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REGIONAL NETWORK FOR THE PRODUCTION, MARKETING AND CONTROL OF PESTICIDES IN ASIA AND THE PACIFIC

DP/RAS/82/006

Technical report: Regional Forum on Pesticide Toxicology (Asia and the Pacific)*.

Prepared for the Governments
of the Member States of the Regional
Network (Afghanistan, Bangladesh, India,
Indonesia, Pakistan, Philippines, Republic of Korea,
Sri Lanka and Thailand) and other participating States
of the region (Australia, China, Japan, Malaysia and Nepal)
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme
in co-operation with the World Health Organization

United Nations Industrial Development Organization
Vienna

*Organized in collaboration with the Fertilizer and Pesticide Authority and the Agricultural Pesticide Institute of the Philippines.

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I. INTRODUCTION

1. The Regional Forum on Toxicology of the Regional Network for the Production, Marketing and Control of Pesticides in Asia and the Pacific (RENPAF) organized by the United Nations Industrial Development Organization (UNIDO) in collaboration with the World Health Organization (WHO), Fertilizer & Pesticide Authority (FPA) and Agricultural Pesticide Institute of the Philippines (APIP) convened in Baguio, Philippines on April 22, 1985 at the Baguio Country Club. On April 24, 1985, due to an earthquake*, the meeting was transferred to Manila where it reconvened on April 25 and closed on April 26 1985.

2. The Technical Advisory Committee (TAC) of the RENPAF acknowledged toxicology as one of the important subjects for regional cooperation and recommended to convene the meeting with the following objectives:

   a. To provide a basis for regional harmonization of pesticide registration requirements;

   b. To examine the elements of a toxicological assessment of a pesticide and the implications of the results for regulatory control;

   c. To exchange Network experience on current toxicological data requirements, assessment procedure, standards and practical implication for registration;

   d. To consider the need for appropriate safety measures in the use of pesticides including education of the public.

3. The meeting was attended by 26 delegates representing the governments of 12 countries, representatives from 3 United Nations Organizations, 3 consultants / resource speakers, 3 observers from GIFAP, and 26 from company members of the APIP. The list of participants are presented as Appendix 1.

4. The proceedings of the meeting are summarized below. Due to the earthquake, these were not approved by the participants before the meeting closed. However, the Recommendations as set out in para 67 were unanimously approved at the final session.

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* Note: Due to the effects of an earthquake, the location of the meeting was transferred from Baguio City to Manila on 24 April 1985. On the resumption of the meeting in Manila on the following day, the delegates passed a vote of thanks to Mrs. Cecilia P. Gaston, Deputy Administrator for Pesticides of the Fertilizer & Pesticide Authority of the Philippines, and Chairman of the meeting, for the efficient manner in which the transfer was carried out. