-chemical properties of the product with the application technique. (Appendix 6A)

20. The quality control practices and methodologies currently employed among participating countries are summarized in Appendices 6 and 7. There was a general concensus in the meeting that as far as possible, FAO/WHO specifications be used as guide in determining national standards and whenever available the corresponding CIPAC and AOAC methods of analysis be followed.

B. FACILITIES/EQUIPMENT

21. The Meeting noted that all participating countries have the basic facilities required for pesticide formulation analysis. However, there is a need for strengthening existing facilities and regional cooperation should be expored along these lines. Appendix 8 idenfifies government quality control organizations, laboratories, facilities and equipment as well as those available from manufacturers or formulators and other agencies.

RECOMMENDATION

The Meeting,

Having noted that although some facilities for quality control are generally available among the member countries, there are specialized instruments available only in a few;

Recognizing that some countries may not have the facilities available to analyze certain samples while others are in a better positionto do so.

Recommends that in cases where a member country may require some special analysis of a pesticide product for which no adequate facilities are available in that country, then any other member country better equipped and trained to do so, should whenever practicable, assist in analyzing the sample in line with strengthening of regional cooperation.

C. MECHANISM FOR DEVELOPING/ADOPTING SPECIFICATIONS

22. The mechanism for development of FAO specficications for pesticides was explained and discussed. FAO issues three classes of specifications:

a) Draft specifications: those submitted for consideration;

b) FAO provisional specifications: those which may require further work;

c) FAO specifications : those which are fully acceptable on the basis of evidence presented.

Draft specifications are submitted by any organization or person for consideration by the FAO Group of Experts on pesticide specifications, who assign a priority to it. The draft is circulated among the FAO Group of Experts and GIFAP, if it is a commodity product or to the concerned manufacturer if it is a patented product. In its annual meeting the FAO Group of Experts considers comments on the draft specifications and takes suitable action such as promotion to provisional or FAO specifications.

23. For WHO specifications, data are requested from manufacturers and these are reviewed by the WHO staff for recommendation to the WHO Expert Group which meets once in about every five years.

24. Four member countries have their respective national standard institutions who formulate National Standards for pesticides and their formulation. The National Standard Institutions have Divisional Councils and sub-committees for the formulation of pesticide standards, consisting of Experts from the industry, Government law-enforcing agencies, research organizations and representatives of the consumers. The sub-committees prepare draft standards, keeping in view available international standards like ISO, FAO, WHO US AID etc. These draft standards are circulated for comments from the members of the sub-committee and other experts in the field, including from the industry and the consumers. After incorporating the comments from the experts, provi0 sional standards are prepared with the approval of the Divisional Councils. The provisional standards are normally put to use for varying periods of time before they are accepted as final specifications. While finalizing the specifications unlike in the case of FAO specifications, the representatives of industry (who are members of sub-committee and Divisional Council) are involved in the decision making.

Whenever National specifications are not available international specifications like FAO, WHO US AID and in some cases ISI specifications are adopted in the participating countries of the region.

25. Member countries which have not as yet adopted standard specifications for pesticides were encouraged to do so, taking into consideration the use of FAO WHO specification as well as those available in the region. The need to look into common specifications was also emphasized.

RECOMMENDATION

The Meeting

Having noted the current quality control methodologies and practices employed among the member countries of the region;

Having considered the importance of adopting uniform standards for pesticide specifications in the region;

Recognizing the extensive use of FAO and WHO specifications within the region;

Further noting that in evolving national standards, FAO specifications have been used as basis in most countries wherever these are available;

Recommends that member countries of the region adopt specifications based on FAO standards wherever possible.

D. QUALIFICATIONS/TRAINING OF LABORATORY PERSONNEL

26. Considering the degree of sophistication of current methods of analysis being developed and the complex nature of pesticides, the meeting agreed that the head of a quality control laboratory or unit should be a qualified analytical chemist with sufficient experience in pesticide analysis techniques. The meeting further suggested that efforts should be taken to provide sufficient number of chemists and laboratory personnel to ensure the efficient functioning of the laboratory.

RECOMMENDATION

Recognizing the need for specialized training on the latest methods developed on pesticide formulation analysis;

Noting that some laboratories have hardly any training programmes for their personnel;

Recommends that the Regional Network organize workshops or seminars aimed at upgrading the knowledge and techniques of analytical laboratory personnel. In this activity, the training facilities availabel in the region. Such as those of the Pesticides Development Programme, India or the Philippine Institute for Pure and Applied Chemistry be taken into account.

Further recognizing that methods of analysis are dependent on the proper operation and maintenance of analytical instruments;

Further noting that in most countries no suitable training is offered on the proper upkeep and maintenance of analytical instruments;

Further recommends that suitable training programmes on operation and maintenance of analytical instruments be organized to meet the requirements of the countries. Services of experts in the concerned area of instrumentation should be made available through the Regional Network.

## REGIONAL SCHEME FOR STANDARDIZATION OF QUALITY CONTROL OF PESTICIDES AND ANALYTICAL METHODS

27. The Meeting identified 15 commonly used pesticides among the participating countries and compared current specifications used (Appendix 9).

28. Out of these, ten pesticides were chosen for which specifications are available either from FAO, or member countries. The methods of analysis, currently used were indicated for each of these pesticides. The participating countries agreed to conduct collaborative trials using one of the methods chosen by the lead country (Appendix 10). The trials are aimed to ensure that common methods of analysis are used throughout the region. CIPAC shall be invited to advise in such trials while technical assistance would be solicited from the manufacturers whenever necessary.

29. In cases where there are no available methods, CIPAC should be requested to initiate collaborative studies jointly with the network member countries.

### RECOMMENDATION

The Meeting,

Having noted that all participating countries have the basic facilities required for pesticide formulation analysis;

Being aware that most of the participating countries are using similar methods of analysis including those of CIPAC and AOAC wherever available;

Recognizing the considerable benefits to be derived from the use of common procedures and methods of analysis;

Recommends that standardized methods of analysis be adopted among member countries in the region using as much as possible available CIPAC and AOAC methods, and in cases where these are not available, further recommends that the Regional Network shall initiate collaborative studies in coordination with CIPAC.

### CONCLUSION

30. The Meeting recognized the importance of quality control measures in ensuring that the pesticides applied are effective and safe for the intended uses;

and agreed to strengthen regional cooperation among member countries of the Network by working towards adoption of common standards and methodologies. The Meeting noted, however, certain constraints in implementing quality control practices:

a) difficulty in obtaining some required chemical reagents for analysis;

b) difficulty in procuring necessary spare parts/components for analytical instruments;

c) difficulty in ensuring availability of analytical standards.

RECOMMENDATION

The Meeting

Noting the above constraints in effective implementation of quality control measures;

Recognizing that such constraints exist in almost all countries in the region;

Suggests that the Regional Network explore the possibility of setting-up a special fund to be utilized for urgent procurement of chemicals, reagents and spare parts for use in quality control;

Recommends that the Regional Network set-up an analytical standards bank for the benefit of the participating countries, so as to supply in time with relative confidence and ensure quality control during inter-country regional trade. Support from United Nation's agencies like FAO, WHO and UNIDO is urgently requested. The cooperation of GIFAP and EPA in this regard is also essential.

31. The Meeting noted the need in some cases to analyse toxic impurities in basic pesticides as well as in formulations. However, the general consensus was that the methods of analysis and necessary standards are not always available. The Meeting was informed that while the manufacturers of the basic pesticides are expected to have carried out studies in this area, the US-EPA might be able to provide useful guidelines on methodology. The Meeting advised the countries interested, to seek guidance of EPA through the Regional Coordination Unit.

32. The need to incorporate mutually acceptable packaging and storage guidelines together with the standard specifications was stressed. However, the Meeting noted that only Korean and Inida currently have specifications for pesticide packaging. The Meeting suggested that such specifications on packaging be circulated to other member countries by the Regional Coordination Unit so that the matter can be thoroughly reviewed and considered firstly on a national level and eventually on the regional level.

33. With the introduction of new varieties of pesticide products, methods of analysis are continuously being improved and revised. Although these informations are available either from international organizations like CIPAC and AOAC or from the manufacturers, they are not generally accessible to the member countries and hence not fully utilized.

