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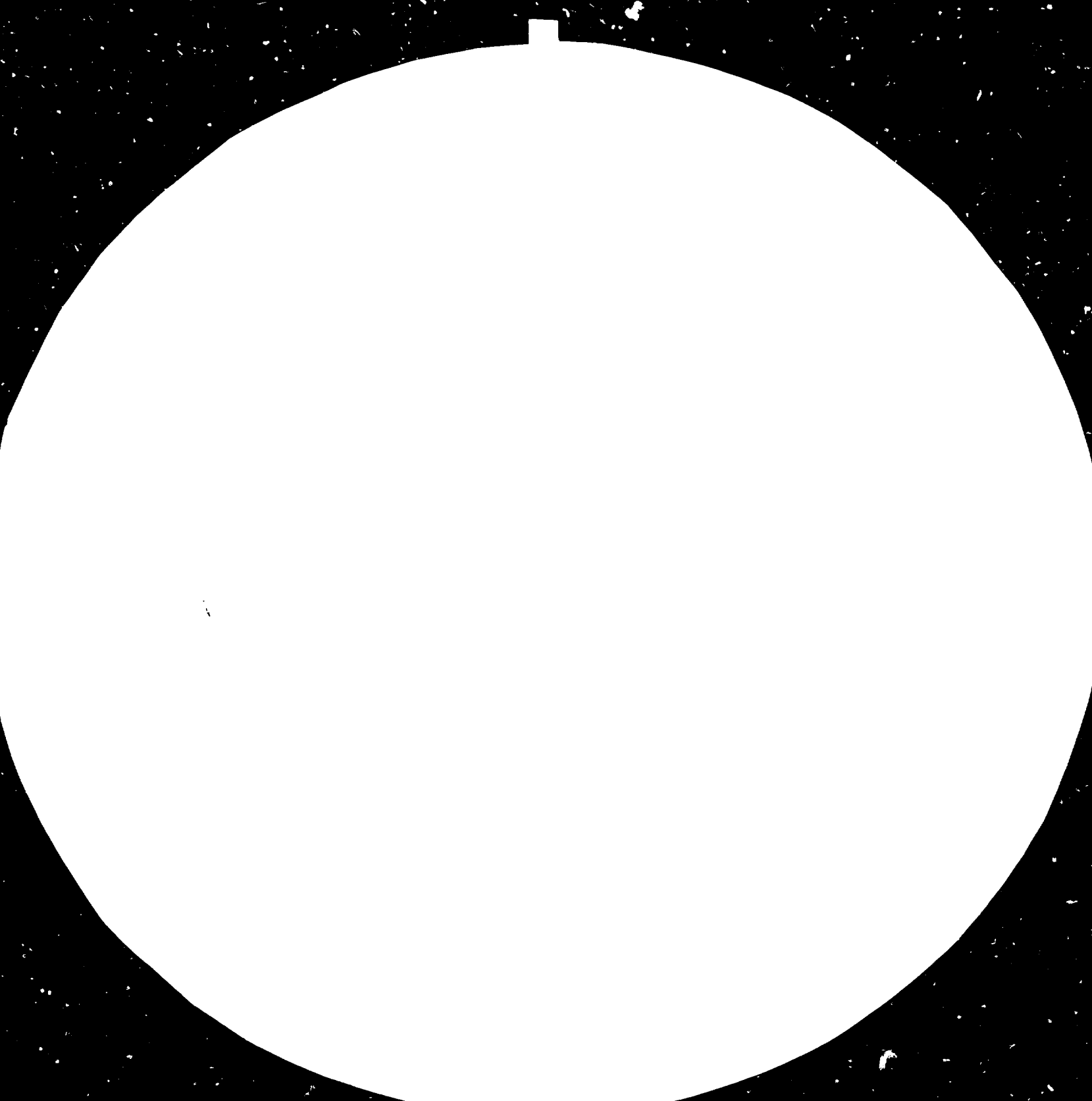

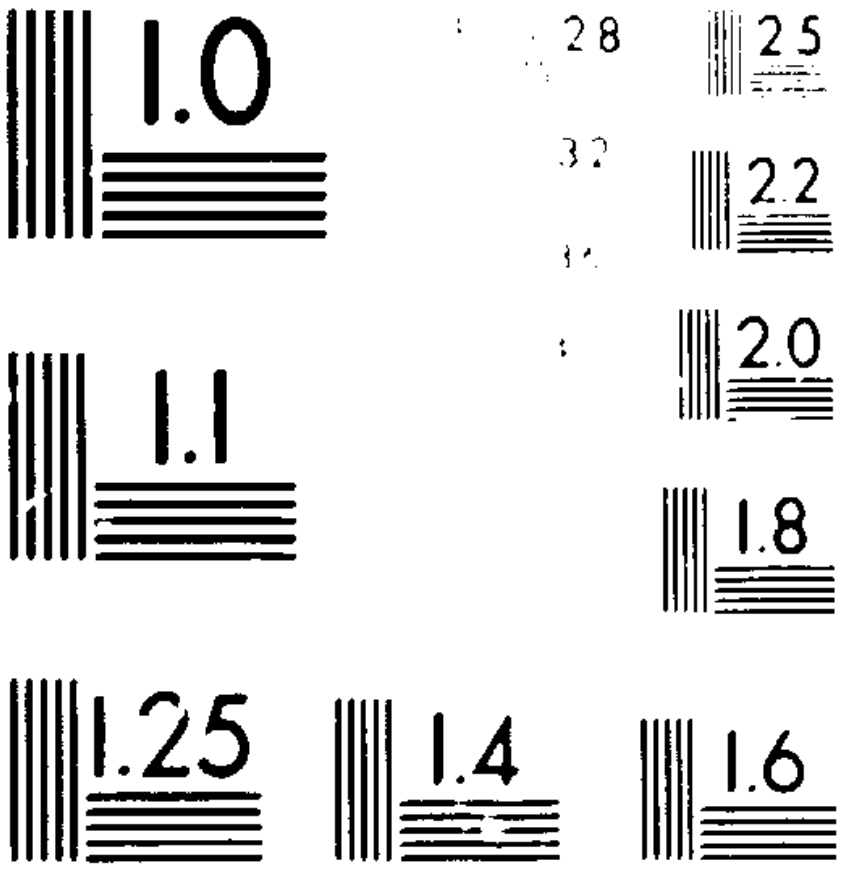

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UNITED NATIONS
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Regional Network for the Production,
Marketing and Control of Pesticides
in Asia and the Far East

Regional Consultation on Harmonization
of Pesticide Registration Requirements*

Baguio City, Philippines 24-29 October 1983

REPORT** (Pesticides registration, Asia).

DP/RAS/82/006

Prepared for the Member Countries of the Network
and other Participating Countries of the Region

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

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INTRODUCTION

1. The Regional Consultation on Harmonization of Pesticide Registration Requirements was held in Baguio City, Philippines from 24 - 29 October 1983.

2 The Meeting was attended by delegates from 11 countries, representatives of UNIDO, FAO, WHO, GIFAP, SPREP and a number of observers. A list of participants is attached (Appendix 1).

OPENING OF MEETING

3 Regional Director Manuel Varquez of the Ministry of Agriculture introduced the distinguished guests who spoke in the opening ceremonies.

4 On behalf of the Fertilizer and Pesticide Authority (FPA) Administrator Miguel M. Zosa, Mrs. Cecilia P. Gaston, Deputy Administrator for Pesticides, welcomed and wished the participants a successful conference. Participants were thanked for their continuing interest and support of the Regional Network in the task of advancing the safe and efficient utilization of pesticides. It was emphasized that the Network provided an ideal framework for this work.

5. The Mayor of Baguio City, General Ernesto Bueno welcomed the participants and wished them an enjoyable and fruitful conference in "the coldest and highest city in the Philippines."

6 The Governor of Benguet Province, Mr. Ben Palispis represented by Mr. Jose dela Cruz, Provincial Agriculturist, also welcomed the participants to the province and said that the province was a large user of pesticides because of the big vegetable production in the area.

7 Mr. Ivan Pluhar representing the UNDP Resident Representative in the Philippines, Mr. Euan Smith outlined the administrative operation of UNDP in the country. He stressed the need, for full support to be given to the Regional Coordinator by National Coordinators in the Regional Project.

8 Deputy Minister Sacay presented the keynote address on behalf on Philippine Minister of Agriculture Hon. Arturo R. Tanco, Jr. He stressed concern over the nagging problem faced by developing countries of declining production trends and emphasized the ever increasing need for optimum pesticide use, as one of the solutions to stave off a possible hunger outbreak. Minister Tanco focused on the need for the small farmer to accept crop protection as an indispensable pre-requisite for optimum production. He acknowledged that the Regional meeting was a definite step towards reducing losses of food due to pests and diseases and officially declared the meeting open.

STATEMENT FROM INTERNATIONAL ORGANIZATIONS

9 UNIDO as the agency responsible for the operation of the project stressed the importance of the meeting to fulfill the aims of the Project.

10 FAO, as an associated agency to the Project was particularly concerned with the technical backstopping of the sub-network on Regional Harmonization of Pesticide Registration Requirements and the Sub-Network on Quality Control (including residues). The subject of the present meeting was of high priority to FAO as it affected all aspects of pesticide use. Consequently, it would have a profound effect on crop protection and food production. Major objectives of harmonization were to promote safety, efficiency and cost effectiveness in pesticide use, as well as to ensure availability of the most appropriate pesticides. The FAO Government Consultation in 1982 had defined a number of important aspects of pesticide registration and control which lent themselves to harmonization. It was now up to groups of countries such as that represented by the sub-network to formally agree to use harmonized requirements, procedures and guidelines and thus draw the benefits of harmonization. It would also set the example for other regions to do likewise and in so doing contribute to international harmonization.

11 WHO, which was not a participating agency in the Network, was nevertheless concerned with all aspects of the safe use of pesticides. In this respect, it was recalled that the registration procedure for pesticides existed only to protect humans and the environment from adverse effects from pesticides, while recognizing the use of these chemicals for the benefit of human health nutrition and comfort. Therefore, every effort toward harmonization will be to the ultimate benefit of populations of the States concerned.

12 GIFAP emphasized that there was need for cooperation among countries to ensure the safe and sensible application of pesticides leading to optimum food and fibre production with minimal hazards for man, animals and the environment. The need to promote harmonization of national and international legislation and regulations concerning control, testing and approval of pesticides was supported by GIFAP.

ELECTION OF OFFICERS

13 Mrs. Cecilia P. Gaston, Deputy Administrator for Pesticides, FPA and Regional Coordinator of the Network was elected Chairman, Dr. Farid Uddin Ahmad from Pakistan, Vice Chairman and Mr. Brian Watts, UNIDO Consultant, Rapporteur of the meeting.

ADOPTION OF AGENDA

14 The provisional agenda was adopted as amended (Appendix II).

EXPLANATION OF OBJECTIVES

15 The objectives of the meeting were identified as follows:

1. To discuss the basis for harmonizing the requirements for the registration of pesticides in the Region;

2. To provide an opportunity for governments and industry to exchange views on registration requirements;

3. To agree on acceptable guidelines suitable for Regional use;

4. To assist member countries in the establishment and administration of procedures designed to provide control over the supply and use of pesticides;

5. To ascertain that action would be taken by governments to introduce harmonized requirements into national registration process.

6. To consider the need for the value of compiling data on pesticide registration on a national and regional basis;

7. To provide guidance in correlating registration requirements to the planning and promotion of investments in production and marketing of pesticides.

16 It was also emphasized that there was a need to know as to which countries had already harmonized registration requirements in the Region, which could agree to such proposals and which countries would find it necessary to reserve their position and the reasons for such reservation.

REVIEW OF CURRENT REGISTRATION STATUS IN THE REGION

17 The UNIDO Consultant summarized briefly the main aspects of his observations on the pesticide registration schemes in member countries following his visit to them. Some major similarities and differences in the registration schemes in countries were highlighted. In all countries visited the Ministry of Agriculture is the implementing agency for registration, registration is compulsory, there is power to control pesticide imports and registration schemes operate through technical advisory committees.

18 Some differences noted are in the type of data requirements for registration, colour coding of labels, and the system of hazard rating of pesticides. A brief summary of the schemes is annexed (Appendix III).

19 Also noted was the need for close cooperation between the Ministry of Health and Ministry of Agriculture, which was not always apparent in the Region. The importance of the label as an essential part of the registration process was highlighted, and it was felt that more emphasis should be placed on this by the registration authority during the registration process.

20 Country representatives presented a resume of the schemes in operation in their countries (Appendix IV).

DATA REQUIREMENTS

CHEMICAL AND PHYSICAL PROPERTIES

21 Information on chemical and physical properties is required to define the essential characteristics of both the active ingredient and the formulated product. To this end data are required to be supplied to the registration authority to enable the pesticide to be identified. Working Paper 3 (Appendix V) was used in the discussion on this subject.

22 All 11 countries partipating at the meeting as well as the pesticide industry through GIFAP agreed to accept the data on chemical and physical properties for registration purposes, as follows;

RECOMMENDATIONS

23 The Meeting

Noting that there should be no difficulty in defining the nature and extent of the information on physical and chemical properties that should be supplied in support of a registration;

Recommends that the basic data related to the active ingredient and the commercial product should include when appropriate:

ACTIVE INGREDIENT

1. Identity

   1.1 common name proposed or accepted by ISO;

   1.2 structural formula;

   1.3 chemical name (according to internationally agreed nomenclature, preferably IUPAC);

   1.4 empirical formula and molecular weight;

   1.5 manufacturers' development code number(s)

2. Physical Properties of the Pure* Active Ingredient

2.1 appearance (physical state, colour, odour);

2.2 melting/decomposition/boiling point;

2.3 vapour pressure (figures should be given at a stated temperature preferably in the range of 20-25°C, but only when above 10^{-3} Pascal);

2.4 solubility in water and organic solvents (at a stated temperature preferably in the range of 20-25°C.);

2.5 partition coefficient between water and an appropriate non-miscible solvent (eg n-octanol);

2.6 density (for liquids only);

2.7 hydrolysis rate under stated relevant conditions;

2.8 photolysis under stated relevant conditions;

2.9 absorption spectra, eg ultra-violet, visible and infra-red, ets;

3. Technical Grade Material

3.1 source; name and address of manufacturers and addresses where manufactured;

3.2 appearance (physical state, colour and odour);

3.3 the minimum (and maximum) active ingredient content in % w/w;

3.4 identity and amount of isomers, impurities and other by-products, together with information on their possible range expressed as % w/w.

FORMULATED PRODUCT

1. General Description (Identity) of the Formulated Product

In addition to the information required for the active ingredient, the general description of the formulated product to be registered should, in all cases, include:

1.1 formulator's name and address;

1.2 trade name (proprietary name);

1.3 use category (herbicide, insecticide, etc);

1.4 type of formulation (water dispersible powder, emulsifiable concentrate, etc.).

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* Pure - Active Ingredient of highest attainable purity.
(Definition provided by FAO)

2. Composition

2.1 content of active ingredient(s)*

2.2 content and nature (identity if possible) of other components included in the formulation, eg technical grade, adjuvants and inert ingredients;

2.3 water content (where relevant)

3. Physical/Chemical Properties of the Formulated Product

3.1 appearance

3.2 storage stability(in respect to composition and physical properties related to use);

3.3 density (for liquids only);

3.4 flammability: liquids - flashpoint
solids - a statement must be made as to whether the product is flammable

3.5 acidity (where relevant);

3.6 alkalinity (where relevant);

3.7 other properties may in certain cases need evaluation.

4. Physical Properties of the Formulated Product Related to Use

The following is not exhaustive for either properties or types of formulation. Some relevant test methods may be found in CIPAC Publications but other proven methods may also be used:

4.1 wettability (for dispersible powders);

4.2 persistent foam (for formulations applied in water);

4.3 suspensibility (for dispersible powders, suspension concentrates);

4.4 wet sieve test (for dispersible powders, suspension concentrates);

4.5 dry sieve test (for granules, dusts);

4.6 emulsion stability (for emulsifiable concentrates);

4.7 corrosiveness (when necessary);

4.8 known incompatibilities with other products; eg pesticides, fertilizers.

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*with more than one active ingredient information should be give on each ingredient separately.

EFFICACY AND CROP SAFETY

24 Proper assessment of the efficacy of a pesticide is an essential component of the requirements for registration. Working Paper 4 (Appendix VI) was used for this discussion. Efficacy evaluation should be based on data provided by the applicant, preferably from a zone with a climatic and crop/pest condition similar to those prevailing in the zone where the application for registration will be made. If efficacy data can be supplied in accordance with internationally agreed evaluation methods, when available, then it should not normally be necessary to repeat all the biological assessments in each and every country where the pesticide is being registered. Applications for registration should contain detailed information on the conditions under which the trials were carried out.

25 All members stressed the urgent need to develop protocols for efficacy testing against major pests of principal crops grown in the Region. It was emphasized that scarce resources were being used to develop efficacy data at national level, leading to intensive duplication of effort by not permitting transportability of data, due to an absence of test protocols.

26 All 11 countries agreed to the principle of transportability and local use of efficacy data, dependent on the development of appropriate trial protocols.

RECOMMENDATIONS

27 The Meeting

Having emphasized, the need to use harmonized methods for efficacy evaluation of pesticides;

Having noted the continuing progress in the development of such methods in particular by European and Mediteranian Plant Protection Organization (EPPO) (in collaboration, for herbicides, with EWRS) by the American Society for Testing and Materials (ASTM), by the American Phytopathological Society (APS) and by the Australian Weed Committee;

Noting the existence of "FAO Guidelines on Efficacy Data For the Registration of Pesticides" prepared by the Group on Registration Requirements of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards.

Recommends that:

(i) this document is of sufficient importance that FAO bring it to the immediate attention of governments and subsequent publication as approved FAO Guidelines;

(ii) agencies developing guidelines should be encouraged to continue their activities in this field;

(iii) in so doing, methods from different parts of the world should be compared with the aim of arriving at least at a common framework for guidelines at world level;

(iv) FAO should encourage appropriate regional organizations and institutes to establish programmes for the preparation of guidelines for the efficacy evaluation of pesticides for the control of pests, diseases and weeds of major tropical and sub-tropical crops;

(v) consideration should be given to the preparation of harmonized methods for efficacy evaluation of pesticides used in animal husbandry.

Further having emphasized that the efficacy evaluation of pesticides for registration should be based as far as possible, on consideration of all available data obtained by recognized harmonized methods;

Having considered the practical advantages to be derived from close collaboration between official agencies,manufacturers and international organizations;

Having recognized that implementation of the use of harmonized methods depends on explicit recognition of such methods by national authorities and positive commitment on the acceptability of relevant data obtained by their use;

Recommends that:

(i) efficacy evaluation should be based primarily on the data provided by the applicant, using harmonized methods and reported in a systematically presented complete dossier;

(ii) registration authorities should positively commit themselves to the recognition of particular internationally harmonized methods and to the acceptability of relevant efficacy evaluation data, produced by such methods, in other countries or regions, or from other competent source;

(iii) where resources permit the registration authority should participate in at least a proportion of the trials carried out by the applicant and, it deemed necessary, organize limited additional efficacy trials and

Having recognized that this progress does not yet extend to harmonized methods for many pests, diseases or weeds of tropical or sub-tropical crops, or for pesticide use on animals or other situations;

Further strongly recommends that UNIDO/FAO give urgent attention to coordinate and provide substantive support to the development of test protocols, through the Regional Network.

TOXICOLOGY

28 Working Paper 5 (Appendix VII) was considered. Sufficient data on toxicology were necessary to show that when used as recommended the product would not cause ill effects to those applying it, to consumers of treated crops or to wildlife. The data should permit a hazard classification of the product and indicate the handling and application precautions necessary and also should indicate diagnosis and treatment in the case of poisoning. The scope, scale and duration of the toxicological studies required will vary, depending on, amongst other things the newness of the active ingredient, the nature of the toxic effects observed, species variability, as well as the proposed use pattern and the physical and chemical properties of the pesticide and its formulation. The majority of the tests should be carried out with the active ingredient, but information may also be necessary on the acute oral and dermal toxicity and irritancy of the proposed commercial formulation.

29 Ten countries indicated they would accept toxicological data developed by companies in accordance with Good Laboratory Practice but one country required some limited local testing.

30 Five countries had accepted the WHO classification of Pesticide by Hazard, for labelling purposes, which was also supported by GIFAP, two countries said they could accept this in the future, four countries indicated that it would be necessary to amend the law before acceptance with two of the four indicating they would be prepared to consider this.

RECOMMENDATIONS

31 The Meeting

Noting the development of complementary documentation by WHO, the Council of Europe and OECD and

Recognizing that the implementation and use of such guidelines would improve the quality, mutual acceptance and relevance of the results of toxicity testing to the evaluation of possible hazards arising from the use of pesticides

Recommends that the guidance on toxicological data requirements contained in the publications by WHO and Council of Europe (see Appendix VII) be brought to the attention of all registration authorities and that they be urged to accept, as appropriate, advice therein, in particular with the view of achieving mutual acceptability of data.

RESIDUES

32 Working Paper 6 (Appendix VIII) was used as a basis for discussion. Information on the chemical nature and concentration of the residues left by a pesticide in foods and feeds after application as directed and in accordance with good agricultural practice should form part of registration application.

33 Nine countries are accepting data developed in other countries with similar climatic conditions, while two countries require local testing to be carried out.

RECOMMENDATIONS

34 The Meeting

Being aware that different countries sometimes require different types of residue data generated by very specific procedures;

Recognizing the considerable variation in current procedures for developing data and the ensuing constraints that this places on acceptance and evaluation of the data;

Noting the existence of the draft "FAO Guidelines on Crop Residue Data" (IUPAC publication in Pure and Applied Chemistry, Vol. 54, No 7 pp 1361-1450, 1982 - which was circulated on a room document)

Recommends:

(i) that this document is of sufficient importance that FAO bring it to the immediate attention of governments and arrange further review and publication as official FAO Guidelines;

(ii) that governments and industry accept and use these guidelines as soon as possible.

(iii) that governments take note of the benefits to be derived from generating and submitting data for consideration by the Joint Meeting on Pesticide Residues and Codex in order that recommendations may be made for maximum residue limits on crops being exported by countries from eithin the Region.

ENVIRONMENTAL IMPACT

35 Working Paper 7 (Appendix IX) was discussed. Before registering a pesticide each country must assess which aspects of its environment might be affected by the proposed use. It should decide the values to place on these aspects and weigh them in light of its needs under its own agricultural circumstances e.g. fish toxicity tests must be done on all pesticides used in paddy. To do this data must be provided in the registration application to allow a reasonable judgement to be made of the environmental behavior of product when used in the manner proposed. The test programme should have been designed according to the characteristics and conditions of the proposed use of the product and the test species carefully selected in order to justify broad environmental predictions from the results of the test.

RECOMMENDATIONS

36 The Meeting

Having considered the report of the Second FAO Expert Consultation on Environmental Criteria for the Registration of Pesticides: (FAO Plant Production and Protection Paper 28).

Emphasized the value of primary data on the properties of the pesticide, fate and mobility studies, data on the toxicity of the pesticide used for assessing possible hazards to man and information on use patterns as a means for predicting the fate of the pesticide in and effect on the environment; and

Recognizing that the main purpose of such studies is to provide data which determines the need for precautionary statements and limitations appropriate to minimize the potential adverse effects on non-target organisms;

Stressed that laboratory studies on environmental effects of pesticides which predict a pronounced positive effect against one or more test species should be checked by field studies where the many interacting environmental factors may exert their influence; and

Recommends that the guidance on data requirements contained in the Report of the 1981 FAO Expert Consultation on Environmental Criteria for the Registration of Pesticides and on procedures for carrying out individual tests issued by OECD be brought to the attention of all registration authorities and that they be urged to accept, as appropriate, advice therein, in particular with the view of achieving mutual acceptability of data; and

Furtner recommends that FAO commissions case studies for several widely-used pesticides to compare the potential fate in and effect on the environment as predicted crom the environmental criteria with data and experience as presented in the world scientific literature.

MODEL REGISTRATION SCHEME (FAO GUIDELINES)

37 Revised FAO Guidelines and Model Scheme for the Establishment of National Organizations for the Registration and Control of Pesticides which were intented to replace earlier guidelines were in an advanced stage of preparation. They would become available in 1984.

38 The meeting used Working Paper 1 (Appendix X) for discussions. It was pointed out that registration is the agreement by the appropriate authority that a product may be used in a defined way and is safe for the registered uses. The main purpose for registration is to provide reassurances to government and the public that pesticides when properly used, are effective for the uses claimed and will not carry unacceptable risks of harming users, consumers of treated crops, or environment in the treated area.

39 The use of a pesticide should be permitted only if the benefits outweigh the risks involved. The balance between benefit and risk will differ greatly under different socio-economic conditions, and, it is important for each country to study its own priorities when deciding what compounds may be registered and not be too much influenced by decisions made elsewhere.

RECOMMENDATIONS

40 The Meeting

Believing that each country should be able to control pesticides in its area of jurisdiction and;

Noting that many countries have already established a pesticide registration process to assess the safety and efficacy of a pesticide before it may be sold;

Realizing that after the registration of pesticides, arrangements must be made to enforce compliance with the conditions under which; the product was registered with regard to the compositional statement, labelling, packaging and availability and;

Recommends that government should implement a pesticide registration and control scheme as soon as practicable;

Further recognizing the considerable variation in the extent of control in different countries and the importance of establishing effective control, and

Noting the existance of the draft of the FAO Guidelines and Model Scheme for the Establishment of National Organizations for the Registration and Control of Pesticides.

Recommends that the draft revision is of sufficient importance that FAO should bring it to the attention of governments and after further expert review it should be published as official FAO Guidance on this subject.

COMMODITY PESTICIDES AND PROPRIETARY RIGHTS

41 The meeting considered Working Paper 2 (Appendix XI) during discussions on these subjects. Commodity products are often referred to as products which were either, never patented, or products on which the patent life had expired.

42 A pesticide product introduced and registered for the first time in a country could be considered to be a proprietary product belonging to the original (first) registrant, on the basis of the fact that as the original registrant had developed and submitted the required toxicological, efficacy and residue data, he should have the right for a period of exlusive use of that data. Subsequent registration should not be acceptable unless the applicant develops the same data or has obtained prior written authority from the original registrant to use his data.

43 It was recognized that there was a difficulty deciding whether or not a product was a commodity product using the patent life as a guide in view of the variation between countries in patent protection and life of the patent.

44 All countries kept registration data confidential and although a few were in favor of the principle of an exclusive use period being provided only one country was operating such a system. The possibility of chemical companies not supplying pesticides to countries who were not operating procedure to protect proprietary rights was raised by GIFAP.

RECOMMENDATIONS

45 The Meeting

Being aware of the problems facing registration authorities in processing applications for the registration of pesticides that are not patented and produced by two or more manufacturers, and;

Recognizing that unforseen risks could arise from the appearance on the market of products, which although copies of fully evaluated and registered products were not themselves fully tested;

Noting that a formulator purchasing an active ingredient should have the right to rely upon the proprietary data which are owned by the producer from whom he obtains the active ingredient in obtaining registration of his own formulation;

Recommends:

(i) that registration authorities proceed with caution in processing the registration of such products and only accept them when fully satisfied that the normal registration criteria for safety and efficacy have been met, paying due attention to the proprietary nature of the registration data;

(ii) that with regard to the proprietary nature of registration data submitted for new pesticides, the procedure used should provide a significant period of exclusive use to the registrant who generates the registration data, and;

(iii) that with regard to the proprietary nature of registration data submitted for new and existing pesticides that registration authorities request a registrant to certify that he generated the data or that he had permission from the original developer of the data to use that data.

Further recognizing that the public has the right to see documents related to the health and safety characteristics of pesticides and that such disclosure provides opportunity for the violation of the proprietary rights of data submitters,

Recommends that countries which provide for such public disclosure do so only under safeguards which will serve to preclude unauthorized competitive use of the data.

PHASED REGISTRATION

46 Some of the benefits of a phased registration scheme as well as some of the concerns which had been expressed were outlined in Workin Paper I (Appendix X). Nine countries were operating a type of phased registration scheme but the majority of these countries had only two clearance steps in their schemes. Two countries were not operating a phased registration scheme, but both said they were considering the introduction of such a scheme.

RECOMMENDATIONS

47 The Meeting

Recognizing that the development of a pesticide is a gradual process and;

Noting that several countries in the Network have acknowledged this fact and devised phased or stepwise registration schemes, that in all known cases have been very successful and to the benefit of all concerned;

Recommends that consideration be given to a phased approach to pesticide registration both in existing national processes and in the establishment of any new national registration authority.

EFFECTIVE NATIONAL CONTROL OF PESTICIDES

AVAILABILITY OF PESTICIDES

48 Working Paper 8 (Appendix XII) was discussed in the meeting. Some deleterious effects of pesticides may be the result of inadequate control of the supply and distribution of a pesticide in a country. In consideration of the Working Paper, the meeting agreed that the proposals contained therein to restrict the availability of pesticides by creating categories under which pesticides are restricted to specially trained classes of operators based on the WHO Classification of Pesticides by Hazard was at this time inappropriate to some countries of the region, and was therefore not acceptable. Two methods of restricting availability can be exercised by the regulatory authority, namely by imposing restrictions by not registering a pesticide or, by restricting its availability (as a condition of registration) to certain groups of users.

49 All countries present at the meeting were using one of the above methods as a means of restricting the availability of pesticides. The parameters used on which such decisions were based vary widely and must be left to the discretion of the registration authority bearing in mind the situation prevailing in individual country.

RECOMMENDATIONS

50 The Meeting

Believing that restrictions or control on the availability of pesticides can contribute to a reduction in the number of accidents with pesticides;

Recommends that registration authorities give special attention to drafting restrictions on the availability of pesticides;

SPECIFICATIONS

51 It was stressed that specifications were particularly of value in the case of older commodity products as a means of ensuring that pesticides in the market were of acceptable quality. It could also be used as a guarantee of the quality and/or as a part of a contract of sale. However certain countries were using FAO specifications for agricultural pesticides and WHO specifications for public health pesticides, respectively, as a standard when evaluating applications for registration.

52 The Working Paper 9 (Appendix XIII) on this subject was accepted by the meeting .

RECOMMENDATIONS

53 The Meeting

Recognizing that the specific composition of a pesticide and products containing it is generally regarded as a trade secret.

Recommends that data on composition submitted during the registration process should be considered "commercial-in confidence" by registration authorities.

Acknowledging that there was a great demand for international specifications, reflecting the international character of trade in pesticides.

Believing that these are necessary only when two or more manufacturers and formulators are involved.

Recommends:

(i) that specifications for all commodity products should be prepared as rapidly as possible on an international basis as FAO specifications when required by trade, or on a regional or national basis if more appropriate;

(ii) that existing FAO specifications should be reviewed where necessary and a revised edition of the FAO Manual on "Use of FAO Specifications for Plant Protection Products" be prepared and published as soon as possible.

LABELLING

54 Working Paper 10 (Appendix XIV) was used as the bases for discussion on this item. It was emphasized that the acceptance of the pesticide label is one of the main responsibilities of the registration authority. The importance of the label and the information it contains cannot be over-emphasized. The label should provide technical information, instructions and advice from the supplier of the pesticide to the purchaser as well as to end users of the product. In those cases where all the required information will not fit on the container, a leaflet could be used, subject to the legal requirements of the country and if such a leaflet is used it should be considered as an extension of the label. The safe and effective use of pesticides depends to a large extent on the completeness and clarity of the statements made on the label, the users understanding of this advice and his compliance with them.

RECOMMENDATIONS

55 The Meeting

Recognizing the importance of providing users and others involved in the handling of pesticides with clear, concise and adequate directions for their safe and effective use, transport, storage and disposal;

Recommends that requirements for labelling pesticides should be harmonized to the maximum extent possible and, to this end, that labels should include the following information:

1. Identification

1.1 Trade name;

1.2 The use category of the product (e.g. insecticide, acaricide, herbicide);

1.3 The names of all active ingredients and their concentration in the product, expressed on a weight/weight basis (g/kg) or weight/volume (g/liter) as the case maybe with the active ingredients being designated by the ISO common name or, if not available, the national common name(s) or the chemical name;

1.4 The name and address of the manufacturer/distributor and/or company responsible for marketing the product;

1.5 Type of formulation;

1.6 Main uses;

1.7 Weight of the contents of the pack (or volume for liquid preparations);

1.8 Manufacturing lot identification; and data of manufacture (shown by month and year) and as an option depending on local requirements, the expiry date.

1.9 Registration number (where required).

2. Precautions

2.1 Appropriate and clear indications of the degree and the type of hazard, using the relevant warning of risk symbols, should appear on the label, when the nature of the formulated product makes it necessary. These should be in keeping with a harmonized Classification of Pesticides by Hazard, preferably that proposed by WHO;

2.2 Appropriate instructions, in the form of standardized safety phrases, for the protection of consumers, operators, livestock, domestic animals, environment and third parties;

2.3 The recommended first aid, antidote (if any) and other information for physicians as required by the appropriate health authorities when the toxicity of the formulated product warrants it;

2.4 For each use, and where appropriate there must be a suitable statement to show the period that must elapse between application of the product and:

- sowing or planting
- harvesting, use or consumption
- sowing or planting of subsequent crop

3. Direction for Use

Directions for use are supplied by the manufacturer in accordance with the type of formulation and application detail specified. These directions include application rate, method, and as far as required the number and time of application.

4. Information and/or Advice on Storage and Disposal

Advice should be given on the label on how to dispose of empty containers as well as unwanted or contaminated product. Guidance on safe storage should also be given on the label.

Recognizing the advantage of a system of standard phrases for instructing users and others in the precautions necessary to ensure human and environmental safety, and;

Having examined the Guidelines on Good Labelling Practice for Pesticides prepared by FAO and endorsed by the Group on Registration Requirements of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards.

Recommends these guidelines should be adopted and used by industry in preparing labels and by registration authorities in the acceptance and approval of labels.

Further believing that recent developments in the use of graphics/pictograms to convey label information may be useful, particularly in countries where users are or may be illiterate;

Recommends that FAO take a lead role in promoting the use of a more extensive use of graphics/pictorgrams in pesticide labelling, and one harmonizing symbols, and colour coding, based on hazard, currently used on labels.

PACKAGING AND STORAGE

56 In discussions on this subject Working Paper 11 (Appendix XV) was used. Containers must be strong enough to withstand the rigors of transport, they must be impervious and they must be constructed of such materials so as not to affect the contents of the containers. Many registration authorities require details of the packages to be used, as part of the registration requirements.

RECOMMENDATIONS

57 The Meeting

Being aware of the inter-relationship of suitable packaging for pesticides and adequate storage standards and;

Recognizing the importance of good packaging and storage in reducing risks from pesticide by sometimes avoiding the need to tackle difficult disposal problems;

Noting the existence of draft "FAO Guidelines for the Packaging and Storage of Pesticides";

Recommends that the document is of sufficient importance that FAO bring it to the immediate attention of government and subject it to further expert review and subsequent publication as official FAO Guidelines.

DISPOSAL

58 Working Paper 12 (Appendix XVI) on disposal of surplus pesticides and pesticide containers was considered by the meeting. It was pointed out that disposal of surplus pesticide and pesticide containers is a problem throughout the world. Little practical information on disposal is published although the Council of Europe had prepared a chapter in their bookiet "Pesticide" 5th Edition on the subject (Background Paper L). The meeting was informed that a Consultant was to commence work for FAO to prepare Guidelines on Disposal.

RECOMMENDATIONS

59 The Meeting

Recognizing that disposal problems may often arise from inadequate packaging and storage of pesticides; and

Believing that guidance on the disposal of pesticides and pesticide containers is vital in minimizing the environmental damage which may be caused by careless disposal of pesticides;

Noting the existence of Guidance on the Disposal of Surplus Pesticides and Pesticide Containers prepared by the "Council of Europe";

Recommends that the document is of sufficient importance that FAO bring it to the immediate attention of governments and develop guidelines based upon it for expert review and subsequent publication as FAO Guidelines.

CODE OF CONDUCT

60 The meeting was informed that FAO, in consultation with other concerned agencies and international organizations, had drafted a "Code of Conduct on Distribution and Use of Pesticides." The draft Code aimed at identifying potential hazards associated with the distribution and use of pesticides and defining the actions needed as well as the responsibilities of the various parties concerned (e.g., governments, manufacturers, distributors, users).

61 The draft was to be sent to Member Governments and appropriate international organizations for comment. Comments received would be taken into consideration in preparing a revised draft Code which would be discussed at a Government Consultation in Rome, tentatively planned for the period 25 to 28 June 1984. The preparation of the Code was being coordinated with other related activities within the U.N.

CONSIDERATION OF THE REPORT OF THE SECOND GOVERNMENT CONSULTATION OF INTERNATIONAL HARMONIZATION OF PESTICIDE REGISTRATION REQUIREMENTS ROME 1982

62 The report of the above Consultation which was held in Rome from 11-15 October 1982 was available to the meeting as Background Paper M. It was of considerable interest as reflected in the wide demand for copies. Many countries throughout the world had already adopted or were considering adopting many of the recommendations of the Consultation which was attended over 120 persons representing 42 countries as well as 11 U.N. agencies and other organizations.

63 FAO had followed up the recommendations directed to it during the Consultation.

IMPLEMENTATION AT NATIONAL LEVEL AND COORDINATION OF ACTIVITIES IN THE REGION.

64 The UNIDO Consultant presented a paper prepared by him on Proposals for the Harmonization of Pesticide Registration Requirements for the Regional Network for Production, Marketing and Control of Pesticides in Asia and the Far East (RENPAF).- Background Paper N. Most points outlined in this paper were discussed in preceeding sessions of the meeting, but in introducing the paper the meeting was reminded that one of the recommendations to the Director-General of FAO from the 1982 Second Government Consultation on International Harmonization of Pesticide Registration Requirements was that every encouragement be given to all organizations engaged in the development of harmonization of pesticide registration requirements and procedures.

65 The First Technical Advisory Committee Meeting of the Network, held in Manila on 8 - 12, November 1982, resolved that there was a need for harmonization of pesticide registration requirements within the Region. A sub-network was established and a Consultant appointed. The Consultant visited the nine member countries, over the past 6 months.

66 The paper defined the term "harmonization" and spelt out the benefits to be obtained by countries when utilizing harmonized registration requirements for pesticides. These included:

- greater transportability of data
- a reduction in delays in achieving registration
- regular and more uniform standards
- greater value from information sharing
- wider availability of pesticides
- reduction in hazards of distribution and use

67 Proposals for harmonizing the specific data requirements were outlined in the paper, as also were some suggestions on how the registration process should be operated. Finally some of the problems in registration procedures such as proprietary rights to registration data, registration of commodity products and change in source of active material were noted.

RECOMMENDATIONS

68 The Meeting

Recognizing the need to harmonize pesticide registration requirements within the Region and,

Noting that many countries in the Region have pesticide registration schemes which have been developed to meet their own needs,

Nevertheless believes there are benefits in having harmonized pesticide registration requirements and

Recommends that countries agree to consider modifying, where necessary their legislation and/or registration procedures to achieve a greater degree of harmonization and in particular to requiring:

1) all pesticides to be registered before they can be sold or offered to sale, without the need to gazette or list same before the registration process can be undertaken.

2) the use of the WHO Classification of Pesticides by Hazard for labelling pesticides and

Noting it is important that:

(a) The Pesticide Industry be made fully aware of the registration requirements;

(b) The label be considered as a vital part of the registration process;

(c) Hazard should be taken into account when considering the availability of pesticides,

(d) Color coding should be harmonized if possible and be based on hazard rather than type of use,

(e) The assistance of Ministry of Health be sought in the evaluation of toxicology and guidance given on label warnings.

(f) Full use be made of the Regional data base for information on which pesticides are registered, and which are no longer registered or which have been refused for registration or restricted in use and for what reason and,

(g) Certain data submitted to regulatory authorities may be proprietary in nature and thus, subsequent use of this data should be subject to adequate protection.

Recommends that each registration authority takes into account the above points to ensure the prudent, safe and effective use of pesticide in their country.

COMPILATION OF DATA AT THE NATIONAL AND REGIONAL LEVELS

69 The meeting was informed that funds had been made available through the Project for computer equipment to process information provided by member countries. Statistics on production and use were being processed at the moment.

70 The meeting agreed that it would be of value to have data on registration available on a regional basis and identified certain headings under which such data could be collected. These were:

- common name (after ISO where possible) of active ingredient
- content of active ingredient; weight/weight - (g/kg) or weight/volume - (g/liter) as the case may be.
- type of formulation - e.g. wettable powder
- type of use - e.g. herbicide, (using WHO letter codes)
- source of active ingredient (country and manufacturer)
- year of first (full) registration
- crops on which registered
- restrictions on use (if any)

71 In the case of products for which registration had been cancelled it was agreed that a separate list was necessary to record the above details (plus date of cancellation) and also to record the reason for such cancellation.

72 Country delegates agreed they could respond within 3 months after receipt of a request for the above information.

OTHER BUSINESS

SPECIAL FORMULATIONS AND CROSS CONTAMINATION

73 These subjects were not discussed but will be referred to the appropriate sub-network within the Network for consideration.

SPECIAL NEEDS

74 A number of special needs in the context of pesticide registrations had been identified earlier in the agenda. There was a continued need for training personnel in all aspects of pesticide registration activities. The meeting was advised that special problems with pesticides existed in countries in the South Pacific.

RECOMMENDATIONS

75 The Meeting

Recommends that the Regional Network considers coordinating a meeting to discuss special problems in the control of pesticides in the countries of the South Pacific Commission.

REPORTING ACCIDENTS AND INCIDENTS INVOLVING PESTICIDES

76 The meeting supported the view expressed by GIFAP that there was a need to have a system in operation to obtain accurate records of accidents and incidents involving pesticides. Likewise there was value in countries establishing Poisons Centers from which information on pesticides and first aid treatment could be quickly obtained should the need arise.

RECOMMENDATION

77 The Meeting

Noting that this subject could well be discussed by the toxicology sub-network,

Recognized that there is a need to have systems to accurately record pesticide poisoning and that the establishment of a Poison Centres from where information on treatment on poisonings could be obtained was desirable.

Recommend that these two aspects be referred to governments.

GENERAL RECOMMENDATIONS

78 The meeting took note of the nature and diversity of national registration schemes operating in the region resulting in:

(a) the use of inappropriate pesticides often of poor quality which poses a danger of causing crop losses,

(b) a waste of the rather limited resources available in the region through duplication of work in developing registration date,

(c) the immediate and long-term hazards which could posed to farmers, the general public and the environment through improper pesticide management practices,

(d) jeopardising the export of agricultural produce due to unacceptable residues of pesticides,

(e) the adverse effects of pesticides on fish which is a much needed source of nutrition in rural areas of the region and

(f) the lack of effective and safe formulations in the context of the climatic and socio-economic conditions prevailing in the Region.

79 Following discussions based on the various working papers, background papers and the Consultant's report;

The Meeting

Noting that although progress has already been made within the region in harmonizing a number of requirement for pesticide registration, and

Acknowledging that further progress had been made as a result of this meeting.

Noted that:

a) Agreed protocols for bio-efficacy trials are either to be developed and/or finalized and adopted,

b) Pre-harvest intervals after pesticide application on crops should be considered and harmonized where possible within the Region as this is one of the key requirement for labelling,

c) Certain recommendations contained in this Report on packaging, and labelling need to be finalized and adopted by the member countries,

d) The activities of the toxicology sub-network may also contribute to harmonization;

Recognized that there is scope for considerable revision and improvement in harmonization of registration requirement in the region, in the context of the Network,

Recommends the promotion of collaborative arrangements, including analytical services within the Network with a particular view to assisting those countries who will be unable to provide their own facilities in the foreseable future.

Further recommends that the operation of the sub-network will need to be continued and non member countries be encouraged to become members, if the defined objectives are to be achieved and

Further recommends that provision be made for further activities of this sub-network and other sub-networks to promote harmonization in specific areas and to monitor the progress of harmonization as a whole within the Network.

ADOPTION OF REPORT

80 The report was adopted

CLOSING REMARKS:

81 The UNIDO Consultant expressed the view that considerable progress had been achieved at the Meeting towards the aim of harmonizing pesticide registration requirements in the Network. However, there was further progress to be made which would largely dependent on delegates and the commitments and endeavor they would make on return to their countries to fully achieve the objectives of the meeting. He expressed his thanks to the many officials in the countries visited for the help they had given him and said he had achieved a great deal of satisfaction from the work.

82 The Rapporteur thanked the Secretariat for the tremendous help and support given by them, not only during the meeting but in the preparation of documents and papers prior to the meeting. The meeting heartily endorsed these thanks.

83 The Chairman thanked delegates for their participation and support of the meeting. She hoped they would carry the message of implementation of the proposals and recommendations back to their respective governments and in the near future, most if not all of the recommendations would be implemented. She also thanked UNIDO for their support of the meeting and hoped there would be provision to be able to follow up on the progress towards the implementation of the recommendations. She thanked the resource people, Mr. D. Campt and Dr. Balasubramaniam for their introduction to various agenda items.

84 The meeting expressed their gratitude to the UNIDO Consultant for his work during the last 6 months, not only to individual countries but also to the meeting.

85 The Chairman was thanked for the untiring dedication she had given to the sub-network on harmonization of pesticide registration requirements as well as to the Regional Network. The meeting had run smoothly and was successful. The delegates also thanked the Government of the Philippines for their support of and hosting the meeting, both notes of thanks being carried with acclamation.

86 The meeting then closed.

APPENDIX 1

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APPENDIX II

AGENDA

1. Opening of the Meeting
2. Election of Chairman/appointment of Rapporteur
3. Adoption of Agenda
4. Explanation of Objectives
5. Review of Current Registration Status in the Region
   - 5.1 Country Statements
6. Data Requirements
   - 6.1 Chemical and Physical Properties
   - 6.2 Efficacy and Crop Safety
   - 6.3 Toxicology
   - 6.4 Residues
   - 6.5 Environmental Effects
7. Model Registration Scheme (FAO Guidelines)
   - 7.1 Special Problems in Registration Procedures- Commodity Pesticides
   - 7.2 Phased Registration
   - 7.3 Proprietary Rights
8. Effective National Control of Pesticides
   - 8.1 Availability of Pesticides
   - 8.2 Specifications
   - 8.3 Labelling
   - 8.4 Packaging and Storage
   - 8.5 Disposal
   - 8.6 Code of Conduct
9. Consideration of the Report of Second Government Consultation on International Harmonization of Pesticide Registration Requirements Rome, 1982.
10. Implementation at National Level (Agreements, plans for future agreements)
11. Coordination of Activities in the Region
12. Compilation of Data on Pesticide Registration at the National and Regional Levels
13. Other Business
    - 13.1 Special Formulations
    - 13.2 Cross contamination
    - 13.3 Special Needs
14. Adoption of Report
15. Closing

APPENDIX III

A SUMMARY OF THE MAIN ASPECTS OF THE PESTICIDE REGISTRATION SCHEMES IN MEMBER COUNTRIES OF THE REGIONAL NETWORK FOR PRODUCTION, MARKETING AND CONTROL OF PESTICIDES IN ASIA AND THE FAR EAST (RENPAF)

BRIAN B. WATTS
UNIDO CONSULTANT

Prepared for the Regional Conference at Baguio City,
The Philippines, 24-29 October 1983.

INTRODUCTION

The Consultant visited 9 countries as a Consultant on the Harmonization of Pesticide Registration Requirements, with the following terms of reference:

1. To visit each of the member countries (Thailand, Indonesia, Korea, Philippines, Bangladesh, Pakistan, India, Afghanistan and Sri Lanka) participating in the Regional Network for the Production, Marketing and Control of Pesticides in Asia and the Far East (RENPAF) and hold discussions with senior officials responsible for the registration and regulation of pesticides in each country with the objectives of -

   (a) Encouraging interest and involvement in the harmonization of pesticide registration requirements in the region.

   (b) Reviewing administrative procedures in use in each country.

   (c) Collecting copies of current or proposed legislation.

   (d) Determining the current registration status in each country.

   (e) Recommending a regional harmonization scheme for discussion during the meeting in October.

2. To call upon local authorities responsible for the regulation of pesticides, and outline the purpose and advantage of working with the network.

3. To provide an analysis of the current status of registration in the region for presentation during the meeting in October.

4. To assist the Government of Sri Lanka in setting up a pesticide registration scheme.

A separate report has been prepared for UNIDO on the registration schemes in each country which were visited at the following dates:

Sri Lanka	1-14 May 1983	India	20-23 July 1983
Philippines	1-3 June 1983	Afghanistan	24-29 July 1983
Thailand	6-10 June 1983	Pakistan	30 July-4 August 1983
Korea	11-15 June 1983	Bangladesh	5-12 August 1983
Indonesia	16-23 June 1983		

A summary of some of the main points of the registration schemes in operation follows.

This summary is not intended to be exhaustive, but may serve as a guide on some of the similarities/differences which occur from country to country in the Region.

TABLE OF CONTENTS

ASPECTS OF REGISTRATION	AFGHANISTAN	BANGLADESH
Title of the Law		The Pesticides Ordinance 1971
ADMINISTERING AUTHORITY Agricultural Pesticides Household Pesticides Public Health Veterinary Pesticides	NO SCHEME YET OPERATING	Ministry of Agr. and Forestry Director, Plant Protection Division
MAIN POINTS Compulsory Control of Imports Control of Manufacture Offence to use contrary to label Control of Advertising Register applicators Agriculture Pest Control Operators Others		 Yes Yes Yes Yes Yes Yes Yes Yes
NAME OF BODY Considering Application Number of members Evaluating Data Issuing Certificates		Plant Protection Tech. Sub Comm (Registration Sub Comm. 9-12 (17) and seconded members As above Director, Plant Protection Division
TYPES OF CLEARANCE Full Limited Sale Experimental Notification		 Yes No Yes - for trial purposes No

INDIA	INDONESIA	
The Insecticides Act 1968 (Act No. 46 of 1968)	Govt. Decree No. 7 1973 on the Control of the Sale, storage and Use of Pesticides	
Ministry of Agriculture Registration Committee	Ministry of Agriculture D-G of Food Crops, Directorate of Food Protection As above plus D-G of Food and Drug As above plus Health As above	
Yes Yes Yes Yes No No No No	Yes Yes - D-G of Imports No Yes Yes No No No	
Registration Committee 6 + seconded members As above As above	Pesticides committee 22 Sub Committee of above Ministry of Agriculture	
Yes Yes Yes No	Yes Yes Yes No	

KOREA	PAKISTAN	
Agrochemicals management Law 1957 (Rev. 1980)	The Agricultural Pesticides Ordinance 1971	
Ministry of Agr. & Fisheries Office of Rural Development Ministry of Health & Welfare Ministry of Health & Welfare Office of Rural Development	Ministry of Food, Agr. & Cooperative, Dept of Plant Protection No one Ministry of Health	
Yes Yes Yes Yes Yes Yes Yes Yes	Yes Yes Yes No Yes No No Aerial sprayers in Dept	
Agrochemicals Management Committee 22 Sub Committees of above Ministry of Ag. & Fisheries	Agricultural pesticides Technical Advisory Committee 20 Sub Committee of above Director, Dept Plant Protection	
Yes No No Yes	Yes No No No	

PHILIPPINES	SRI LANKA	THAILAND
Presidental Decree 144 30 May 1977 creating the Fertilizer and Pesticide Authority	Control of Pesticides Act No. 33 of 1980	Poisonous Articles Act 1967 and Amendment Act No. 2 1973
Fertilizer and Pesticide Authority " " " " " " " "	Ministry of Agricutlrue, Div. and Research - Department of Agriculture " "	Ministry of Agr. & Coop. D of AG Ministry of Health Ministry of Health Ministry of Agr. & Coop. D of AG
Yes Yes Yes No clear Yes Yes Yes Yes	When implemented yes Yes No No Yes No No No	After gazetting Yes Yes Yes No Yes yes Yes Yes
Pesticides Technical Advisory Committee 17 Sub Committee of above Fertilizer and Pesticide Authority	Pesticide Formulary Committee 10 Pesticide Formulary Committee Registrar, Dept of Agriculture	Piosonous Articles Control Board 14 Sub Committees Agricultrual Regulatory Div (of the Dept of Ag) or Health Dept in case of Health products.
Yes No Yes No	Yes ? ? No	yes No No No

DATA REQUIREMENTS (FORMULATION)	AFGHANISTAN	BANGLADESH
CHEMICAL AND PHYSICAL PROPS.		Not specified
TOXICOLOGY	NO SCHEME YET OPERATING	Oral Dermal Inhalation
EFFICACY		2 seasons trials to be carried out by Govt. Res. Station (unless standardised)
EFFECT ON ENVIRONMENT		Fish
RESIDUE		Method testing

INDIA	INDONESIA	
Type Chemical composition Analytical Test Report Methods of Analysis	Type Composition Stability Methods of Analysis	
Extensive Amount. Depends on status of pesticide. None required if conc. less than existing registered formulation. If conc. greater than existing formulation require all data.	LD 50 oral and dermal LD 50 inhalation Interperitonial Short term	
Laboratory and field	Laboratory and Field Trials	
Fish Birds Bees	Fish Toxicity Birds Bees etc.	
Comprehensive protocols	Amount and type of residue	

KOREA	PAKISTAN	
Type Compositon Shelf Life Methods of Analysis	Largely after FAO	
LD 50 (oral and dermal) Where tests done.	None	
Location of Experiments Year Variety comparison with standard. Stat. Analysis. Phyto. date (A useful book on trials)	Location of Experiment Year Variety Comparison with standard.	
Fish toxicity	As FAO	
5 tests - 1 on crop 2 on field soil 2 on lab set PHI, variety and type of residues found	As FAO	

PHILIPPINES	SRI LANKA	THAILAND
Yes - Comprehensive	Yes - proposed	Type Composition Structural & Emperical formula Shelf life SG
Yes - Comprehensive	Yes - proposed	Limited - Not spelt out LD 50 to animals
Commodity - none (unless new use). Proprietary - comprehensive	Yes - proposed	None required in Thailand. Overseas data accepted.
Commodity - none detailed Proprietary - Soil Water Birds etc.	Yes - proposed	Limited Fish Bees
Commodity - none detailed Proprietary - Identity Decline studies Animal studies Effects of processing	Yes - proposed	None spelt out. Possibly none required

DATA REQUIREMENTS (TECHNICAL)	AFGHANISTAN	BANGLADESH
CHEMICAL & PHYSICAL PROPS.	NO SCHEME YET OPERATING	Yes Standard specification
TOXICOLOGY		Not stated
SOURCE To be notified. If changed what?		Yes

INDIA	INDONESIA	
IUPAC Common Name (ISO) Identity and Physiochemical properties	IUPAC name Common name (ISO) Structural and emperical Composition Stability Physical properties	
Acute toxicity Sub-acute Carcinogenicity, teratogenicity, mutagenicity, metabolism	Carcinogenicity neurotoxicity potentiation teratogenicity mutagenicity	
"Identicality" or else new tests	Not stated New tests?	

KOREA	PAKISTAN	
Appears No - Not stated	As for FAO	
Appear Not	As for FAO	
No Nothing	Yes Not clear	

PHILIPPINES	SRI LANKA	THAILAND
Comprehensive whether a commodity of proprietary product	Yes – proposed	Unclear
As above.	Yes – proposed	Not spelt out
Yes More data may be required.	Yes New application	No

LABELLING	AFGHANISTAN	BANGLADESH
REQUIREMENTS SPELT OUT Yes/No Where		Yes Ordinance and proposed Rules
LANGUAGE Local Mixed		Bengali - small packs English - large packs
COLOUR CODING Yes/No Yes colour	NO SCHEME YET OPERATING	No
NAMES ISO COMMON Full Chemical IUPAC CA Inerts		Optional Yes Yes No No
HAZARD RATINGS WHO Like WHO Completely		No Yes - on formulation dermal only No
SKULL AND CROSS BONES Some products All products No products St. Andrews Cross		No Yes No No

INDIA	INDONESIA	
Yes Insecticides Act 1968 Insecticides Rules 197i	Yes Minister of Agr. Decree No. 429 1973 - Article 5	
Hindi and English and 1 or 2 regional languages	Indonesian	
Yes, Bright Red Tox ClassI Bright Yellow Tox Class II Bright blue Tox Class III Bright Green Tox Class IV	No	
Yes or ISI Yes if No Common name Yes No Yes	Yes Yes Yes No No	
No Yes - no dif. between form type and based on active No	No yes - no dif. between form type No	
Class I No No No	Most hazardous No No Second hazard category	

KOREA	PAKISTAN	
Yes Agrochemicals Management Law	Yes Pesticides rules	
Korea No	Pakistan No	
Yes Pink - fungicides Green - insecticides Yellow - herbicides	Yes - Toxicity I - Red II - Blue III - Yellow IV - Brown	
No Yes NS NS NS	Yes No NS NS No	
yes - -	No Yes No	
No No Yes No	No Yes No No	

PHILIPPINES	SRI LANKA	THAILAND
Yes Guidelines issued pursuant to Act V PB 144	Yes Section 8 in Control of Pesticides Act	Yes Section 21 of the Poisonous Articles Act
Filipino or English	Sinhala and Tamil and English	Thai and if desired English
Yes Blue - fungicides Red - insecticides Green - herbicides Orange - other	Not determined	No
Yes ? ? ? ?	Yes - proposed No " No "	Yes ? ? Yes?
Yes plus inhalation and irritancy and only one Class I	Yes - proposed	No No Yes
Most Hazardous class No No No	Most hazardous No No Possibly next hazardous	No Yes No No

POST REGISTRATION ACTIVITIES	AFGHANISTAN	BANGLADESH
ANALYSIS OF FORMULATION Routine Specific	NO SCHEME YET OPERATING	Yes - extensive at Registration and release of every batch and import.
RESIDUE ANALYSIS		Very limited
MAXIMUM RESIDUE LIMITS (MRL's) Like CCPR Compl Diff.		Accepted codes for some MRLs
POISONING NOTIFICATION		No

INDIA	INDONESIA	
No Yes	Yes - at Registration yes	
Yes - limited	Yes - limited	
Yes, but limited No	Yes No	
No	No	

KOREA	PAKISTAN	
Yes Yes	No Yes	
Yes, but limited	Yes, but very limited	
No yes	No No None	
No	No	

PHILIPPINES	SRI LANKA	THAILAND
Limited Yes	No) limited resource No)	Yes Yes
Yes, but limited	Yes, very limited	Yes - limited
None yet	None yet	None set?
Yes - localised basis	Yes to start on a district basis	No

APPENDIX IV

COUNTRY STATEMENT

AFGHANISTAN*

There is no special legislation related to registration of pesticides yet in operation in Afghanistan, but it is understood that discussions are being held on proposals put forward by Dr. G. L. Baldit following his report to FAO on the Technical requirements for Proposed Pesticide Legislation in Afghanistan in 1981.

*Statement submitted by B.B. Watts, UNIDO Consultant, in the absence of the delegate from Afghanistan.

COUNTRY STATEMENT

BANGLADESH

The Law under which pesticides are registered in Bangladesh is the Pesticides Ordinance 1971 (as Amended in 1980 and 1983). This law requires that all pesticides shall be registered before they can be imported, manufactured, repacked, formulated, sold or advertised. Submissions for registration are made to the Director, Plant Protection Division, initially for an application for standardization (a type of pre-registration) and if acceptable then an application for registration may be lodged. If the application does not meet the standard up to 2 seasons efficacy testing could be required by an accredited research institute.

The Pesticide Rules are still in a draft stage but the draft is being acted on as far as registration requirements are concerned.

The Act also requires licenses to be issued to import, to manufacture, to formulate, to repack, to sell, to advertise and be licensed as a pest control operator.

There is only one type of registration which is valid for 3 years; there is no phased scheme in operation.

Registration data are evaluated by experts who are members of the Plant Protection Technical Sub-Committee. There is no color coding for labels, all of which are marked "POISON" with skull and crossbones.

Considerable emphasis is placed on analysis of formulations with it being a requirement that all formulations and imports of technical and formulations must be cleared by the Pesticide Laboratory (set up under the Act) before they can be sold or used.

APPENDIX IV (Cont.)

COUNTRY STATEMENT

INDIA

I. LEGISLATION FRAMEWORK:

1.1 The Insecticide Act of 1968 and the The Insecticides Rules 1971, regulates the import, manufacture, sale, transport, distribution and use of pesticides. As per the Act, insecticide means any substance specified in the schedule to the Act and such other substances including fungicides and weedicides as may be included in the Schedule.

1.2 The administering Ministry is the Ministry of Agriculture.

1.3 The Act provides for a Central Insecticides Board, to advise on technical matters, consisting of 29 experts in various disciplines with Director General of Health Services (Under Ministry of Health) as the Chairman.

1.4 The Act also provides for a registration Committee consisting of a chairman, Drugs Controller of India and the Plant Protection Adviser and not more than three other members. The board can co-opt experts. The Secretariat of the Board has 7 specialized experts viz Entomologist, Plant Pathologist, Agronomist, Medical toxicologist, Packaging Engineer,Chemist and Law officer.

2. STEP-WISE REGISTRATION

2.1 There are three basic steps:

a. Trial Clearance: of small quantities on basis of permission given by the Plant Protection Adviser.

b. Provisional Registration : Section 9 (3B) of the Act enables provisional registration for a period of two years, on specified conditions.

c. Regular Registration: Section 9 (3) enables regular registration with no time limit; there is provision for cancellation of registration.

3. LICENSING

The Act provides for licensing of manufacturing, selling, etc. of pesticides. The license is valid for specified period and can be renewed.

4. DATA REQUIREMENT

FAO guidelines have been given due consideration while framing national guidelines and more or less are keeping with them . Broadly data requirement relates to:

4.1 Product specifications, chemical composition and allied data, including source of supply, minimum purity and details of impurities, physico-chemical properties of active ingredient.

4.2 Shelf-life data

4.3 Packaging and labelling requirements (including colour labelling by toxicity and leaflet)

4.4 Bio-efficacy and residues

4.5 Detailed toxicology data.
Details are documented in the country statement circulated.

5. Certain laboratory bound toxicological data, generated in other countries are accepted but bio-efficacy and residue work should be under Indian conditions; environment dependent data has to be generated under Indian condition.

6. Post-registration Activities

The Act provides for inspection of manufacturers for ensuring compliance of the Act.

7. A Group of Experts has been constituted to get into, inter-alia, the organization systems, procedures, methods and policy of registration of insecticides. Views of this Expert Group may be sought on the recommendations of the Regional Consultation on Harmonization of Pesticides Registration Requirements.

APPENDIX IV (Cont.)

COUNTRY STATEMENT
INDONESIA

Registration of pesticides is administered by the Directorate of Food Crop Protection, Ministry of Agriculture as provided under Government Decree No. 7 of 17 March 1973. Registration procedures are contained in the Agricultural Ministerial Decree No. 280 of June 11, 1973.

In principle registration is not based solely on registration in other countries. Nevertheless information on registration in other countries may be required when registration of pesticide containing a new active ingredient is to be considered. Some guidelines prepared by international and regional organizations such as FAO and Council of Europe have been used in developing the national registration procedure.

Data on mammalian toxicity and other selected data generated in other countries can be accepted. Data generated by official stations recognized by the Pesticide Committee are used as primary data to support registration. Data on efficacy, fish toxicity and residues are required to be generated locally in the country.

"Phased" or "Stepwise" registration procedure is adopted, viz. experimental, provisional and permanent registration.

Availability of some pesticides which are highly toxic, persistent and bio-accumulative is restricted. These pesticides which are not registered for general public use can only be used by licensed users. All pesticide formulations with LD-50 values smaller than 50 or 500 mg/kg body weight for acute oral and dermal toxicity respectively, fall into this category.

Registered products are listed in the Agricultural Ministerial decrees on pesticide registration and approval which are issued periodically. All pesticides registered for agricultural use which are listed in the decrees are re-listed by trade name, common name, registration type, approved usage and registrant in a publication "Pesticida untuk Pertanian" issued annually.

COUNTRY STATEMENT

JAPAN

Any pesticide products must be registered by the Ministry of Agriculture, Forestry and Fisheries before being offered for sale under the provisions of the "Agricultural Chemicals Regulation Law" which was enacted in 1948 and amended largely in 1971.

For the registration application, it is necessary to submit required documents following to the "Guidelines " published as a Ministerial Ordinance. It is not considered whether a pesticide is already registered in other countries, however, the data on toxicology generated by authoritative laboratories in other countries are generally accepted. Data on efficacy, phytotoxicity and residues must be generated by authorized experiment stations in Japan.

Neither "Phased" nor "Stepwise" procedure are adopted. Availability of highly toxic pesticides is restricted by the "Poisonous and Deleterious Substance Control Law". Official list of registered pesticides (in Japanese) is annually published.

Check control on products, monitoring of pesticides in food or in environment, reporting of occupational health incidents and collection of data statistics on quantities of pesticides manufacture, imported or used are conducted.

COUNTRY STATEMENT

REPUBLIC OF KOREA

The procedures of pesticide registration requirements are based on Agrochemicals Management Law established in 1957 and revised in 1980.

All applications for registration of pesticides are managed by Agricultural Chemicals Research Institute, Office of Rural Development of the Ministry of Agriculture and Fisheries.

The application has to be accompanied by experimental data concerning chemical and physical properties of the active ingredient and formulated products, efficacy data of two cropping seasons on crops, toxicological data include the acute oral and dermal, and chronic toxicity, residue data with plants and two different soil type conditions, phytotoxicity data of two field experiments at higher dosage rates.

Then all the data should be submitted to the two committees of sub and main pesticide management and if accepted then registration is permitted by the government authority.

For the effective control of pesticides, all labels are approved by the government and these must contain the trade or brand name with full name of active ingredient, concentration, dosage rate, method of application, warning and precaution etc. Also environmental pollution with pesticides is controlled under the Environmental Protection Law.

APPENDIX IV (Cont.)

COUNTRY STATEMENT

MALAYSIA

The pesticides Act 1974 provides for a Board comprising of heads of various government agencies in the country. The Pesticides (Registration) Rules were implemented on 1 October 1976 following which applications for registration were considered. Under these rules all importers and manufacturers (including those carrying out formulation, packing, re-packing, and labelling) are required to register their pesticide for a period of three years.

The information required for registration includes chemical and physical properties; method of formulation and residue analysis; detailed toxicological data; first-aid, medical treatment and antidote statement; if packaging complies with the Malaysian code of Practice for Packaging; storage stability of the product; whether the product meets Malaysian, FAO or WHO specification, etc. The information is evaluated by a Technical Committee comprising of members from the various disciplines and is approved, rejected, or further information requested for consideration. The details of the label are also considered and approved. Among others the label has a colour band based on the WHO hazard classification and the two most toxic classes also have a "skull and crossbones" symbol on the label.

Following registration, samples of pesticides are obtained from the market and analyzed for a.i. content and occasionally for other parameters as stipulated in the specification.

There is no phased or step-wise registration system being practiced at present and unregistered pesticides for purposes of research or development are allowed to be imported under a permit.

Advertising of pesticides over the radio and TV have also to be approved by an advertisement committee established under the Board. Advertisements in other media are controlled by means of guidelines which disallows overclaims on safety or efficacy of the product.

APPENDIX IV (Cont.)

COUNTRY STATEMENT
NEW ZEALAND

The Pesticides Act 1979 replaced the Agricultural Chemicals Act 1959, differing mainly from earlier Act in that industrial and public health pesticides are now required to be registered where previously they were not.

No pesticide can be sold unless it is registered or has an Experimental Use Permit (EUP). The Act sets up the Pesticide Board and sets out the functions of the Board, the main one of which is to ensure the prudent, effective and safe use of pesticides. There are three types of clearances:

EUP	- Not for sale	- Trials Clearance
EUP	- Limited sale	- Provisional Clearance
Registration		- Full Registration

Data requirements for registration are identical, to those put forward by the 1977 and 1982 FAO Consultation, the amount of date required varying with the type of clearance sought. The WHO classification of pesticide hazard is followed with the skull and cross bones being required on the first two categories only, and, pesticides falling into these two categories are available only to commercial users. There is no color coding for labels.

Protection of proprietary data is practiced with those being a period of exclusive use for 15 years (plus the possibility of a further 5 years) from the date registration was first given.

There is no routine analysis of formulation. A system of notification of poisoning is in operation.

A voluntary registration scheme for ground spray operators is in operation, and compulsory licensing schemes for users of 1080 and cyanide, as well as aerial applicators are in force.

APPENDIX IV (Cont.)

COUNTRY STATEMENT
PAKISTAN

In 1971 an ordinance called Agriculture Pesticide Ordinance was promulgated by the Government to regulate the import, manufacture, formulation, sale, distribution and use of pesticides in Agriculture. The rules under were framed and notified in 1973. Under the ordinance, the Federal Government constituted a Committee called Agricultural Pesticides Technical (APTAC) for the registration of Pesticides. The APTAC Committee has constituted a 20 member technical sub-committee of Experts drawn from all the provincial research institutes, autonomous bodies/agencies with the Plant Protection Adviser/Director as its convener.

An application has to be made to the Department of Plant Protection in a prescribed proforma along with a sample of the pesticide to be registered. After verification of the specification claimed in the application, the samples are forwarded to the Provincial Governments to conduct, in direct association with the applicant, biological tests for 2 crop seasons under the necessary field conditions. The trial results are evaluated by the Technical Sub-Committee and also by the main Committee, APTAC. A registration certificate is issued by the Department of Plant Protection which remains valid for 3 years which can be renewed for another 3 years. There is no provision in the rules for granting provisional registration.

The recommendations of the 2nd Consultation held in Rome in October 1982 for the harmonization of pesticide registration requirements were reviewed by a committee of National Experts including representatives of Pesticide Industry with a view to determining and revising, if necessary the data requirements in respect of chemical and physical properties; efficacy and Crop Safety; toxicology; residues and environmental effects; availability of Pesticides; specifications; labelling; packaging and storage disposal and some additional data requirement which were not in operation have now been requested.

Pesticides have now been classified into 4 categories according to the hazards and toxicity based on WHO classification as Extremely Toxic (red), Highly Toxic (blue), Moderately Toxic (yellow) and Toxic (brown). The colors indicated in each category have to be displayed on labels.

APPENDIX IV (Cont.)

COUNTRY STATEMENT

PHILIPPINES

The Fertilizer and Pesticide Authority is mandated by law under Presidential Decree (PD) 1144 to regulate the pesticide industry in the Philippines.

Registration of pesticides to ensure safety and efficacy is one of the primary concern of the Authority, the requirements for such process includes submission of data on efficacy, toxicology and residue and fate in the environment, the details of which were based on international and local standards.

Allied to this activity, FPA, also undertakes control of pesticides for testing through the granting of experimental use permits; evaluation of product labels to ensure consistency between claims and those approved in the registration; and classification of pesticides into those for general and restricted uses while banning those which pose danger to the user/environment.

To support the registration system the following activities are also on-going concern of FPA:

1. Regulation of importations
2. Training programs towards

    a. medical and paramedical personnel
    b. agro-pesticide dealers
    c. farm technicians
    d. pesticide applicators (exterminators and fumigators)

FPA continually reviews/evaluates the above-mentioned programs and formulates policies to become more responsive to the need challenge of providing the public/user with safe and effective pesticides.

APPENDIX IV (Cont.)

COUNTRY STATEMENT

SOUTH PACIFIC COUNTRIES

Only a few of the countries of the South Pacific Commission have legislation and registration requirements for pesticides. Where present the administering authority is one of agriculture, health or environment.

Countries in association with the United States are under FIFRA, though both Guam and TTP I pesticide laws also exist. French territories are under French law. In Fiji, The Pesticide Act, 1972; in Solomon Island, The Safety at Work Act (Pesticide) Regulations, under Safety at Work Act, 1982; in Tonga, Pesticide Act; in Papua New Guinea, The Poisons and Dangerous Substances Act, 1952 and Environmental Contaminants Act, 1978 - a Pesticide Act is being proposed. Few of these countries actually implement their legislation, and in come no registration requirements yet exist.

In consideration of the situation a few points need to be made:

1. South Pacific countries, have very limited expertise facilities and funds to enable effective implementation of pesticide registration requirements and enforcement. For registration all countries will have to rely upon overseas information and assistance.

2. Many users of pesticides at present are little educated. Many of these people are handle "restricted" pesticides which in other countries requires certification of users.

3. Much concerning the safe use of pesticides, what pesticides are used, what restrictions apply still depend upon the goodwill of distributors. However at times South Pacific countries still get supplied with low quality, ill-labelled products, many of which in thier concentrated form are very toxic, and this results in problems.

In the light of the above the South Pacific Regional Environmental Program has initiated a "Pesticide Project" which includes the following objectives:

1. To review existing information on pesticides use and abuse within the region and on the level of residues within environmental samples.

South Pacific Countries

2. To identify the existing legislation on importation, sale, storage, use and disposal and its enforcement within the region, and on registration requirements.

3. To present a detailed proposal for monitoring pesticides within the region (in human blood, foodstuffs, environmental samples), and for evaluating environmental effects of pesticide use.

I am presently unable to summarize the pesticide situation throughout the South Pacific precisely and accurately, but I hope that by mid-1984 I could provide UNIDO/WHO/FAO/UNEP with an accurate statement concerning the situation, especially on registration requirements and enforcement of legislation. Moreover, I intend to bring to the attention of the appropriate government officials in each country the findings and decisions of this consultation and will try to ensure harmonization of pesticide registration requirements throughout the countries of the South Pacific Commission.

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25th October 1983

APPENDIX IV (Cont.)

COUNTRY STATEMENT

SRI LANKA

The current situation in Sri Lanka indicates that the Registration of Pesticides, provided for in 1980 Legislation drawn up on guidelines laid down by FAO, which is incorporated in the Control of Pesticides Act of 1980 of the Sri Lanka government, is now in active operation. Consequently, this would enable requirements for any harmonization within the region to be achieved without difficulty.

It will be evident, however, from the results obtained from action taken, that the delay of over 2 years involved in the operation of the control of Pesticides Act of 1980 would necessarily be a handicap in the achievement of desired results in the immediate future.

The areas of present priority for action are broadly: -

a) The further development and establishment of an efficient infrastructure for the implementation of the Control of Pesticides Act of 1980.

b) The strengthening of Extension and Research arms in the Pest Control Sectors of the State Department of Agriculture, in order to back up the post-registration action required for enforcing compliance with registration conditions and monitoring the effects of pesticide use in the country.

APPENDIX IV (Cont.)

COUNTRY STATEMENT
THAILAND

The registration procedures have been done under the Poisonous Article Act 1967 and Poisonous Article Act 1973. Control of pesticides under these Acts are the responsibility of different agencies of three Ministries. Department of Agriculture, Ministry of Agriculture and Cooperatives is responsible for the pesticide used in Agriculture. Food and Drug Administration, Ministry of Public Health is responsible for pesticide used in public health and for chemicals used in household products, Department of Industrial Factory, Ministry of Industry is responsible for chemicals used for industry.

Companies who wish to apply for pesticide registration in agriculture are able to obtain detailed information from the Pesticide Registration Section, Agricultural Regulatory Division, Department of Agriculture.

Guidelines for Registration

1. Technical information of the pesticide must bear details as follows:

   Chemical and physical properties, formulation, type of packaging, biological data, uses, recommendation, pre-harvest interval, storage, toxicities to human, animals, poultry, bee, fish and environment including LD_{50} of test animals, symptom of poisoning, first aid and treatment, guide for physician, analytical method for both formulation and residue.

2. Sample for analysis and trials clearance.

3. Type of packaging and material.

4. All labels must be contain the skull and crossbones in red or black color, trade name, common name, chemical name, and percentage of active ingredient, registration number, net quantity, name of manufacturer and dealer with address, usage, rate of application, storage, precaution, symptoms of poisoning, first aid treatment.

APPENDIX V

WORKING PAPER 3

CHEMICAL AND PHYSICAL PROPERTIES

In order to define a pesticide chemical it is imperative to have clear, accurate and precise details of its chemical and physical properties in terms that can be measured. To this end, pesticide manufacturers are required to supply to registration authorities comprehensive data on those physical and chemical characteristics which are identifiable and determinable.

Information is required on the physical and chemical properties and purity of the technical grade material used in the formulation as well as on the formulated product itself. Further precise information on the properties and characteristics of the active ingredient are usually needed for control purposes.

In addition it is usual to include certain data that are used in other aspects of hazard evaluations of a pesticide (for example: partition coefficient water/n-octanol can often be used to assist in the estimation of the bioaccumulation potential of a compound. FAO Plant Protection Paper 28)

Analytical methods for the determination of the active ingredient and impurities in the technical and formulated product are an essential part of the information required. Where standardized or published methods are not available, details of an appropriate method must be provided by the manufacturer.

This information is needed to define the composition of the technical grade active ingredient in the product registered. It is implicit that the toxicological, residue and efficacy studies submitted in support of a registration have been carried out with material of corresponding composition. It is also presumed that the registrant will ensure that the marketed product complies with the compositional statement made at the time of registration.

Some of the descriptive characteristics and certain properties which influence mobility and degradation of a pesticide are obviously important in predicting its environmental behavior.

In the control of the marketed pesticide it is important that certain criteria of identity, quality and reasonable performance should be identified and selected from the physical and chemical properties. Such a selection may then form the basis of a specification (Working Paper 9 - Appendix XIII).

APPENDIX VI

WORKING PAPER 4

ASSESSMENT OF EFFICACY OF PESTICIDES

The pests, diseases and weeds of major food crops and pest of significance to public health continue to be controlled by the use of chemical pesticides which offer, in many cases, the only satisfactory method of limiting losses at the present time. Thus registration authorities have to assess the efficacy and crop safety of new pesticides in order to evaluate the benefits to be obtained from their use. These benefits have to be weighed against the potential hazards from the introduction of a new compound, the decision on granting registration incorporating this benefit/risk analysis.

The term "efficacy evaluation" is proposed here to cover the evaluation of pesticides for efficacy and safety to crops (and thus is synonymous with the commonly used term "biological evaluation").

Registration authorities need to make use, as far as possible, of available efficacy evaluation data that may be obtained in the country or region of use, or in other countries or regions with similar climatic and agricultural conditions. Utilization of the latter data presents a number of very positive advantages, in particular:

1. the avoidance of duplication of effort, unnecessary repetition of trials and consequent saving in costs and staff resources;

2. the acceleration of the registration process, permitting the more rapid utilization of effective new pesticides, and

3. the possibility of registering products for minor uses that would not justify a full trials programme in every country.

Need for International Harmonization of Efficacy Evaluation Procedures and Trial Methods

The use of efficacy evaluation data from a diversity of sources is facilitated if evaluation procedures and methods are harmonized at national and international levels. The 1977 Ad Hoc Government Consultation on the International Standardization of Pesticide Registration Requirements recommended that every effort should be made to define the basic principles and requirements of efficacy evaluation and that harmonized guidelines be developed.

Substantial progress in harmonized methods has been made since 1977. In particular, the European and Mediterranean Plant Protection Organization (EPPO), taking as its basis nationally harmonized methods submitted by its member countries, has now drawn up 37 internationally agreed harmonized Guidelines for the Biological Evaluation of Pesticides for the control of particuiar pests and diseases. Regular publication of new guidelines can be expected. The work of a joint panel involving specialists from EPPO and the European Weed Research Society (EWRS) should shortly result in publication of Guidelines for the Biological evaluation of Herbicides. All EPPO guidelines follow a unified framework.

Attention should also be drawn to activities in the field of national harmonization of efficacy evaluation methods, particularly those of the American Society for Testing and Materials (ASTM), the American Phytopathological Society (APS) and the Australian Weed Committee. The harmonized methods developed by these national agencies can form the basis for the elaboration of internationally harmonized guidelines. Finally, attention should be drawn to the Council of Europe's publication "Pesticides" which provides a valuable general background of recommendations for the conduct of an efficacy trials programme, set in the broader context of the whole registration procedure.

In spite of the considerable progress which has been made, there are still areas where harmonized efficacy evaluation guidelines are lacking. In particular, there is an urgent need for methods on pesticides applied against the pest, diseases and weeds of the major tropical and sub-tropical crops. Developments in this field could with advantage be modelled on the activities referred to above. A common framework for guidelines should be established and Regional Organizations and Institutes in the tropical and sub-tropical zones should be encouraged to identify the priorities for harmonized guidelines and to undertake a programme for their preparation in consultation, where appropriate, with agencies already working in the field. Harmonized methods are also lacking for the evaluation of pesticides used in animal husbandry and consideration needs to be given to the most suitable way of encouraging progress in this field, recognizing the different authorities which deal with the problem at national and international levels.

Need for Commitment

If progress is to be made in using efficacy evaluation data from different sources and produced by harmonized methods, a commitment is required from national authorities that they recognize particular harmonized methods and that they accept data obtained with their use. The possibility now exists, with the availability of internationally agreed harmonized guidelines (at least for the member countries of EPPO), for significant progress to be made toward the aims outlined in the introduction to this working paper.

APPENDIX VII

WORKING PAPER 5

TOXICOLOGY

The toxicity of a pesticide is its ability to cause injury to living things and is therefore the sum of the various effects when administered or absorbed through certain routes. The hazard or risk presented to living things by a pesticide of a given toxicity depends not only on its toxicity but also on the circumstances under which it is used and whether or not these uses lead to a significant exposure to the pesticide.

In order to assess the hazard or risk of using a pesticide its toxicological properties must be investigated thoroughly and the type of the tests depends, to a large extent, on the manner in which man is likely to be exposed.

Appropriate toxicity data should be required for registration purposes to allow consideration of the following:

- The possible short- and long-term hazards to field workers handling a product and appropriate precautionary measures necessary to allow safe working conditions;
- The diagnosis and most effective methods for treatment of accidental poisoning;
- The estimate of an acceptable daily intake for man (ADI) so that the significance of any residues in food commodities can be assessed;
- Hazard classification of the formulated product for sale.

Toxicological Requirements

The toxicological studies relevant to pesticide registration were listed by the 1977 Ad Hoc Government Consultation (FAO: Ad Hoc Government Consultation on International Standardization of Pesticide Registration Requirements. 1977 (AGP 1977/M/9). These are still considered to be valid. Acute toxic hazards to operators, by-standers and those exposed during transport or storage are determined by the short-term toxicological properties of the formulated product and may not necessarily be reflected by rests done on the technical active ingredient. Therefore, additional acute studies conducted on the formulated material are considered valuable. In the meantime, a more elaborate review for toxicological investigation of pesticides has been published by the Council of Europe (council of Europe :

Pesticides (5th Edition) 1981). It should also be noted that the WHO Criteria Document No. 6 referred to in 1977 has been issued (Principles and Methods of Evaluating the Toxicity of Chemicals, Part 1 - Environmental Health Criteria 6, WHO, Geneva, 1978 (Part II to be completed in 1983).) and this supplies further details which could help the investigator to select the most suitable technique for a specific study. It must be noted that the toxicological concerns related to biological agents used as pesticides may be considerably different from those for conventional toxic chemicals (Burges H D et al, 1981 Mammalian Safety of Microbial Agents for Vector Control: A WHO memoradum. Bull. Wld Hlth Org., 59, 857-863. Therefore registration authorities should consider these special needs in determining data needed to register biological agents.

Classification of Pesticides Hazard

To assist countries to work towards the acceptance and introduction of the WHO classification of pesticides by hazard, WHO regularly issues guidelines in which pesticide active ingredients are classified (Guidelines to the use of the WHO recommended classification of pesticides by hazard. WHO published document VBC/78.1/ Rev. 3 July 1982).

Where the safety of a pesticide to workers involved in its application cannot be evaluated with sufficient confidence from laboratory studies with animals, a standard protocol "Field Survey of Exposure to Pesticides" has been developed to promote a uniform procedure of such monitoring where indicated (Field survey of exposure to pesticides: Standard Protocol. WHO unpublished document FBC/82.1. available from WHO, Geneva.)

APPENDIX VIII

WORKING PAPER 6

RESIDUES IN AGRICULTURAL PRODUCE

The use of certain pesticides in accordance with good agricultural practice can result in residues in crops or livestock and, further, may leave residues in food derived therefrom. For reasons of public health, authorities should and do take the possible occurrence of residues into account in the registration process. Many national authorities have adopted maximum residue limits (MRLs) on food and/or feeds.

The limits, in most cases, are based on residue data required or otherwise available at the time of registration. The residue data considered by registration authorities are mostly derived from supervised trials, and it is these data that form the basis for setting MRLs.

Development of Harmonized Guidelines

Variations in methodologies in conducting these trials (including the selection, preparation and analysis of samples) have created difficulties in evaluating the significance of information relating to the occurrence, disappearance and fate of residues on or in crops, or groups of crops during their production, preparation for market and processing. These variations have also made it difficult to compare information from different sources and have contributed to differences in the MRLs adopted in different coutnries.

Although the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has provided guidance on the kind of data required for its work on the evaluation of residues in foods, the activities of those meetings and of the Codex Committee on Pesticide Residues (CCPR) have been impeded or affected by the lack of uniformity in approach to the development of data.

In response to an invitation from the Ad Hoc Government Consultation in 1977, CCPR through its Working Groups has developed "Guidelines on Residue Trials Methodology" and these have already been published by FAO, GIFAP and IUPAC. Further guidance on the portion of the agricultural commodity to be analyzed, recommended methods of analysis and on good analytical practice in pesticide residues analysis has also been prepared by CCPR and also published by IUPAC.

In view of the Consultation, these recommended procedures provide a basis for harmonizing the development of residue data suitable for use by national regulatory authorities both for registration purposes and for setting MRLs. Moreover, adoption of these harmonized procedures will increase transferability of data between countries, facilitate the proposal of MRLs by the JMPR and introduce consistency between the bases of data from supervised trials and surveillance data. The Consultation noted that proposals to harmonize procedures for reporting laboratory results and for developing data for foods or animal origin are also being considered by CCPR and it expressed strong support for this continuing work.

WORKING PAPER 7

PREDICTION OF ENVIRONMENTAL EFFECTS

The Ad Hoc Government Consultation on the International Standardization of Pesticide Registration Requirements in 1977 considered that the potential effects of pesticides on the environment were of great importance. Such effects must be carefully evaluated as a part of the registration process to avoid lasting damage to beneficial non-target organisms, soil, water and other important resources which could reduce the quality of life.

The risks to environment from a pesticide are dependent on many factors, such as its toxic properties, its solubility and persistence in the environment, volatility, the amount applied, the formulation, method and time of application and particularly the extent of use. The overall effect of the pesticide also depends on the development stage of non-target species involved, the feeding habits of these species and the extent to which toxic residues of metabolic compounds may accumulate or be concentrated in successive species in food chains. The risks to wildlife may also be accentuated if the animals in the treated area are subject to some external stress; for example, by a lack of food or by adverse weather prevailing at the time.

Some pesticide effects on wildlife may be too complex, subtle, or delayed to be detected by ordinary routine testing in the laboratory or the field. It is impossible to test in such trials all the infinite variety of conditions under which the pesticide may be used in practice. Nevertheless, experience has shown that in many cases, predictions can be made of probable effects of a compound on the environment from consideration of certain basic studies.

The 1977 Consultation concluded that

(a) in most cases a reasonably confident evaluation can now be made of the likely environmental effects of a pesticide product when the use pattern is known. Such an evaluation could be derived from a step-wise procedure of tests each of which was designed to provide meaningful data;

(b) There are good prospects that scientists in different countries could agree on a range of basic tests designed to produce information that should be provided at the time of registration;

(c) During the early years of the registration of a product there might be a need to conduct further studies to confirm predictions or indicate a need for further information.

The Consultation recognized that the potential environmental effects vary greatly from country to country and situation to situation and recommended that registration authorities evaluate environmental risks implicit in the proposed use of a pesticide by considering the basic chemical, physical, toxicological and biological data on the product in the light of the proposed use pattern. It drew attention to the desirability of obtaining certain data specific to the environmental conditions after registration and an appropriate period of use, existing in the particular country or region and urged national authorities to carry out appropriate field observations and monitoring programmes to confirm predictions or determine the need for further studies. It further recommended that all registration authorities agree, as far as possible, on requirements for data needed to predict the impact of pesticides on the environment and, to this end, recommended that the FAO Panel of Experts on Pesticide Residues and the Environment should be convened to draw up, in consultation with experts government, academic institutions and industry, guidelines for the evaluation of the probable hazard to the environment of pesticides being considered for registration.

Environmental Criteria for Registration of Pesticides

Responding to these recommendations FAO convened Expert Consultations in 1979 and 1981. A composite report of the two meetings is available (FAO Expert Consultation on Environmental Criteria for Registration of Pesticides, 1981. Plant Protection Paper 28.)

The 1981 Expert Consultation agreed that the test methods should be harmonized by defining common criteria for test systems. The Consultation recognized however, that flexibility is essential to make differing registration requirements sufficiently compatible.

In deciding whether whether a risk is acceptable it is of fundamental importance to consider the benefits likely to accrue from the use of the chemical. The balance between risk and benefit may differ under different socio-economic systems. Each country undertaking registration must decide what aspects of its environment might be affected by proposed pesticide use. It must also decide what values to place on these aspects and to weigh them in the light of the needs under its own agricultural and socio-economic circumstances.

In practice, information of environmental significance comes from three basic sources: application and use pattern, the fate and possible occurrence of residues in relevant parts of the environment and the effects of predicted exposures on non-target species.

Prediction of Environmental Behavior of the Pesticide

Data have to be developed prior to registration to allow a prediction to be made of the environmental behavior of the product when applied according to the recommendations for use.

The mobility and degradation of a pesticide are of fundamental importance in the evaluation of its environmental fate. These are determined by the vapour pressure, solubility in water, partition coefficient between water and non-miscible solvents, chemical stability and adsorption/desorption characteristics.

Assessment of fate of a pesticide after its release into the environment is essential to the assessment of environmental loading and subsequent evaluation of exposure and risks from that chemical. Degradation and mobility studies are therefore the most important sources of information on the fate of a pesticide in the environment. These studies usually include analytical procedures for estimating residue levels; degradation rates and residue levels in plants, soil and water; identity of major metabolites in plants, soil and water; and leaching through soil.

Prediction of Effects on Non-target Organisms

Although the data on the toxicity of a pesticide used for assessing possible hazards to man are normally obtained from studies carried out with rodents, some of the results are also relevant for the prediction of potential effects on non-target species in the environment (eg, biaccumulation). However, since many naturally occurring organisms belong to other taxonomic groups, toxicity data on other species such as birds, aquatic invertebrates, honey bees and other beneficial arthropods form an additional part of the primary data needed for predicting potential adverse effects to non-target species. The test species should be carefully selected in order to justify broad environmental predictions being made on the basis of results from a feasible test programme. From a knowledge of the habitat of the species of concern and the sites of deposition, as well as the mobility and degradation rate of a pesticide it is possible to estimate the exposure of the species to the pesticide.

The toxicity data available for the different organisms tested may then be used to estimate the effect of the likely exposure on related species at risk in the area. The predictive value of the basic data depends on the concept of extrapolation from one species to another. Experience has shown this to be a valid concept although it is clearly more reliable with closely related species. By applying these considerations it should become apparent whether particular groups of non-target species are likely to be at risk when the product is used as recommended.

Post Registration Activities

If field surveillance, monitoring studies or further research give rise to doubts about the validity of predictions regarding environmental effects, the continued use or the conditions for use have to be reconsidered. Further studies on occurrence of residues, or the possible biological effects etc. may have to be carried out. On the other hand, experience of the use can suggest extended use of a pesticide.

APPENDIX X

WORKING PAPER 1

GUIDELINES AND MODEL SCHEME FOR THE ESTABLISHMENT OF NATIONAL ORGANIZATIONS FOR THE REGISTRATION AND CONTROL OF PESTICIDES

The main purpose of pesticide registration is to ensure that pesticides, when used in accordance with the directions for use, warnings and precautions, will be effective for their intended purpose while not posing unacceptable hazards to users, consumers of the treated crops, and wildlife or other non-target organisms.

A well-devised and operated registration scheme also has to advise on the adequate control of the registered pesticide products in the market in respect of their specified quality, their labels, packages and manner of distribution.

The authority assigned the responsibility for administering a registration scheme needs the legal power to ensure that all products are registered, adequate data are supplied by the applicant in support of the application, only registered products are offered for sale, and that products are used in a manner consistent with the labelling.

The procedures should apply at least to pesticides for use in agriculture, horticulture, forestry, public health, food storage areas, and areas in or around the home. Co-ordination between various government departments, particularly Health and Agriculture, is essential so that all aspects related to the registration of pesticides can be centrally controlled by one comprehensive process.

For the smooth introduction of a comprehensive scheme for the registration of pesticides, it is critical to plan carefully the various operations involved. Sufficient time must be allowed for the selection and training of staff, the selection of an advisory panel or committee, and for making necessary legislative changes.

Registration schemes can be developed to very elaborate standards and the various phases are described in some detail in the draft FAO "Guidelines and Model Scheme for the Establishment of National Organizations for the Registration and Control of Pesticides" (Background Paper C). However, countries intending to utilize the FAO model scheme for the first time should not be too ambitious in the initial stages of the introduction of a registration scheme.

While such a scheme may require submission of all relevant data, some of it, eg toxicology, could be in the form of summaries instead of fully detailed research reports, provided that the registrant can support his application with evidence of registration in countries which operate a comprehensive registration scheme, as well as his right to use such data for purposes of registration. Interpretation of data by international groups of scientists such as the FAO/WHO joint Meeting on Pesticide Residues also provide an important guide which a country could use in relation to its own needs and purposes. National governments must still, of course, make their own decisions on the applicability of an international evaluation to their country and would need to set up national procedures to register and control pesticides, labels and use.

In many countries that do not operate a formalised pesticide registration process a primary infrastructure for control may exist and with appropriate training and motivation of staff, practical control of pesticides could be achieved quickly.

Phased Registration

A number of countries operate a phased registration system. This is a procedure by which the introduction and use of a pesticide is permitted by the registering authority at various levels of introduction, each of which is subject to limitations decided by the authority. Provided that an initial set of basic data are available then limited clearance could be considered.

The 1977 Ad Hoc Consultation suggested that there were three clearly identifiable stages in the development of a pesticide:

- Trials (or experimental) clearance;
- Provisional (or limited) clearance;
- Commercial (or full) registration;

The benefits of such a scheme are that it:

(1) permits full development of practical use experience during the product's development. This increases confidence in the decisions of full registration.

(2) enables practical user experience to supplement the manufacturer's information so that he can make sounder decisions on commitments to expensive long-term manufacturing investments than is possible without adequate field data.

On the other hand, concern has been expressed that it is wrong to market products that are not fully tested. This view of course has merit and it is vitally important that the authority does not allow the use to be more widespread in a given phase than the data justify.

With regard to the data needed at each phase it is inappropriate to attempt a formalised "checklist" approach and each product should be judged on its merits. Some general guidance on the level of data needed at each phase was suggested in Background Paper D.

APPENDIX XI

WORKING PAPER 2

SPECIAL PROBLEMS IN REGISTRATION PROCEDURES

Registration of Commodity Products

Many pesticides are based on active ingredients which are chemicals which have been widely available for many years and some of which were never patented for pest control. Other pesticides are based on active ingredients which though patented many years ago were not subject to registration procedures comparable to those required in more recent times. These products are often referred to as commodity pesticides, some of which are the subject of FAO Specifications. It is not unusual for these pesticides to be manufactured or formulated by many companies including local enterprises in developing countries.

Registration authorities are faced with a dilemma when considering applications for registration for products developed as copies of pesticides that have been on the market for a long time. It could be considered unreasonable for registration authorities to demand the full package of registration data for such products especially when there is extensive information in the open literature and worldwide experience with similar formulations, supported in some cases by many years of safe use. In such cases it is reasonable to required evidence of composition and quality and compliance with specifications such as those published by FAO, together with the information normally required for labelling and packaging. Registration authorities are urged to assure themselves that such manufacturers are competent to produce pesticides of acceptable and uniform quality and provide the technical service necessary to ensure effective and safe use.

Following the expiry of patents covering the manufacture and/or use of proprietary pesticides, other manufacturer and formulators often seek to exploit the market by offering pesticides manufactured as copies of those previously covered by patent. Since the registration of the original pesticide product had been based on an extensive package of proprietary data submitted by the patent owner who developed the data at his own expense, registration authorities cannot in all good faith agree to register the copy on the basis of data supplied by the original proprietor without his agreement. On the other hand, government authorities cannot reasonably deny the public the benefits to be derived from commercial competition.

The new applicant for registration should be required to produce documentary proof of his right to use any unpublished proprietary data. He should also supply adequate evidence of equivalence to the product being imitated. This could include proof that the pesticide came from the same source, or that it was of corresponding composition and quality but in many instances would necessitate evidence of comparable biological and toxicological performance. It is impossible to give detailed guidance and each case must be considered on its own merits, with due regard to the proprietary rights to the use of data.

Proprietary Rights to Registration Data

The 1977 Ad-Hoc Consultation on the International Standardization of Pesticide Registration Requirements accepted the claim of the Pesticide Industry that there must be adequate protection provided for companies with respect to proprietary data. The position of industry is that in the absence of acceptable rules and their implementation on a worldwide basis, it has no option but to request that registration data are kept strictly confidential. By doing so industry does not wish to evade its social responsibilities by keeping secret the results of its "safety data" but it must reduce the possible advantages competitors could gain through the use of data submitted by a company whilst evading sharing the commercial risks associated with the development of pesticide products and the updating of the data base for safety evaluation.

The 1977 Consultation recommended that the Group on Registration Requirements, in consultation with representatives of the pesticide industry, "investigate ways and means of reconciling the public interest in data submitted to registration authorities in both developed and developing countries with the manufacturers' interest in having some of the information treated as confidential while at the same time providing such protection from competitive use of data by other registrants as would be appropriate".

It is important to appreciate that the issue of concern to industry is the unauthorized use either directly or indirectly by a competitor of data generated by another company, ie without either license or agreement to do so. Confidentiality per se is not important except where it related to accepted trade secrets, eg manufacturing or formulating know-how. Consequently, if and when a solution is found and implemented by all registration authorities, the legitimate interests of all parties concerned - industry, government and general public - will be provided for. One serious consequence of allowing competitors to benefit from the use of data to which they have no right is the discouragement of the research and development required for the production of new pesticides because it becomes unrewarding.

With regard to confidentiality per se, it is the expressed opinion of GIFAP that there are no objections concerning public access to health and safety data submitted in support of pesticide registrations as long as this public access does not include the right to copy that proprietary data.

Many countries already protect the proprietary data supporting registration. The period of protection varies from country to country depending upon its own circumstance. As one example, in the USA an exclusive use period of 10 year plus compensation for the use of data for an additional 5 years exists. Currently, legislative changes are being considered to replace this scheme with an exclusive use period of at least 15 years with the possiblity of extending the period to 20 or 25 years.

APPENDIX XII

WORKING PAPER 8

RESTRICTIONS ON THE AVAILABILITY OF PESTICIDES

Many pesticide incidents are the direct result of inadequate control of the supply and distribution of pesticides in a country. Pesticides should be available only to those capable and instructed in their use or able to read, understand and follow a label. Restricting the availability of a product to an appropriate user can be an important way of reducing hazards to man and his environment.

Restrictions Through the Registration Process

In countries that exercise effective control of the availability of pesticides through a pesticide registration process, the registered product may be marketed only with the restrictions or controls on packaging, labelling, supply and use agreed by the registration authority. It is essential to recognize that an effective registration process with subsequent supervision can play this vital role in restricting the availability of certain pesticides. One of the advantages of a phased registration process is that a tight rein can be kept on the more hazardous products during their introduction, if this is deemed necessary.

Role of Classification by Hazard

In many countries registration decisions on availabilty, labelling, etc., are influenced by the use of a classification of pesticides by toxicity or hazard. The WHO Recommended Classification of Pesticides by Hazard was issued in 1975 and has since gained wide acceptance. Guidelines on the use of the classification together with extensive examples have been published. The WHO Classification is open-ended but it is clear that there must be a point at which the acute hazard posed by the use of a pesticide is so low as to be negligible, provided that common sense precautions are observed, as when dealing with any chemical. This point has been assumed by WHO to be at an oral LD 50 of 2,000 mg.kg for solids and 3,000 mg/kg for liquids, both figures referring to the formulated product.

The Council of Europe has endorsed the WHO Classification in the 5th Edition of its booklet 'Pesticides' and also makes recommendations on how the classification may be used to control sales and purchases and labelling. In addition the Council of Europe Resolution AP (81) 3 recommends that only formulated products with an LD50 greater than 2,000 mg/kg should be available for purchase for domestic use.

FAO/WHO Data Sheets on Pesticides

To provide countries with basic information on individual compounds, data sheets are issued by FAO/WHO. These include recommendations on the control of availability of pesticides and their use. It is expected that such recommendations which are based on the WHO Recommended Classification of Pesticides by Hazard, will contribute to a degree of international harmonization in restrictions on availability.

An outline of the categories of availability recommended is as follows:

Category 1 The pesticides should be available only to trained applicators, individually licensed, who have demonstrated a good knowledge of the chemical, its uses and hazards, and the precaution to be taken in use.

This category applies only to a few very highly toxic pesticides (eg WHO Classification Ia, extremely hazardous).

Category 2 The pesticides should be available only to concerns that will apply them under strictly controlled and supervised conditions, using trained operators. The application of pesticides will normally be the major part of their commercial operation (eg WHO Classification Ib, highly hazardous).

The term "concern" includes contractors, pest control operators, etc. This category applies to most very highly toxic pesticides and other pesticides for which it is felt that special training on supervision in use is necessary.

Category 3 The pesticides should be available to commercial applicators for whom its application is not a major part of their commercial operations, subject to a permit being received from a competent authority, specifying the pesticide, conditions of use and the precautions to be taken (eg WHO Classification II, moderately hazardous).

The term "commercial applicators" includes farmers, fruit growers foresters, etc., and those responsible for bulk food storage. This category applies to pesticides which are moderately toxic, and to pesticides which have an adverse effect on the environment to the extent that their uncontrolled use without permit is undesirable.

Category 4 The pesticides should be available in the same manner as for category 3, without requirement that a permit be issued.

This category applies to toxic pesticides that may be distributed for commercial use and could be available to the general public (eg WHO Classification III, slightly hazardous).

The categories set out do not include the prohibition of the use of a very highly toxic product. Such prohibition may be desirable if control measures cannot be enforced to the extent that safety in the use of the compound can be assured. However, this is a matter for national decision in the light of prevailing circumstances.

In addition, categories of availability actually utilized by national authorities should be compatible with the level of training and expertise in handling that exist even though this will most likely lead to adoption of different schemes or categories in different countries. Use of the WHO toxicity classifications can provide a consistent benchmark for test data and labelling. The system used must be simple and practical and consistent for different types of chemicals of the same toxicity.

APPENDIX XIII

WORKING PAPER 9

COMPOSITION OF PESTICIDES AND SPECIFICATIONS

The report of the 1977 Ad Hoc Government Consultation stated that:

1. Specifications include physical and chemical properties used to define the products for procurement purposes. Certain of these physical and chemical properties are identical to those provided for identification of the product for registration purposes.

2. In the case of pesticides based on new active ingredients or novel formulations it may not be possible to provide international specifications prior to registration. Therefore the manufacturer should supply relevant data and his own specifications, based on the FAO model specification, together with those chemical and physical characteristics that are identifiable and determinable.

Although substantially correct, these statements have led to some confusion on the subject, and the Consultation agreed it would be helpful to provide further explanation of the concepts and definitions used.

The technical grade pesticide and its formulated products are identified and defined by the data normally supplied for registration purposes. This is, and always has been, an essential and standard requirement of all registration systems. Registration is granted on the basis of this declaration of composition and the registrant is thereby required to ensure that the marketed product complies with the declarations made for technical grade material and formulations. It is implicit that the toxicological residue and efficacy data submitted in support of the application for registratinn have been developed with material of corresponding composition.

Regulatory Authorities interested in ensuring that pesticide products on the market maintain an adequate standard of performance are unable to check the biological activity conveniently. However, they are able to examine samples taken from the market and to monitor the important physical and chemical characteristics which determine the biological performance. The most important of these characteristics is the active ingredient content. In the case of complaints or doubts, authorities may extend their examination of samples to determine whether product composition complies with that given by the manufacturer.

For contractual purposes between seller and buyer, it is longstanding practise to provide a guarantee of composition and quality which can be defined and checked by a series of physical and chemical characteristics which are identifiable and determinable. This is generally referred to as a specification. Such a specification should not require judgement to be exercised by the buyer and thus should consist of quantifiable parameters which should include tolerances to allow for expected fluctuations arising from the inherent variability of the manufacturing process.

Where there are two or more sources of the technical grade ingredient and a number of formulations it is necessary to develop a specification to ensure that adequate standards of quality and performance are maintained.

It is clearly not practicable to check all the criteria of definition, nevertheless, criteria of identity, quality and reasonable performance standards should be identified and selected and should form the basis of the specification. A specification should be as brief as possible and unambiguous and be supported by appropriate test methods to determine whether the material conforms to the criteria and standards of the specification. It should not necessarily indicate biological efficacy nor give information on hazards although certain relevant information may accompany a specification even though it does not form a part.

It should be the responsibility of the appropriate authority to design such a specification in collaboration with the registrant(s).

A specification has two main post-registration uses:

1. For the competent authority to check that each product on the market complies with that specification.

2. For use as part of a contract of sale so that the buyer may purchase a pesticide with some guarantee of the quality expected.

The requirements of a specification can be built into a seven point basic outline:

(i) Physical state including any undesirable features

(ii) Physical properties including any undesirable features eg. that the product cakes very easily.

(iii) Identify tests using more than one criterion whenever possible.

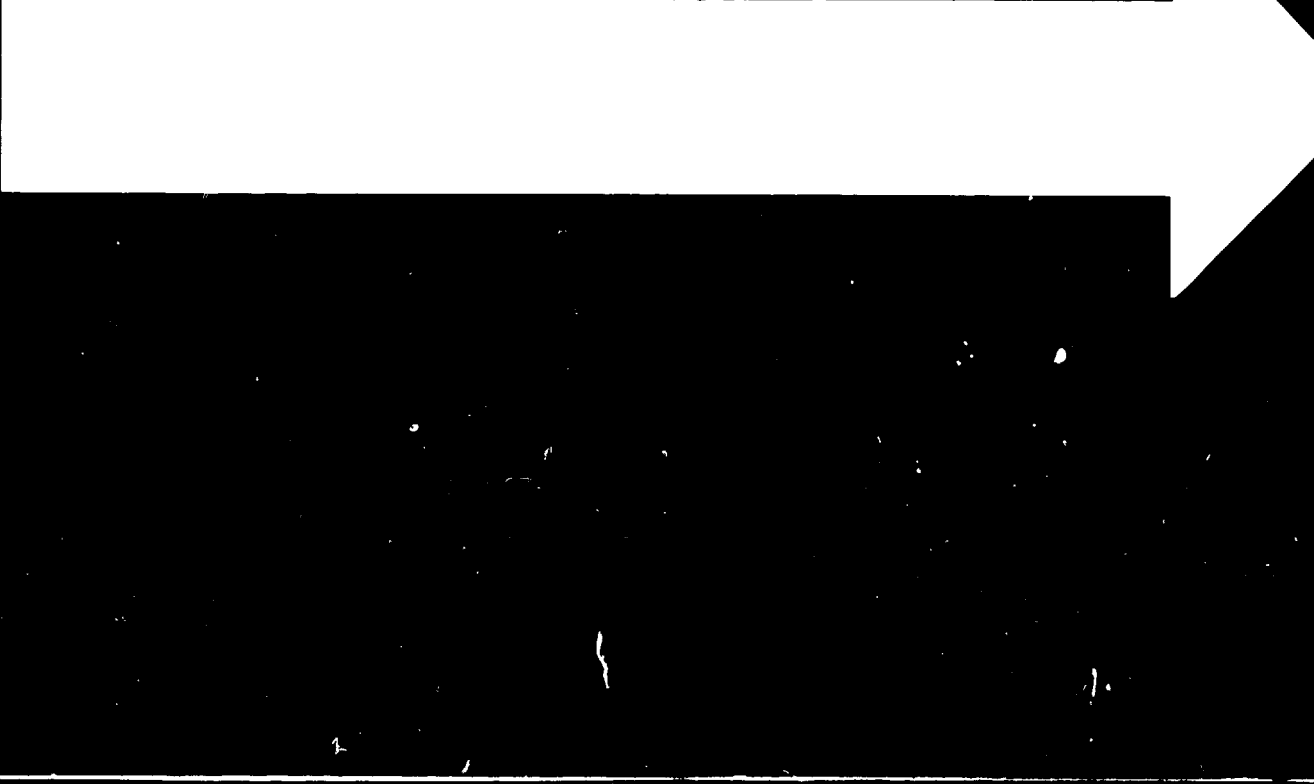
(iv) Assay: The parameters to be used should be defined and any minimum recommendation should be stated. The declared content of active ingredient must be a feature of all specifications and provisions must be made for a tolerance around the nominal value of content which is achievable in practice.

(v) Methods of assay or analysis for the active ingredient should, as far as practicable, be based on an agreed collaboratively studied method so that everyone makes the same interpretation in practice of the written method to ensure that consistent results are obtained.

(vi) Impurities and other contaminants These should be listed as far as they are known and limits should be placed on those which are important. Methods of analysis should be given.

The specification should not include limits or methods of analysis for unimportant impurities.

(vii) Stability Information on both the chemical stability and that of the physical state should be given.



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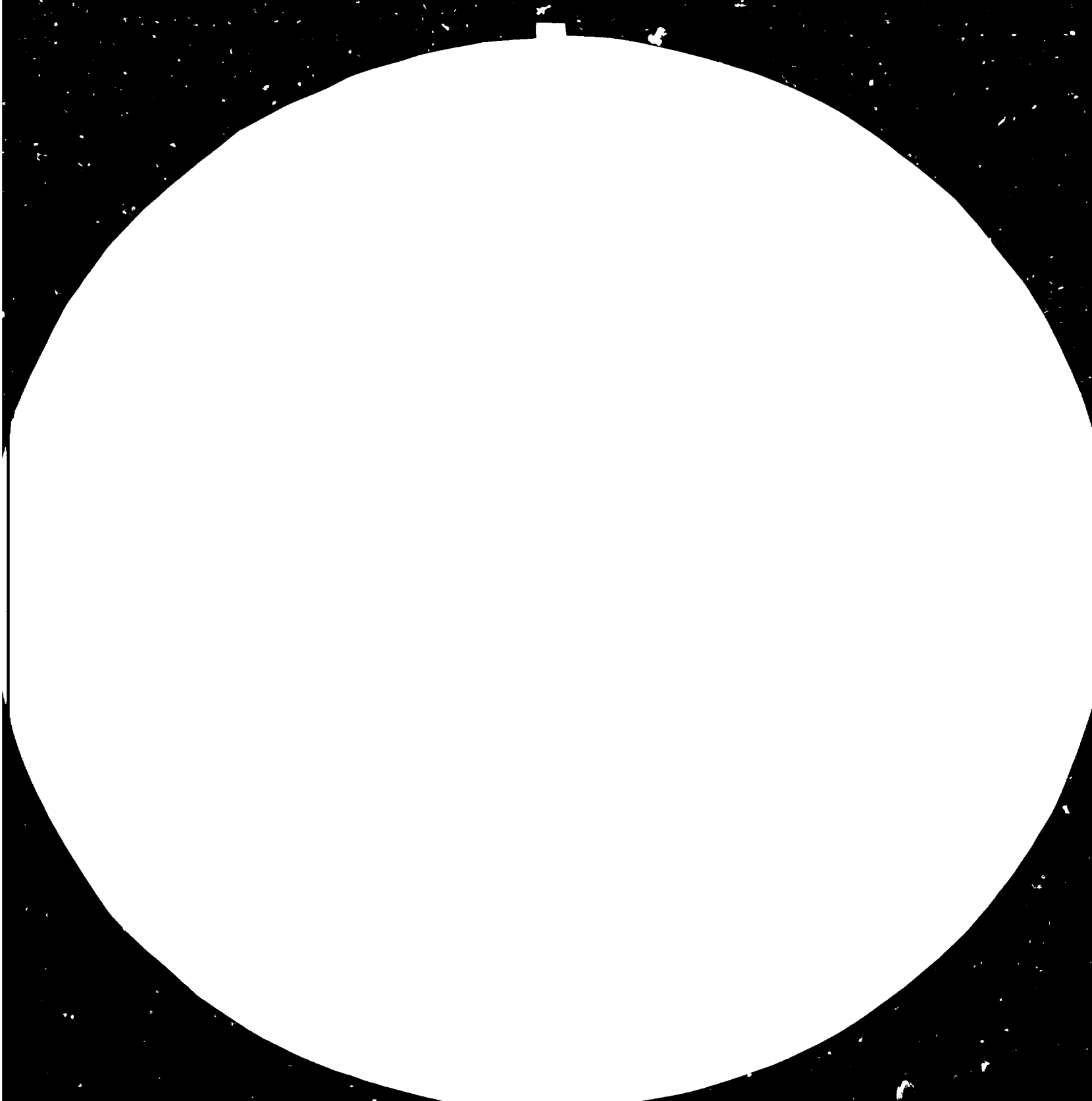