RECOMMENDATION

The Meeting

Having noted that considerable information on new and improved methods of analysis are available;

Recognizing the difficulty in some cases of obtaining such information on a regular basis;

Further noting that the countries in the region are continuously evolving national standards for specifications of pesticides;

Further recognizing the benefits to be derived from mutual exchange of information on quality control measures among member countries;

Recommends that the Regional Coordination Unit includes among its responsibilities, the retrieval and dissemination of relevant information on pesticide specifications, methods of analysis, packaging and quality control practices.

34. In general, the participating countries agreed to adopt whenever practicable FAO and WHO specifications for pesticides and utilize CIPAC methods of analysis. The Meeting however noted that FAO specifications and CIPAC methods are not available for some of the pesticides considered important in the region. Appendix 9 illustrates this point clearly.

RECOMMENDATION

The Meeting

Recognizing the value of using FAO specifications and CIPAC methods of analysis;

Noting that in the above cases some FAO specifications and CIPAC methods are not available;

Recommends that the Regional Network urgently draw to the attention of FAO and CIPAC the above cases and urge both FAO and CIPAC to give immediate consideration to establish specifications and methods of analysis for pesticides recommended by this Meeting.

Further noting that some of the available FAO specifications may need updating and revision;

Further suggests that the Regional Network request FAO to give due consideration to revision of specifications for the pesticides identified as above; and

Further recommends that Network member countries take active participation in this field, particularly in carrying out collaborative studies with CIPAC aimed at developing and standardizing methods of analysis, taking into account availability of instruments among member countries.

35. In consideration of the requirements of individual participating countries, and in an effort to initiate activities for the sub-network on quality control, the Meeting prepared a work plan for a period of two years. The details are presented in Appendix 12. The Meeting recommended that the proposed work plan be considered by the forthcoming TAC.

## CLOSING OF THE MEETING AND ADOPTION OF THE REPORT

36. The Chairman summarized the proceedings and recommendations of the Meeting and finally closed the Meeting after the Report was adopted as amended.

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EXPERTS GROUP MEETING ON QUALITY CONTRO OF PESTICIDES

AGENDA

1. Opening
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3. Adoption of Agenda
4. Presentation of Country Papers
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   - 7.3 Mechanism for adopting or developing specifications
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8. Regional standardization of Methodologies
   - 8.1 Identification of key pesticides used in the region
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9. Regional Scheme for Standardization of Quality Control of Pesticides and Analytical Methods
10. Other Business
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12. Closing Session

SUMMARY OF COUNTRY PAPER

BANGLADESH

The registration of pesticide is a statutory requirement in Bangladesh, and is governed by the Agricultural Pesticide Ordinance, 1971 and the Amendments made in 1980 and 1983. The process of registration is based on test results of physico-chemical properties carried in the pesticide Laboratory of Plant Protection and also on the results obtained after biological experimentation under Laboratory and field conditions conducted in different Research Institutions. So far, 115 pesticide formulations have been standardized and registered in the country, of which about 30% are locally formulated and the rest being imported.

Formulation plants have their own laboratories for production quality control, and follow mostly conventional methods. The Pesticide Laboratory of Plant Protection is the only regulatory laboratory in the country for testing of pesticides for registration and quality control purposes of the products marketed through about 20,000 licensed dealers.

Generally, FAO specifications for pesticides and analytical methods as outlined in CIPAC Handbooks are followed. Where not available, other international specifications and analytical methods are accepted.

About 470 technical officers stationed at Upa-Zilla level are appointed as pesticide Inspectors under the provisions of the ordinance for the purpose of inspection and execution of the regulations.

Commonly used pesticides are malathion, fenitrothion, phosphamidon, diclorvos, dimethoate, dieldrin, diazinon, fenthion, copper oxychloride, 2,4-D Sodium salt, paraquat dchloride and zinc phosphide.

The sampeles collected by inspectors and other authorized persons are referred to the Pesticide Laboratory for testing. The Government Analyst appointed under the ordinance, analyses or causes to be analyzed these samples and submits reports to the agency concerned in prescrived form for appropriate action.

Laboratory analyses have shown up defects and mistakes in formulations, packing or repacking materials or labels, whether they were accidental or intentional.

Regional cooperation in the field of uniform specifications, analytical methods, exchange of information on new methodology and one common source of analytical standards deserves utmost consideration.

For efficient quality control scheme suitably qualified and skilled staff members having wide working experience in solving analytical problems are essential. Such staff members need to be specially trained and created so that each one of them is convinced that there is something he can do in his daily work to contribute to the quality control programme of the government.

## SUMMARY OF COUNTRY PAPER

## INDIA

The Pesticide Industry in India is fairly well-established. The present consumption of Pesticides in Agriculture and Public Health is of the order of 60,000 MT technical grade material. The demand analysis of pesticides in India indicates that about 81% of the total demand constitutes insecticides, 14% fungicides, 2.4% herbicides, 1.3% rodenticides and fumigants and 1.3% other pesticides.

The production of pesticides in India is largely in the private sector. The major producer of pesticides in the public sector is Hindustan Insecticides Ltd. There are about 32 large industrial units engaged in the manufacture of about 50 technical grade pesticides. There are over 400 small scale formulators in the private sector. The estimated total pesticides formulation capacity in India is of the order of 1.6 million MT of formulated products. Out of this total formulation capacity, 10-15% is estimated to be in the organized sector and the remaining in the small scale sector.

The manufacture, import, sale, transport, distribution and use of pesticides in India are regulated by the provisions of the Insecticides Act 1968 and Insecticides Rules 1971. All pesticides are required to be registered under the provisions of the Act and Rules.

All technical matters pertaining to insecticides till the grant of compulsory registration is the central responsibility of the statutorily constituted bodies like Cental Insecticides Board and the Registration Committee.

The Central Insecticide Laboratory functions as the statutory laboratory to verify the claims made by the manufacturer or formulator at the time of registration.

The Central Insecticides Laboratory has already been established with four technical divisions namely: i) Bioassay Division, ii) Toxicology and Pharmacology Division, iii) Pesticide Residues and Quality Control Division, iv) Packaging and Processing Division.

The enforcement of various provisions of the Insecticides Act lies with the State Goverments and Union Territories. Accordingly, the States and Union Territories have appointed all the principal functionaries namely: Licensing Officers, Insecticide Inspectors and Insecticide Analysts to discharge various prescribed duties. There are 31 pesticide testing laboratories in 16 States and one Union Territory. Three more laboratories are being established.

The Government of India has recently approved setting up of 5 regional Pesticide Testing Laboratories for quality Control. Action has been initiated to set up these units.

Indian Standards Institution is operating certification mark scheme under which manufacturers are licensed to use the ISI mark on goods produced by them in conformity with the relevant Indian Standards. It is obligatory on the part of the manufacturer to have the ISI mark, but the ISI mark is a third party assurance for the quality of the product. ISI has a Central Laboratory at Delhi and regional laboratories at Bombay, Madras and Calcutta.

Indian Standard specifications are generally adopted as standard specifications for pesticides in India. Indian Standards specify methods of analysis and sampling procedures also. Wherever Indian Standards are not available, internation specifications like FAO, WHO, etc. are followed. Samples of analytical standards are supplied by ISI in some cases. Standard samples are also obtained from EPA and other internationa agencies. Action is on hand for making available standard analytical samples indigenously.

Quality control facilities are fairly adequate at the manufacturers' end, especially those engaged in the manufacture of technical grade pesticides. Quality control facilities with the small scale formulators need improvement in some cases.

Pesticides Development Programme, India, a UN- aided project being implemented by Hindustan Insecticides Ltd. on behalf of the government of India had built up the necessary infrastructure for quality control of pesticides and training the personnel engaged in quality control work. The activities of the project have already been started.

Other agencies associated with pesticide analysis and quality control are private organizations like Sri Ram Test House, Industrial Testing and Analytical Laboratory, etc., National Test House under the Ministry of Commerce, National Laboratories under CSIR and Pesticide Analysis Laboratories attached with various agricultural universities.