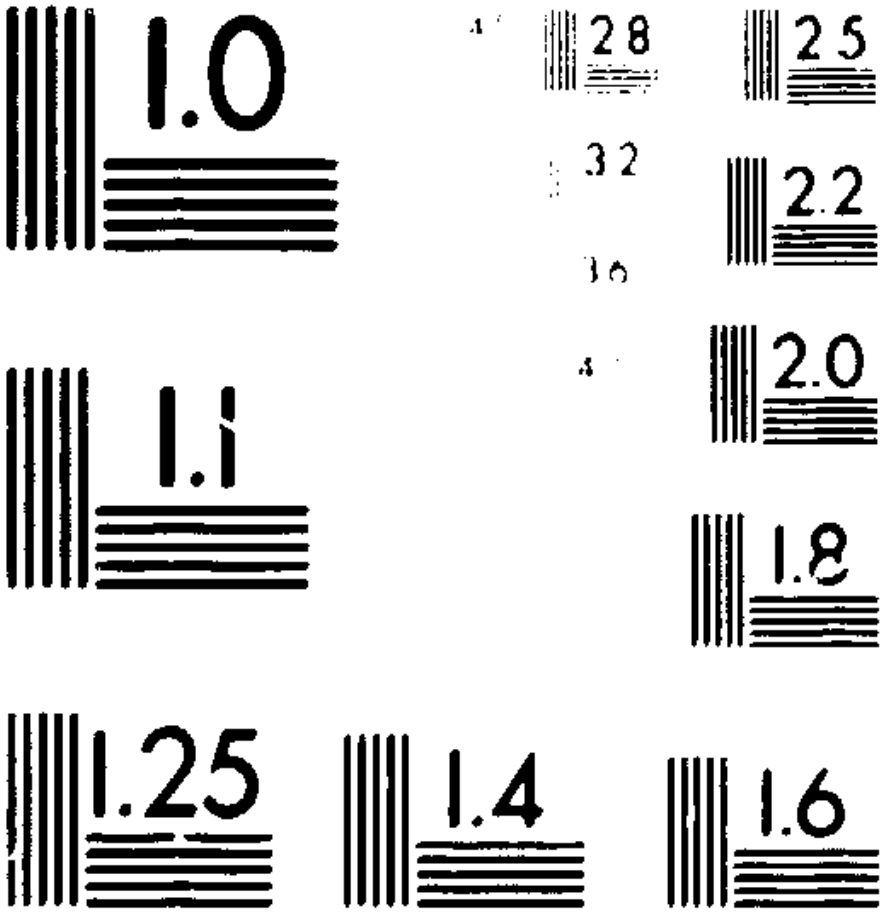

FAO and WHO Specifications

The trade in pesticides being of an international character it is desirable that, at some stage, international specifications should be developed. Harmonization of relevant national standards through the greater use of FAO and WHO specifications should facilitate world trade in pesticides and make satisfactory products available economically to the user.

FAO Specifications for pesticides used in agriculture (plant protection and protection of food in store) provide internationally accepted standards of quality for technical grade material and their formulations which will guarantee the quality the user expects of a product. They define the essential chemical and physical properties linked with certain biological requirements for a product and are designed to reflect generally acceptable product standards. The specifications may be used to provide one international point of reference against which products can be judged, either for regulatory purposes or in commercial dealings and should be reviewed when necessary. The FAO Manual on 'Use of FAO Specifications for Plant Protection Products', second revision, was published in 1979 and needs further revision to reflect current recommendations.

The Consultation agreed that it was important to maintain the distinction between:

1. data supplied to registration authorities on the composition of pesticides, (declaration of composition);

2. a normal specification designed to maintain quality and used as a basis of contract for buying and selling; and

3. an international specification such as those produced by FAO and WHO that would be used as an international point of reference.

and concluded that FAO Specifications on their own are insufficient to define a product for registration purposes.

APPENDIX XIV

WORKING PAPER 10

LABELLING OF PESTICIDES

Although registration procedures for pesticides have become increasingly complex, the end-product of any registration has remained the same - a labelled package containing a pesticide formulation. Research and development and the assessment of pesticide safety and efficacy in use are finally reflected in the accumulated information which needs to be communicated to those who handle that package and use its contents. The hazards during transport, storage, use or disposal, will have been assessed during the registration procedure, and labelling is the main method of identifying the product and communicating instructions and advice to all concerned with its handling.

Documents listing national registration requirements indicate that appropriate labelling is a mandatory requirement but there are obviously many important differences in the details and methods of meeting the objectives required by different national authorities which could lend themselves to a high degree of harmonization without reducing the validity or effectiveness of these requirements.

The Ad Hoc Government Consultation on the International Standardization of Pesticide Registration Requirements in 1977 discussed the labelling and packaging of pesticides. The development of a satisfactory label was considered to be the joint responsibility of industry and government and the label was recognized to play a major role in transmitting advice and defining responsibilities. For successful communication a label must be easy to read and understand and the printed and graphic material on a pesticide label should bear all the necessary information and instructions for effective and safe use in a language understood by the user. Without doubt, the most widely advocated advice by both official agencies and industry is "READ THE LABEL".

Recent developments in the use of graphics to convey label information may be useful, particularly in regions where users are or may be illiterate. It was recognized that the value of any such system would depend on its being used on a wide scale and graphics could be most useful for those key aspects of labelling which relate to operator or environmental protection. However, it is evident that not all label information could be presented graphically and available label space may limit the extent to which graphics can be used in practice.

The 1977 Consultation proposed that a Group from the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards be convened as a matter or urgency to develop "Guidelines on Good Labelling Practice" for adoption and use by industry and registration authorities.

Guidelines on Good Labelling Practice for Pesticides

In response to the proposal of the 1977 Consultation FAO has prepared Guidelines on Good Labelling Practice for Pesticides (Background Paper I). These are intended particularly for the consideration of government officials involved in the acceptance and approval of labels as integral part of the registration of pesticides.

Part I first describes and explains the Hazard Classification scheme for pesticides recommended by the World Health Organization, then defines the label information likely to be needed for a conventional product for ground spraying of crops, possible requirements for special products or purposes, then the construction and layout of the label and its contents, and ends with emphasis on the benefits possible from training in label compliance.

Part II then provides detail of the recommended standardized symbols and phrases giving warning of the risk, the standard precautionary phrases which may be needed for normal ground spray operations and products, and additional or alternative phrase suited to special products or purposes.

APPENDIX XV

WORKING PAPER 11

PACKAGING AND STORAGE OF PESTICIDES

Although registration authorities do not, in general, dictate packaging requirements they do expect packaging to be fully described as part of an application and expect the package to be appropriate, ie the packaging material must be impervious to and must not affect the contents under a range of conditions. The size and ease of handling of a package are relevant to safety and the registration authority will take into account the way in which a package will be used. Unit area packs reduce left-overs which are a major cause of storage/disposal problems.

Whereas the wide variation in user requirements and commercial development makes it difficult to envisage complete standardization of packaging, the rationalization of the packaging industry will contribute to the concept of standard packaging.

Adequate storage of pesticides is important both for safety and for maintaining the efficacy of a product, and storage conditions should keep containers and contents in good condition. Metal containers should be stored in a dry area to prevent rusting. Metal, glass or plastic containers should not be stored near steam pipes or where there will be temperature extremes. At low temperatures some chemicals may crystallize and although the crystals may sometimes be re-dissolved by warning and agitation it is obviously better to prevent freezing.

Storage areas should be securely locked unless supervised and necessary precautions should be taken to prevent injuries. Leaks and spillages should be cleaned up immediately and in addition to the usual fire precautions the local fire department should be informed on the type of chemicals being stored, so that they can take appropriate precaution in case of fire.

Although rarely a registration requirement, pesticide labels often carry advice on suitable storage and occasionally specify temperature limits. Since these are likely to vary from one country to another it would be difficult to standardize storage statements, and these where desirable should be realistic for and agreed in the country or area concerned. Deterioration of a product due to inadequate storage could ultimately cause a disposal problem.

FAO Guidelines on the Packaging and Storage of Pesticides

The FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, in its report of the second session, Rome, 15-19 October 1979 expressed the view that a study on pesticide packaging should be carried out urgently.

A study was carried out in 1981 to investigate the conditions in several countries under which pesticides are formulated, repackaged, transported and stored. The draft FAO Guidelines (Background Paper I) were prepared on the basis of this study and existing national and international advice. The guidelines include advice on standards for pesticide containers, the selection of appropriate containers for pesticides and standards for the storage of pesticides.

WORKING PAPER 12

DISPOSAL OF SURPLUS PESTICIDES AND PESTICIDE CONTAINERS

Pesticide containers present an unusual problem since they can be as dangerous when they are thought to be empty as when they are known to be full. Under no circumstances should empty containers be abandoned or be allowed to accumulate in an area accessible to unauthorized persons. A pesticide residue remaining in these containers may be a hazard to children, pets, livestock and wildlife, as well as to adults who may convert the containers to other uses.

Pesticides users seldom decontamimate containers after use and product labels do not yet contain enough information or instructions on usage and cleaning of containers to make them less hazardous. Registration authorities are now beginning to ask registrants for information on methods of safe disposal of surplus products and containers based on existing knowledge of the chemical, physical and other relevant properties of the product.

Disposal methods and necessary precautions will depend on the products, the container and facilities available. It is important that advice given to the user is relevant to his capability of following that advice successfully. There are many publications discussing these problems and offering advice; and the problems seem in general to be categorized into those of:

(a) combustible containers;

(b) small non-combustible containers;

(c) large non-combustible containers;

Surplus pesticides and residues in containers can be largely avoided by good housekeeping and by following a few simple rules. Combustible containers holding solids can often be emptied completely and there are data which indicate that double or triple rinsing of containers holding liquid formulations can produce relatively safe empty containers. The advise to triple rinse a container and add the rinsings to the spray tank is important and practicable.

Council of Europe Guidance

The Meeting examined the Guidance on the Disposal of Surplus Pesticides and Pesticide Containers (Background Paper L) based on Council of Europe booklet on 'Pesticides' recognizing that this represented the only current international guidance on disposal problems. The Meeting endorsed the contents as being technically sound but appreciated the difficulties in giving specific advice suitable for all situations. General principles on the various aspects of disposal could be agreed but each situation, bearing in mind the facilities for disposal and decontamination, should be considered individually.

APPENDIX XVII

WORKING PAPER 13

CODE OF CONDUCT IN THE TRADE AND USE OF PESTICIDES

A number of organizations and countries have expressed concern about the propriety of supplying pesticides to countries which do not have infrastructures to register pesticides or to use these materials safely. There have been a number of cases of poisoning due to pesticide misuse and, while recognizing that it is impossible to eliminate such incidents completely, it is essential that every effort should be made to handle pesticides only in accordance with good and recognized practice.

In the absence of an effective pesticide registration process and infrastructure for controlling the availability of pesticides, an importing country must depend heavily on the pesticide industry through its national association and its international trade association (GIFAP) to promote the safe and sensible trade and use of pesticides by working with whatever infrastructure that exists in a country. The role of industry and the ability of a responsible company to contribute to education and safe practices should not be underestimated and countries with limited resources should avail themselves of any help offered. Distributors, re-packers, advisers and users also have a responsibility towards the safe trade and use of pesticides.

The role of the exporting country is yet another factor to be considered. Considerable emphasis have been given recently to the desirability of regulating pesticide exports from producing countries. While no company should trade in pesticides without evaluating the risks the fact that a product is not registered in an exporting country is not necessarily a valid reason for that country refusing to allow exports of the pesticide. For example, the particular pest problem requiring its use in the importing country may not exist in the exporting country.

Ensuring that the importer knows the nature of its purchases will not, in itself, end or even reduce the risks from pesticides. Only effective control and education in the country of use will do that and FAO strongly favours the development of a strong national internal framework, legal and technical, for pesticide control.

Although an exporting country could supply relevant information to the importer on the use of a pesticide, for a variety of reasons, this may be difficult. Most cases of poisoning are the result of misuse. Education and training in the country of use especially at village level would be a major contribution to progress in reducing such incidents.

Until a country has the infrastructure and resources to manage the restriction of pesticides usually required to control the supply, the elaboration of an internationally agreed Code of Conduct in the Trade and Use of Pesticides could offer a major contribution to the safe and efficient use of pesticides.

Whilst a Code of Conduct may not solve the problem, nevertheless, it should go some way towards defining and clarifying the positions of the various parties involved in trade and use of pesticides and should be of value in countries which do not yet have control procedures. Where there is a pesticide regulatory process in a country, the need for a Code of Conduct will obviously be less than where there is no such scheme in operation.

Because of its wide interests and responsibilities in the use of pesticides in agriculture the Consultation considered that FAO is the most suitable organization to prepare such an international Code.

In developing such a Code the Consultation expressed the view that the Director-General should consider the responsibilities of all people involved in the safe and effective use of pesticides including governments, manufacturers, distributors and users and the following topics should be considered, among others for inclusion:

User information including labelling, storage and disposal; International trade and information exchange; Advertising and marketing; Restriction of availability; Training and education of users; Packaging.

LIST OF DOCUMENTS

Agenda Item	Title	Document No.
General	Inter-agency Consulation on Impact on Human Health and the Environment of Small Scale Formulation of Pesticides for Local Use	Room Document
5	A Summary of the Main Aspects of the Pesticide Registration Schemes in Member Countries of the Regional Network for the Production, Marketing and Control of Pesticides in Asia and the Far East.	BP. A (App. III)
6.1	Chemical and Physical Properties	WP 3 (App.V)
6.2	Assessment of Efficacy of Pesticides	WP 4 (App. VI)
6.2	FAO Guidelines on Efficacy Data for the Registration of Pesticides	BP F
6.3	Toxicology	WP 5 (App. VII)
6.3	WHO Activities of Safe Use of Pesticides and their Relationship to International Harmonization of Pesticide Registration Requirements	BP G
6.3	Guidelines to the Use of the WHO Recommended Clasification of Pesticides by Hazard	Room Document
6.4	FAO Guidelines on Crop Residue Data	Room Document
6.4	Residues in Agricultural Produce	WP 6 (App. VIII)
6.5	Prediction of Environmental Effects	WP 7 (App. IX)
6.5	Second Expert Consultation on Environmental Criteria for Registration of Pesticides (FAO Plant Production and Protection Paper No. 28).	Room Document
7	Draft FAO Guidelines and Model Scheme for the Establishment of National Organizations for the Registration and Control of Pesticides	BP C

Agenda Item	Title	Document No.
7	Registration Procedures: Guidelines and Model Scheme for the Establishment of National Organization for the Registration and control of Pesticides	WP 1 (App. X)
7	GIFAP Viewpoints on Harmonization of Pesticide Registration Requirements	BP B
7.2	A Phased Registration Scheme for Pesticides	BP D
7.3	Special Problems in Registration Procedures	WP 2 (App. XI)
7.3	GIFAP Views on International Principles for Safeguarding Proprietary Rights on Registration Data of Pesticide Active Ingredients	BP E
8.1	Restriction on the Availability of Pesticides	WP 8 (App. XII)
8.2	Composition of Pesticides and Specifications	WP 9 (App. XIII)
8.2	Role and Use of Pesticide Specification	BP H
8.3	Labelling of Pesticides	WP 10 (App. XIV)
8.3	Guidelines on Good Labelling Practice for Pesticides	BP I
8.4	Packaging and Storage of Pesticides	WP 11 (App. XV)
8.4	FAO Guidelines for Packaging and Storage of Pesticides	BP J
8.4	Report and Guidelines for the Packaging and Storage of Pesticides	BP K
8.5	Disposal of Surplus Pesticides and Pesticide Containers	WP 12 (App. XVI)
8.5	Guidance on the Disposal of Surplus Pesticides and Pesticide Contrainers	BP L
8.6	Code of Conduct in the Trade and Use of Pesticides	WP 13 (App. XVII)

Agenda Item	Title	Document No.
9	Report of the Second Government Consultation on International Harmonization of Pesticide Registration Requirements	BP M
10	Implementation at National Level: Harmonization of Pesticide Registration Requirements	WP 14
11	A Proposal for the Harmonization of Pesticide Registration Requirement for the Regional Network for Production, Marketing and Control of Pesticides in Asia and the Far East (RENPAF)	BP N
13.2	Cross Contamination of Pesticide Formulations	WP O

BP = Background Paper
WP = Working Paper