Proposal for intercountry regional cooperation in the field of quality control has been included.

SUMMARY OF COUNTRY PAPER

KOREA

Quality control of pesticides in Korea is regulated by Pesticide Management Law and it is basically responsible for the formulators themselves. The Pesticide Management Law prescribes in detail the inspection procedures, specifications, equipment and facilities for pesticide quality control.

1. Persons and Facilities required for Quality Control of Pesticides:

In order to ensure the quality control of pesticides, we have legally established the criteria of the persons who engage in the pesticide manufacturing business, and the facilities required for manufacturing the pesticides.

Person who intends to conduct manufacturing of pesticides shall major in agricultural chemistry, chemistry, chemical engineering or biology in a 4 year college and graduate therefrom according to the Educational Law, or persons who obtain a license of pharmacist according to the Pharmacist Law.

Pesticide manufacturing business have to insure the acreage of laboratory and experimental field, and laboratory equipment regulated by Pesticide Management Law.

2. Inspection criteria of Pesticides for Quality Control

We have three ways of inspection procedures for quality control of pesticides, that is self-inspection, applied inspection and ex-officio inspection. And also, we have 3 inspection methods, that is, external inspection, physico-chemical inspection and biological inspection.

Concerning the quality control of pesticides, National Agricultural Materials Inspection Office (NAMIO) is a major adimistrative organization in Korea. This agency conducts ex-officio inspection of pesticides periodically and applied inspection for request of pesticide manufacturers.

When the pesticides have been judged "Rejectable" as a result of physico-chemical inspection and biological tests, the manufacturer can raise objection thereto within 15 days from the date of notification of the result of the inspection. The Director of NAMIO may conduct re-inspection on the pesticides claimed by the manufacturer.

3. Method of Inspection:

   a. External inspection

      For all samples taken on the basis of complete randomized sampling method, external inspection shall be made with regard to condition of packaging, description of label, adhesion of inspection stamp and weight.

   b. Physico-Chemical Inspection

      The Director of NAMIO shall conduct physico-chemical test in accordance with publicly announced method "NAMIO Analysis Method" within one month from the date of sampling.

      Method of analysis of active ingredient are available for all the formulations registered in Korea except antibiotics and microbial insecticides. The method of physico-chemical analysis are used NAMIO method which was modified the specification of WHO, CIPAC and other international organizations.

4. Most Common Pesticide in Korea

   IBP, edifenphos, probenazole, isoprothiolane, mancozeb, phenthoate, cartap, fenthion, diazinon, BPMC, EPN, dichlorvos, butachlor, benthiocarb and alachlor which are applied over 200 MT active ingredient basis in 1982.

5. Proposals for intercountry regional cooperation in quality control

   a. to establish the analytical standard bank

   b. to prepare the analysis specifications of the impurities in technical material

## SUMMARY OF COUNTRY PAPER

## NEPAL

There is no separate regulation for manufacturing, importing and distribution of pesticides in Nepal. Partly, it is governed by the Drug Act. No national standard specifications have been stablished yet. The Nepal Bureau of Standards is responsible for it and efforts are being made to formulate the standards.

Currently, Indian Standard specifications are adopted for controlling the quality of pesticides. When the IS specifications are not available, FAO and WHO specifications are followed.

The Entomology and Plant Pathology Laboratory of the Department of Agriculture is responsible for quality control activities. Agriculture Input Corporation is mainly responsible for import and distribution of pesticides. There are only a few formulators in Nepal.

Recently, a Pesticides Board has been established. This Board is responsible for import recommendation, distribution and control of pesticides.

SUMMARY OF COUNTRY PAPER

## PAKISTAN

The paper presents the fact that import of pesticides, when in public sector, was erratic (4419 MT in 1979-80 and 16225 MT in 1976-77). In private Sector since 1980, the position has stabilized and sales have doubled to over 6000 MT in 1983.

All candidate pesticides for registration are required to be cleared first by the Federal Pesticides Research Laboratory of Pakistan Agricultural Research Council before field bioefficacy tests to qualify for registration. So far 189 formulations have been registered for use.

FPRL at Karachi as well as a regional laboratory in Punjab are presently providing pre- and post-registration quality control which is largely voluntary. Similar facility exist with the only operational manufacturing unit. For monitoring purposes, 5 more regional laboratories are in the process of establishments. For undertaking the job, the FRPL is equipped with MPLC, GLC, IR, UV and TLC facilities.

National specifications of pesticides in association with Pakistan standards Institution, and the trade and with reference to FAO and WHO and similar international standards are being framed (28finalized and 54 under process). CIPAC test methods are generally followed.

Fifteen pesticides most commonly used during 1983, with sales in three figures, are: Monocrotophos, BMC, DDT, Diazinon, Disulfoton, Endrin, Hostathion, Lorsban, Methyl Parathion, Dimecron, Polytrin-C, Endosulfan, Thimet, Zolone DT, Sumithion, Sevin, Sevidol, Sumicidin, Padan and Antracol.

SUMMARY OF COUNTRY PAPER

PHILIPPINES

An important aspect in pesticide applications is a well-standardized pesticide formulation. Reports of sub-standard or adulterated pesticides in the hands of farmers, particularly vegetable farmers, and subsequent overdosing for "effective" control has prompted the need for a program to monitor batches in formulation plants and to check the quality of pesticides on dealers' shelves and farmers' residual samples. This special concern is in recognition not only of the economic importance of these products in agriculture and public welfare, but of the potential hazards they present.

The Fertilizer and Pesticide Authority was created in 1977 to regulate the importation, exportation, manufacture, formulation, distribution, sale transport, storage, use and disposal of pesticides. For all formulation and residue analyses requirements, the FPA utilizes the facilities of the Pesticide Analytical Laboratory of the Bureau of Plant Industry.

There are a few formulators, the small-scale single product mixers, who practice very little quality control, but most larger formulators maintain their own laboratories and have developed quality control systems.

At the production site, quality control begins with inspection and analysis of incoming raw materials and packaging materials. Only materials which conform to company specs are accepted and used. For formulated products, a batch sample is analyzed and if found to meet established specs, approval is given to refill into desired container. During the refilling process, constant inspection is conducted to be able to spot faults during production: improper fill, poorly affixed labels, and anything that will create a marked reduction in quality.

As a regulatory laboratory, the BPI Pesticide Analytical Laboratory is responsible for checking conformity to registered specifications and monitors quality of formulations in the market. The scope of activities in this unit include: checking whether the identity, purity and concentration of the active ingredient in a pesticide product is as stated; checking whether the physical properties like appearance, emulsion stability, viscosity, alkalinity/acidity, specific gravity, particle size, flowability and wettability, conform with the minimum requirements; and investigating storage stability under local climatic conditions.

The most commonly used pesticides in the country are: butachlor, carbofuran, chlorcthalonil, methomyl, monocrotophos, mancozed, thiophanate methyl, BPMC, carbaryl, diazinon, malathion, MIPC, paraquat dichloride, azinphos ethyl, and endosulfan. Analysis is made with specialized equipment like gas chromatographs, high pressure liquid

APPENDIX 4

## Status of Quality Control of Pesticides in Participating Countries of the Network

Based of the Study Tour of N.K. Pillai on Quality Control in Philippines, Korea, Thailand and Pakistan, his visit to Indonesia and Bangladesh and the visit of Ruhul Amin to Afghanistan and SriLanka

Dr. N.K. Pillai, India, undertook a study tour in Philippines, Republic of Korea, Tahiland and Pakistan from July 17 to August 14, 1983 to study the Quality Control Practices in these countries. Mr. Preecha Chupanish, of Tahiland and Mrs. Emi of Indonesia were in the study tour team in Philippines, Korea and Pakistan. Mr. Ruhul Amin of Bangladesh was in the study tour team in Philippines and Korea, while Mr. S.A. Khan of Bangladesh undertook the tour of India and Pakistan. While the rest of the memberof the team were in India, Mr N.K. Pillai undertook the study tour of Thailand. Salient points in each country as follows:

### PHILIPPINES

Fertilizer and Pesticide Authority is the regulatory agency of the government for pesticides. Responsible for registration, licensing and regulatory activities commencing manufacture, imports, distribution and sale of pesticides. Mostly pesticides requirement met by imports and local formulation of imported technical material. Twenty-two (22) formulation units are functioning in the country. Quality control and residue analysis carried out at the Pesticide Analytical Laboratory of the Bureau of Plant Industry, sister concern of FPA. Analytical facilities available are good, including 7 gas chromatographs with various detectors, HPLC, IR and UV spectrophotometers and TLC run by qualified chemists. More trust given to residue analysis than quality control only active control analysis monitored. Has three (3) satellite Laboratories in other parts of the country. Visited a few formulation manufacturing units. Quality control facilities available with the industry are fairly good, including gas chromatographs and HPLCs. No uniform specifications from the suppliers of the active materials and also FAO/WHO specifications. Some formulation units are housed in the same campus with pharmaceuticals.

### REPUBLIC OF KOREA

The pesticide committee of the Ministry of Agricultural and Fisheries is the regulatory authority on pesticides in Korea. The Agricultural Chemical Research Institute of the office of Rural Development responsible for R & D of pesticides Bioefficacy, Toxicity and residues studies, while National Agricultural Material Inspection Office responsible for quality control and quality assurance of pesticides. Pesticides requirement met mostly by indigenous manufacture and to limited extent formulation of imported active materials. Seventeen (17) units

## SUMMARY OF COUNTRY PAPER

## THAILAND

Pesticides used in Tahailand, with exception to locally manufactured paraquat are totally imported. Approximately 300 different pesticides in more than 1000 strengths/formulations are distributed by more than 2000 sales agencies.

The quality control of pesticide is implemented by the government agency and the industry. This begins with the analysis of imported materials taken at the customs level. The quality control of locally formulated/manufactured pesticides is undertaken by the industry. Periodical monitoring of these pesticides and in the market materials are carried out by the government inspectors.

The government organizations within the Department ofAgriculture involved in the quality control of pesticides: The Division of Agricultural Regulatory looks after the regulation whereas the analysis of pesticides is conducted by the Division of Agricultural Toxic. Substance.

Methyl parathion, malathion, dimethoate, monocrotophos, carbaryl, sulfur, copper oxychloride, zineb, mancozeb, propineb, 2,4-D, dalapon, paraquat, atrazine and diuron are the most commonly used pesticides in the country. The analysis of these pesticides is done by a chemist/pharmacist. The Division possesses a range of analytical equipment, e.g., TLC, GLC, and HPLC. The analytical methods employed are those of CIPAC, AOAC, EPA and those of manufacturers' origin. No national specifications of agricultural pesticides are as yet available. However, as and where appropriate, reference is made to FAO specifications.

Additional resources, qualified personnel such as analytical chemists and training in the areas of operation and maintenance of specialized analytical instruments are seen to be the prime areas of improvement needed.

Suggestions have been given on the intra-regional technical collaboration on the quality control of pesticides as well as the atandardization of the performance of regional laboratories through interlaboratory collaborative studies on the analysis of pesticide formulations.

for manufacture of technical material and eleven (11) units for formulations. Facilities available at Agri and Namio good including many gas chromatographs having various detectors, liquid chromatographs and spectrophotometer. Operated by qualified persons. The self inspection system of products by qualified self-inspectors of the manufacturing organizations and subsequent rechecking by Namio seems efficient methods of quality assurance. There are stringent legal sanctions against manufacture of sub-standard products. Specifications for quality control stipulated by Namio mostly based on manufacturers specifications. It is also obligatory for every formulation unit to have experimental field for field tests of all formulations.

THAILAND

The poisonous active control Board constituted by officials from Ministry of Agriculture, Ministry of Trade and Ministry of Public Health is the regulatory agency for pesticides in Thailand. The Agricultural Toxic Subatance as Division of the Department of Agriculture does the quality control and residue analysis of pesticides. Pesticidesrequirement met by imports of finished products and formulations of imported active materials. Formulation carried out by private industry. Analytical facilities available at Agricultural Toxic Substance Division included many GC, HPLC, spectrophotometers and other analytical instruments. However, quality control system needs improvement although private fromulations generally market good quality products. Quality checking and assurance by Cov't Agency not comparable to earlier two countries. Specifications followed by Agricultural Toxic Substances Division are those of international agencies like FAO, WHO, AOAC and EPA. Physical formulation characteristics generally not tested. Emphasis given to residue analysis. Visited a few formulation units also. Production pracesses are sophisticated, although quality mainly dependent on quality of the technical material imported. The Agricultural Toxic Substances Division also undertake extension services to farmers in the field of choice and proper usage of pesticide.

PAKISTAN

Visited pesticides Research Laboratory of the Pakistan Agricultural Research Council at Karachi and a few formulation manufacturing units. In Pakistan the pesticides committee headed by the Secretary, Department of Agriculture and Food is the regulatory agency for pesticides. Chemical and residue analysis are carried out by Federal Pesticides Research Laboratory at Karachi. Analytical facilities include two GC, HPLC, UV and IR spectrophotometers. Run by qualified persons. Being the only laboratory in Pakistan for quality control of pesticides the facilities need strengthening both in terms of equipments and personnel. Extension work is the responsibility of provincial Government and it is their responsibility to get the products tested in the Federal Pesticides Research Laboratory at Karachi. There are about 30 private formulation companies in Pakistan some of these are only dealers for imported materials. The quality control facilities in the few formulation units visited not very satisfactory, they depend mainly for analysis on the pesticides analysis laboratory of the Federal Government.

INDIA:

The quality control of pesticides in India, in brief, is as follows:

The Manufacture, import, sale and distribution of pesticides in India are regulated by the provisions of the Insecticides Act 1968 and Insecticides Rules 1971. All pesticides are required to be registered under provisions of the Act and Rules. The Central Insecticides Laboratory under the Ministry of Agriculture functions as the statutory laboratory to verify the claims made by the manufacturer or formulator at the time of registration. The Central Insecticide Laboratory has four divisions namely: i) Bioassay; ii) Toxicology and Pharmacology; iii) Pesticide residues and quality control and iv) Packaging and Processing.

The quality control and residue section is equipped with instruments like GC with integrator, IR and UV spectrophotometers, polarograph and TLC sets. It is manned by qualified chemists.

The enforcement of the provisions of the Insecticide Act after registration lies with the State Governments and Union Territories, who have appointed Pesticide Analyst and Pesticide Inspector for the purpose. There are at present 31 Pesticide Testing Laboratories in 16 state and one Union Territory. The central insecticide laboratory functions as an appellate laboratory in case of dispute on the result of analysis by the State Laboratories. 5 Regional Pesticide Testing Laboratories are being set-up under the Central Insecticide Laboratory.

There is also the Indian Standard Institute certification mark schem in India, under which manufacturers are licensed to use the ISI mark is obligatory. ISI has a Central Laboratory at Delhi and 3 Regional Laboratories.

The manufacturers of technical materials of pesticides and also most of the formulation units have well equipped quality control laboratories attached to their manufacturing plants.

Besides the above, other laboratories having facilities for quality control of pesticides are the PDPI laboratory, which was established with UN Aid, and laboratories of the Agricultural Universities and National Laboratories under the Council of Scientific and Industrial Research.

INDONESIA

The pesticide requirement of Indonesia are met mostly by local formulation of imported technical materials. Some of the formulations are also imported, specially for public health purposes. Major crop is rice. Indonesia started using pesticide as an agricultural input only since last 15 years. Government is encouraging the increased use of pesticides in agri culture by subsidising the pesticides required for agricultural programmes through schemes like BIMAS AND INMAS.

The manufacture of pesticide formulation is done by private industry Government is presently establishing a Technical Pesticides manufacturing facility for the manufacture of 4 pesticides namely, Diazinon, Phenthoate, Fenthion and BPMC, in one complex. The existing formulation capacity is much in excess of requirement. It is estimated that existing formulation capacity is adequate to meet the pesticide formulation production requirement for the next 5-10 years. There are about 17 formulation units mostly based on imported plant and machinery. The pesticide Committee of the Department of Agriculture is the regulatory agency for pesticides in Indonesia. The Institute for Research and development of chemical Industry in Jakarta, under the Ministry of Industry has facilities for quality control This laboratory has recently procured analytical equipment like GC, IR, UV and HPLC. However, these are not fully being utilized, because of the non availability of well trained personnel for the purpose. There are plans to depute a few persons for training abroad in this area.

Manufatures of pesticide formulations have quality control laboratories with the required analytical facilities and personnel. Generally Indonesia relies for the quality of pesticides on the manufacturers.

AFGHANISTAN

1. Major crops are rice, wheat, maize, cotton and fruits. Use of pesticide is quite limited, perhaps, owing to inconsistent attack of pests. Wheat, cotton and fruit trees sometimes become the target of pest. Pesticides are also used in domestic pest control, public health and for veterinary purposes.

2. Afghan Fertilizer and Agricultural Services Company, a Government Enterprise is solely responsible for importing,storage, distribution and sale of pesticides in this country. It has one Central Ware-house in Kabul, 28 depots in the 28 Provinces and about 550 licensed retailers. Price of pesticides is fixed by the Government, and it is no "no loss no profit" basis. Farmers can buy pesticides both from the depots and the retailers. Pesticides are also available for purchase from the street dealers who have no license. Quality is too uncertain there (Street dealers).

3. A few of the pesticides like methyl parathion 50 EC, Trichlorofor 80 WP and BHC dust which were found in central warehouse seemed to have undergone deteriorati n. No quality control facility is available in the country. All concerned with procurement and distribution and sale of pesticides feel that quality control facilities should be developed without any delay. One pesticide laboratory is being set up with the assistance of UNDP/FAO. It may need more than one year yet to start any analytical work there.

4. No specification is followed for procurement of pesticides and no preshipment inspection is got done. Some FAO specification as needed by them have recently been supplied to them by FAO. Rome at the request of the Consultant (Amin). A final report on "Quality Control of Pesticides and other related matters in Afghanistan" has been submitted to UNIDO,

Vienna for approval and then consideration for the Government of Afghanistan. The report deals in details on the matter.

5. Azinphos methyl, malathion, oxydemiton methyl, BHC, propoxur, parathion methyl, fenitrothion, trichlorfon, copper oxychloride, sulphuf, phenyl- murcury acetatec, 2,4-D sodium salt, aluminum phosphide (tablets) and zinc phosphide are considered to be important pesticides. Farmers prefer methyl parathion as they find it to be very efficacious.

SRI LANKA

1. The major crops using pesticides are rea, rubber and paddy. Copper and sulphur play important part. Other important pesticides are diuron, simazine, paraquat, parathion and propanil.

2. Malathion and fenitrothion are used only in mosquito control. Free import of pesticides is permitted which meet international specifications. An act to control pesticides has been passed but not being implemented now. Pesticide laboratory has very limited facility for quality control. The laboratory suffers very much from resignation and transfers of trained staff. Standard methods for quality control are needed

RECOMMENDATIONS:

1. Specifications for quality control should be fixed and be made uniform in the regional countries wherever possible. International specifications like FAO, WHO can be follwed wherever possible.

2. It should be made obligatory for all manufacturing units to have well equipped and well manned quality control laboratories. The self inspection system being followed in Korea can be considered for adoption.

3. Controlling agencies of the Government should have facilities form periodic and random checking of samples and enforcing legal sanctions on inferior product manufacturers. Regional laboratories under a central controlling laboratory can efficiently function.

4. Training programmes on quality control may be oragnized for the benefit of formulation manufacturers. There is need for training in modern methods of quality control.

# SOME INFORMATION CONCERNING CIPAC

by

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## 1. Aims of CIPAC

The sigla CIPAC means "Collaborative International Pesticides Analytical Council Limited". It is an international non-governmental organization whose aims are:

a) to promote international agreement on:
   - methods for the analysis of pesticide products and of such other substances as the council may, from time to time determine;
   - methods for the physico-chemical evaluation of technical pesticide materials and formulations;
   - methods for correlating biological efficacy with physical and chemical properties of pesticide products.

b) to foster inter-laboratory collaborative analysis among interested laboratories.

c) to sponsor symposia to encourage the development of, and to promote discussion on, new or better methods of analysis and physico-chemical evaluation of pesticide products.

d) to publish from time to time:
   - agreed methods;
   - reports on the work carried out on such agreed methods;
   - proceedings of symposia;
   - any other appropriate material.

e) to collaborate with other organizations and persons concerned.

## 2. Members

CIPAC groups three kinds of members:

- the full members who are official analytical chemist personally apponted on the basis of their competence in the pesticide analysis,

of their contribution to collaborative studies and of their agreement to promote the CIPAC aims. Only onf full member is appointed per country.

- the correspondents who are representatives of official international organizations (AOAC, EED, FAO, ISO, WHO) or official national scientists who have contributed to CIPAC collaborative works.

- the observers who are scientists from official national laboratories invited to attend the annual meeting and to join CIPAC in its collaborative studies.

Moreover, CIPAC has established a close liaison with industry through GIFAP (International Group of National Associations of Manufacturers of Agrochemical Products), and invites scientists from industry to attend the annual meeting as Expert Witnesses for reporting and discussing on the analytical problems on pesticides from their own industry.

## 3. Organization of the Work

The main aim of CIPAC consists in the standardization of analytical methods and physico-chemical tests for evaluating the qualities of pesticide formulations. Any problem related to the residues is outside the scope of its activity.

The organizati n of the work for the standardization of a method can be summarized as follows:

a) Allocation of the leadership

The responsibility to study the methods and to carry out the collaborative trials is generally allocated to the member from the country where the pesticide is synthetized and is, or has been patented for the first time.

In countries with important pesticide production, the CIPAC member organizes a national committee grouping official and industry scientists in view to be helped in his work. He creates also sub-committees, panels or groups, the the chairmanship of which can be given to official or indstry scientists.

b) Survey of methods

Several analytical techniques can be used for determining the a.i. content. Therefore, before undertaking the preliminary trials, it is useful to gather information on the methods used in different laboratories generally by means of a letter-questionnaire.

c) Selection of methods

Depending on the replies, the leader can select one or several methods and investigates them in order to define the advantages and disadvantages of each of them.

d) Confirmatory trials

After having completed this investigation, the leader can decide on the method to be proposed to a collaborative study at an international level. However, before carrying out this collaborative study, it is recommended that the selected method be tested by two or three other laboratories in order to ascertain that the description of the method does not allow different interpretations which could render the method not workable.

e) International collaborative study

When the confirmatory trial has proved that the method is suitable and workable, a collaborative study is carried out on an international level.

For solicitating the participation to this study, the CIPAC Secretary sends an information letter to every members, AOAC and GIFAP, specifying:

- the name of the pesticide to be studied;
- a short description of the proposed method;
- the kind and the number of samples to be analyzed;
- the name and address of the leader.

f) Report of the international collaborative study

As soon as the leader has received back the results, he writes a detailed report in which the repeatability and the reproductibility of the method are calculated according to standard statistical analysis methods, and he presents his report at the CIPAC annual meeting.

g) Standardization and publication of methods

When the report proves that the method is workable and suitable, it is adopted at the annual meeting with the status "full method."

When the report proves that the method is not entirely satisfactory, it is adopted with the status "provisional method." When several methods have been standardized, only one is declared as the referee method and is to be used in case of dispute.

h) Publication of methods

The full and provisional methods are published from time to time in CIPAC Handbooks and Proceedings.

## 4. Organization of the annual meeting

CIPAC organizes an annual meeting called "technical meeting" in member countries in rotation.

The objectives of the meeting are:

- the study of the analytical methods and physico-chemical tests proposed for standardization;
- the review of the pesticide active ingredients for which methods of analysis are desirable;
- the review of the physical properties of the pesticide formulations for which physico-chemical tests are desirable;
- the supply of reference products;
- the allocation of the leadership for carrying out the collaborative studies;
- any other problems related to the CIPAC aims.

This technical meeting is open to members, correspondents and observers. However, recognizing the help from industry, a part of the meeting is open to their scientists who are invited as Experts Witnesses.

Moreover, since 1967, a one-day symposium is organized in which papers are presented to a larger audience, on the following subjects: analytical methods, physico-chemical tests, impurities in technical products, specifications and any other subject dealing with the chemistry of pesticides but excluding residues.

## 5. Availabitlity of the CIPAC methods

The CIPAC methods are available to organizations, institutions and individuals but on the condition that the CIPAC source is quoted. They are extensively used by FAO and WHO as bais of the clauses included in their specifications, by national organizations for pesticide registration purposes and by industry for their own specifications.

APPENDIX 6

## SCOPE OF QUALITY CONTROL PRACTICES

| | COUNTRY | PRE DISTRIBUTION STAGE | | | | POST DISTRIBUTION STAGE |
|---|---|---|---|---|---|---|
| | | IMPORTED | | LOCALLY PRODUCED | | |
| | | TECH MAT. | FORMULATED | TECH MAT. | FORMULATED | |
| 1. | Bangladesh | A | A | - | A | B |
| 2. | India | E | - | B/E | B/E | B |
| 3. | Korea | E | - | B/E | B/E | B |
| 4. | Nepal | C | C | - | - | C |
| 5. | Pakistan | B/E | B/E | E | B | B |
| 6. | Philippines | B/E | B/E | E | B/E | B |
| 7. | Thailand | B/E | B/E | - | B/E | B |

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A - Mandatory by enforcement agency

B - Monitoring by enforcement agency

C - Optional by enforcement agency

E - Self-inspection by manufacturers

APPENDIX 6A

# Some Notes On Pesticide Quality Control

by

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## 1. Introduction

A technical product of a pesticide active ingredient is rarely suitable to be used as such in the field. Therefore, it has to be formulated.

This definition means a set of processes consisting in presenting an active ingredient in such a form that it develops a maximum biological efficacy in a given pesticide application technique, but remaining in acceptable economical limits.

This definition involves to know:
- the chemical and physical properties of the a.i.
- the application techniques : e.g. dusting, spraying ...
- the biology and behavior of pests.
- the industrial engineering processes.
- the chemical and physical properties of the formulation adjuvants and their action on the biological efficacy.
- the toxicity, secondary effects and risks of pollution.
- the industrial economical laws for reducing the production cost.

Whatever the physical state of the technical material, the formular must be able to present it in different types of formulation by choosing the appropriate formulation adjuvants and industrial processes.

The formulation is an art and that explains why different commercial products based on the same active ingredient content behave differently in the field.

The aim of a quality control is therefore to check that the chemical and physical characteristics of a commercial product shall be appropriate for obtaining a good performance in the field and to protect the pesticide users against the poor quality products.

The quality control must be based on two aspects:
- the chemical one consisting in the checking of the active ingredient content and of the absence of harmful impurities.
- the physical one consisting in the checking of the conformity of the physico-chemical properties of the product with the application technique.

2. Chemical Quality Control

This control is based on the availability of chimical analytical methods.

A perfect method should fulfill the following requirements:
- accuracy : giving the true value.
- precis ion or repeatability : giving the true value with a very low degree of variability in replicate analysis by the same or different analyst in the same laboratory.
- reproductivity : giving the tru value with a very low degree of variability in analysis in different laboratories.
- specificity : giving only the active matter to be determined and excluding any related compounds or interferences.
- practicability : not involving too much sophiscated apparatus and reagents not easily available.
- economy : not too much time consuming and applicable in routine work.

Moreover, in some particular cases, such as determination of toxic impurities in technical material and in formulations, or of pesticide residues, two other requirements are to be added :
- detectability : for measuring extremely small concentrations.
- sensitivity : exhibiting a high degree of response for small changes in concentration.

Of course, a perfect method does not exist. In practice, the analyst has to define what requirements the method must fulfill depending on the particular analytical problem he has to solve, and on the availability of equipment and facilities (special apparatus, reagents, ...).

As you know, many different methods are available, based on different analytical techniques :
- gravimetry
- titrimetry
- spectrophotometry (UV, visible, IR)
- electrometry (alectrolysis, polarography)
- chromatography (column, thin layer, gas-liquid and performance liquid chromatography)
- mass spectrometry.

It is one of the basic objectives of this meeting to exchange information on these techniques and on the standardization of the analytical methods, and we shall discuss deeply this matter later on during the meeting .

3. Physico-chemical Quality Control

This quality control is very important, because the performance of pesticide treatment depends mainly on the physical characteristics of the formulations.

Let us consider the different types of formulations, giving for each of them the basic requirements to ensure a suitable pesticide treatment.

## 3.1 Dusting Powders (DP)

Dusting is an application technique in which a powder is dispersed as a cloud of particles by means of an air stream which is deposited on the target by gravity.

Properties :
- to flow easily, freely and regularly from the hopper into the air stream and to be wholly dispersed in order to ensure an uniform deposit on the target.
- to adhere on the target to be protected.
- to contain an appropriate particle size distribution. Too many fine particles mean a danger of drift, too many coarse particles mean a very poor covering ratio on the target.
- to be free of particles agglomerates.

## 3.2 Wettable (or water dispersible powders) (WP)

Wettable powders are applied by spraying a liquid in which they are dispersed as a suspension.

Properties :
- to be wetted easily and immediately
- to be dispersed easily in water forming a suitable suspension
- to be maintained in suspension for a sufficiently long time
- to be free from stable foam
- to be free from coarse particles or non-dispersible agglomerates which could cause the blockage of spray nozzles.
- to wet the target and spread on it to ensure a good covering ratio.

## 3.3 Solutions

Three (3) types of solutions are available.

### 3.3.1 Soluble Concentrates (SC)

They are liquid, homogenous formulations to be applied as true solutions of the active ingrdient after dilution in water.

Properties :
- to be free from extraneous insoluble matters.
- to give clear solution after dilution in different hard waters.
- to be not subject to crystallization when stored in cold conditions.

3.3.2 Ultra-low Volume Liquids (ULV)

They are homogenous liquids ready for use through ULV equipment.

Properties :
- to be free from extraneous insoluble matters.
- to have a flash point as high as possible.
- to be sufficiently viscous.
- to be adequately volatile
- to be not subject to crystallization when stored in cold conditions.

3.3.3 Oil Miscible Liquids (OL)

They are liquid, homogenous formulations to be applied as a homogenous liquid after dilution in an organic liquid.

They must possess the same properties as those defined for ULV formulations but in addition they must remain clear after dilution in the recommended organic liquid.

3.4 Emulsifiable Concentrates (EC)

They are liquid, homogenous formulations to be applied as an emulsion after dilution in water.

Properties :

- to be free from extraneous insoluble matters.
- to be free from water
- to form a stable emulsion for a given period of time, when diluted in different hard waters and to reemulsify easily after a long standing.
- to be free of stable foam
- to have a flash point as high as possible
- to be not subject to crystallization when stored in cold conditions.

3.5 Suspensions (or flowable) concentrates (SC)

They are stable suspensions of active ingredients in a fluid intended for dilution with water before use.

Properties :
- to be homogeneous or to be easily homogenized with a minimum agitation of the container.
- to flow easily when poured out of the container.
- to be dispersed spontaneously in different hard waters and to be maintained in suspension for a sufficiently long time.
- to be free from stable foam.
- to be stable during storage, especially free from cystal growth, bleeding, claying, caking, gelling, thickening and skinning.

3.6 Granules

Three kinds of granules are available.

3.6.1. Water soluble granules (SG)

They are formulations consisting of granules to be applied as a true solution of the active ingredient after dissolving in water but which may contain insoluble inert ingredients.

Properties :

- to be easily and rapidly dissolved in water
- to form a clear solution, but in certain cases, a small amount of insoluble material is allowed (e.g. anticaking agents).
- to be free from coarse particles or undissolved agglomerates which could cause the blockage of spray nozzles.
- to be stable when stored, especially to be not subject to caking.

3.6.2. Water dispersible granules (WG)

They are formulations consisting of granules to be applied after disintegration and dispersion in water.

Properties :

- to be disintegrated and dispersed easily and rapidly in water.
- to form a suitable suspension which is stable for a sufficiently long time.
- to be free from coarse particles or non-dispersible agglomerates which could cause the blockage of spray nozzles
- to be free from stable foam.
- to wet the target and spread on it to ensure a good covering ratio.

3.6.3. Granules (GR)

They are free flowing solid products of a defined granule size range ready for use.

Properties :

- to flow easily, freely and regularly from the hopper.
- to possess a suitable granule size range which is defined by a lower and upper limit and by the ratio between these limits.
- to be free of dust, especially toxic dust.
- to be not friable nor abrasive
- to be not hygroscopic
- to allow a suitable desorption and diffusion of the active ingredient.

4. Comments

That lists the properties to be evaluated for the main pesticide

formulations. Theoretically all these properties should be included as clauses in a specification. But, of course, a clause must must always be based on an analytical method, and presently such analytical methods are not yet available for all the clauses. Researchers are carried out for filling the gap, but many CIPAC methods are already available and published in CIPAC Handbooks.

An important property is to be added to every formulations. It concerns the chemical and physico-chemical stability during storage. It is not always proved that a relationship exists between a heat stability test in the laboratory conditions and what really occurs in the storage practice. But it is useful to foresee such a heat stability test together with clauses on water content and alkalinity-acidity - pH and other chemical and physical properties.

In Table 1, I have summarized :

- the main physical properties .
- the aim of every property
- the formulations to which the property is applicable
- the availability of CIPAC methods
- the normal limits

Of course, I must point out that all this information is to be considered in respect of each particular pesticide and that modifications or alterations of methods, normal conditions and limits are to be brought depending on each particular case.

TABLE 1

AIM OF THE PHYSICAL PROPERTIES AND AVAILABILITY OF CIPAC METHODS

| | Physical Property | Aim of Property | Applicable to formulations* | Availability of CIPAC Methods | Normal limits |
|---|---|---|---|---|---|
| 1. | material soluble/insoluble in a solvent | to determine the purity or impurity of the product | TC, SL. | Soluble: MT.4,5,6,7,9 71, 76, 87, 90 Unsoluble: MT.8,10,11, 16, 27, 35 | depending on the act. ingred. |
| 2. | acidity-alkalinity-pH | to ascertain decomposition of the act. ingred., deterioration of physical properties, danger of corrosion. | TC, DP, WP, GR, EC, SL, UL, SC | MT. 31, 66, 75 | depending on the act. ingred. |
| 3. | Water content | id. | TC, DP, WP, GR EC, SL, UL | MT. 17, 30, 40 | depending on the formulation |
| 4. | dry sieve test | to limit particles of unwanted sized | DP, GR<br>DP, GR | MT. 59<br>MT. 59 | Max. 2% on 150 um<br>5% on 75 um |
| 5. | flowability | to ascertain the free flowing nature of the product | DP, GR | MT. 44 revised (for DP) no method for GR | max.: 12 |
| 6. | dustability | to ascertain the ability of dust to be dispersed | DP | No CIPAC method, but WHO/EQP/4R2. | |
| 7. | wet sieve test | to avoid the blockage of spray nozzles | WP, SC. | MT. 59.3. | Max.: 2% on 75 um |
| 8. | suspensibility | to determine that a sufficient amount of a.i. is still in suspension to give a satisfactory, homogeneous and effective spraying. | WP, SC | MT. 15 (for WP) | min. 50% but mainly depending on the a. i. |
| 9. | wettability | to ascertain the product is rapidly wetted when added to water | WP | MT. 53 | max.: 1 min without swirling. |

| Physical Property | Aim of Propoerty | Application to formulations* | Availability of CIPAC Methods | Normal limits |
|---|---|---|---|---|
| 10 persistent foam | to avaoid exessive foam when filing the spray tank | WP, EC, SC | MT. 47.1<br>MT. 47.2 (For SC) | max.:25 ml after 1 min. |
| 11. flash point | to evaluate the danger of flammability | EC, SL, UL | MT. 12 | depending on nat. or interr regulations |
| 12. viscosity | to evaluate the flow properties of liquid | UL, SC | MT. 22 | depending on the formulations |
| 13. emulsion stability | to evaluate the stability of the emulsion on standing | EC | MT. 36, 20 | Cream : max. 4ml after 2 hours<br>free oil : nil |
| 14. re-emulsification | to evaluate the ability to be re-emulsified after standing | EC | MT. 36 | Cream : max. 4 ml<br>oil : max. 0.5 ml<br>after 30 min. |
| 15. pour-tap bulk density | to provide information for packaging and application requirements | DP, WP, GR. | MT. 33 | depending on the f formulations |
| 16. dispersability | to assure that the product is adequately dispersed throughout the spray tank | WP, SC | MT. 160 (for SC) | not yet fixed |
| 17. cold test | to evaluate the danger of crystallization or separation of ingredients in cold climate | EC, SL, UL, SC | MT. 39 | separation less than 0.3 ml at 0°<br>for 7 days |
| 18. heat stability | to evaluate the influence of temperature and time on the chemical and physical stability | DP, WP, EC, UL SC, GR, SL | MT. 46 | Normal conditions<br>54°C for 14 days |



* Code of Formulations :

| | | | | | |
|---|---|---|---|---|---|
| TC | : | Technical | SL | : | soluble concentrate |
| DP | : | dusting powder | UL | : | ULV formulations |
| WP | : | wettable (water-dispersable) powder | GR | : | granules |
| EC | : | emulsifiable concentrate | SC | : | suspension concentrate |

## SPECIFICATIONS

| | Country | National Standard | FAO/WHO | Manufacturers | Others |
|---|---|---|---|---|---|
| 1. | Bangladesh | Bangladesh Standard Inst. specification - F | M | B | India Standard Institute |
| 2. | India | India Standard Institute specification - M | A | B | |
| 3. | Korea | NAMIO specification - M | F | M | |
| 4. | Nepal | - | F | - | ISI specification |
| 5. | Pakistan | Pakistan Standard Inst. specifications only 28 so far | M | B | ISI BS US AID |
| 6. | Philippines | - | F | M | |
| 7. | Thailand | - | F | M | |

Following countries contemplating adopting National Standards based on FAO/WHO specifications and using CIPAC/AOAC methodology: Philippines, Thailand.

M - Mainly

F - Few

A - Where National specifications are not available

B - Where no National/International specifications are available.

APPENDIX 8

## QUALITY CONTROL LABORATORIES/FACILITIES AND EQUIPMENT

| Country | Quality Control Organization | Laboratories of the Enforcement Agencies | Facilities Available | Laboratories of the Manufacturers | Facilities Available | Others | Remarks |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Bangladesh | Plant Protection Wing of the Dept. of Agricultural Extenstion. | Pesticide Laboratory of the Dept. of Agricultural Extension | Facilities available for chemical and instrumental methods of analysis including 4 GC, 1 UV, 1 IR and 3 TLC sets (expected to receive 1 HPLC) | Quality control laboratories available in a few manufacturing units | 3 sets TLC, 1 GC, 1 Spectrophotometer (in future 1 GC 1 HPL) | | Quality control facilities at the manufacturers' end need strengthening. |
| India | Ministry of the Central Agriculture and for Dept. of Agriculture of the State Gov't. | Central Insecticide Laboratory under the Ministry of Agriculture and 31 Pesticide Testing Laboratories of the State Givt. (3 more State laboratories being set up for regional laboratories) | CIL is equipped with facilities for chemical and instrumental methods of quality control. Also Bioassay testing toxicology studies. Instruments for quality control include 2 GCS, 1 IR, 1 UV, 1 polarograph. Some State Pesticide testing labs well equiped while others need strengthening (1 HPLC available). | Quality Control Tech Manufacturers of pesticides and also formulators. | Facilities available for Physican and chemical testing of pesticides. Quality control labs of small scale formulators need strengthening. | ISI Lab and PDPI Laboratory equipped for quality control of pesticides. Instruments include HPLC. | Quality control facilities of small scale formulators need strengthening. Also facilities of some State pesticide testing laboratories need strengthening. |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|
| Korea | National Agricultural Material Inspection office (NAMIO) of the Ministry of Agriculture. | NAMIO Laboratory | Laboratory equipped for physical, chemical and biological inspection of pesticide instruments include 5 GC, 4 LC liquid chromotograph 2 UV, 1 IF spectro photo meters and other analytical instrument (HPLC). | By rule manufactures are required to have well equipped quality control labs including facilities for physico-chemical and biological testing. | Facilities available good including GC and HPLC. | | |
| Nepal | Department of Agriculture | No separate quality control laboratory. Presently quality control being done in other Govt. labs like Royal Drug Research Laboratory Agricultural Dept. Laboratory Food Research Labs etc. | 1 AAS, 1 GC 1 UV. TLC facilities for conventional materials of analysis. | | | | Independent Pesticide Quality control Laboratory need to be established. |
| Pakistan | Pakistan Agricultural Research Council | Federal Pesticide Research Laboratory, Karachi and Provincial Laboratory at Punjab Province. | FPRL equipped with facilities for physico chemical testing of pesticide and residue analysis Instrument include 2 GC, 1 HPLC, 2 UV and 1 IR spectro photometer. | Manufacturers laboratories need strengthening in terms of of equipment and personnel. (One manufacturer has facilities). | IR | | Plans to have 5 more regional laboratories have been finalized. |

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| Philippines | Fertilizer and Pesticide Authority | Pesticide Analytical Laboratory of the Bureau of Plant Industry. | Analytical facilities include 1 HPLC and 5 GC, 1 UV, 1 IR, 1 TLC set |
| Thailand | Pesticide Authority of the Department of Agriculture | Laboratory of the Agricultural Toxic Substances Division of the Dept. of Agriculture | Facilities include 2 GC 1 HPLC, 1 UV 1 IR, 1 Atomic Absorption Spectrophotometer and 10 TLC sets. |

| 5 | 6 | 7 | 8 |
|---|---|---|---|
| Most of the formulation plant have quality control laboratory | Facilities in these laboratories include analytical instruments like GC, HPLC and UV spectrometers | | |
| The manufacturers of pesticides formulation have quality control laboratories. | These labs are equipped with facilities for physico chemical analysis of pesticides | | The formulations control laboratory of the Agriculture Toxic Substance Division need strengthening Analytical instruments through available need to be operational (HPLC). Qualified Analytical Chemists required. |

## FIFTEEN MOST COMMONLY USED PESTICIDES IN THE PARTICIPATING COUNTRIES

| | PESTICIDE | FAO SPECS | CIPAC METHOD | NATIONAL SPECS |
|---|---|---|---|---|
| 1. | Carbaryl | * (1973) | * | ISI (1975), PSI (Tech) |
| 2. | Malathion | * (1979) | * | ISI (1978) BDSI, PSI(1968) |
| 3. | Methyl Parathion | * (1971) | * | ISI (1980) |
| 4. | Diazinon | * (1973) | * | ISI (1980) BDSI, PSI (1971) |
| 5. | Monocrotophos | - | - | ISI (1976) |
| 6. | Endosulfan | * (1973) | * | ISI (1978) |
| 7. | Carbofuran | - | - | ISI (1980) |
| 8. | Mancozeb | * (1973) | No suitable identification test | ISI (1978) |
| 9. | Paraquat | * (1980) | * | ISI (1982) |
| 10. | Aluminum Phosphide | - | - | ISI (1980) |
| 11. | Oxydemeton Methyl | * (1980) | * | ISI (1976) |
| 12. | Phosphamidon | - | - | ISI (1981 BDSI |
| 13. | 2,4-D | * (1984) | * | ISI (1982) |
| 14. | BPMC | - | - | - |
| 15. | Zinc Phosphide | - | * | ISI (1973) |

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* available

\- not available

APPENDIX 10

TEN PESTICIDES RECOMMENDED FOR COLLABORATIVE STUDIES AND METHOD OF ANALYSIS FOLLOWED BY PARTICIPATING COUNTRIES

| Pesticide | CIPAC | Bangladesh | Pakistan | Thailand | Nepal | India | Philippines | Korea |
|---|---|---|---|---|---|---|---|---|
| Carbaryl | IR, HPLC | IR, UV, Chemical | Chemical, GLC | EPA | AOAC | Titration, Colorimetry | GLC, UV HPLC | GLC |
| Malathion | GLC | TLC, GLC | Chemical, GLC | GLC | GLC | Colorimetry | GLC | GLC |
| Diazinon | GLC | TLC, GLC | Chemical GLC, IR | GLC | GLC | GLC, Column Chrom | GLC, HPLC | GLC |
| Monocrotophos | - | TLC, GLC | TLC, GLC | EPA | Titri-metry | Titrimetry | GLC, HPLC Titrimetry | GCL, TLC |
| Endosulfan | IR, GLC | GLC | IR, GLC | GLC | GLC | Titrimetry | GLC | GLC |
| Mancozeb | Identity test not suitable. Until an acceptable identity test is adopted, CIPAC Method MT 130 may be considered. | | | | | | | |
| Paraquat | Colori-metry | Colori-metry | Colori-metry | Colori-metry | Colori-metry | Colori metry | Colori-metry | Colory metry |
| Aluminum Phosphide | - | Chemical | Chemical | Chemical | Chemical | Chemical | - | Titrimetry |
| Phosphamidon | - | Chemical GLC | Potentia-metry, GLC | GLC | - | No info | GLC | GLC |
| Zinc Phosphide | Chemical | Chemical | Chemical | Chemical | Chemical | Chemical | - | - |

APPENDIX 11

## PROPOSED LEAD COUNTRIES AND COLLABORATING COUNTRIES FOR COLLABORATIVE TRIALS OF ANALYTICAL METHODS

| | Pesticide | Lead Country | Collaborating Countries |
|---|---|---|---|
| 1. | Carbaryl | India | Bangladesh, Pakistan |
| 2. | Malathion | Bangladesh | India, Korea |
| 3. | Diazinon | Korea | India, Philippines |
| 4. | Monocrotophos | Thailand | India, Philippines |
| 5. | Endosulfan | Philippines | Pakistan, India |
| 6. | Mancozeb | CIPAC | India, Bangladesh |
| 7. | Paraquat | Korea | Thailand, Philippines, Bangladesh |
| 8. | Aluminium Phosphide | Pakistan | India, Bangladesh |
| 9. | Phosphamidon | India | Philippines, Korea |
| 10. | Zinc Phosphide | India | Pakistan |

APPENDIX 12

## PROPOSED WORKPLAN FOR THE SUB-NETWORK ON QUALITY CONTROL

1. Training

| Country | Field of Training | Proposed Duration | Proposed Location |
|---|---|---|---|
| Bangladesh | Modern instrumental methods of analysis, e.g., HPLC | 2 man-months | EPA (USA) Denmark |
| India | Advanced instrumental methods of analysis; analysis of imputities | 1 man-month | EPA |
| Korea | Analysis of impurities | 1 mm | EPA |
| Nepal | Pesticide analysis | 3 mm | Where training facility is available |
| Pakistan | Analytical instrumentation; | 2 mm | US or any 1 developed country |
| Philippines | Analysis of impurities<br>Lab techniques(residency) | 1 mm<br>2 mm | EPA<br>India |

2, Consultancy/Experts

| | | |
|---|---|---|
| India | Instrumentation and equipment maintenance | 2-3 mm |
| Pakistan | Instrumentation | 1 mm |
| Philippines | Formulation analysis | 1 mm |
| Thailand | Formulation analysis | 1 mm |

3. Study Tours/Attendance at Specialized Meetings

| | |
|---|---|
| Bangladesh | One participant to CIPAC/AOAC Meetings |
| India | ---do--- |
| Pakistan | ---do--- |
| Philippines | ---do--- |
| Thailand | Study tour to visit other Pesticide Analytical Laboratories in the region (2 man-months) |

4. Group Activities (Workshops/Seminars)

Annual workshop of one-week's duration to review and discuss the the latest developments in quality control of pesticides with two participants representing each participating country and international organizations like FAO, WHO CIPAC, AOAC and GIFAP. Venue can be decided at the next TAC Meeting.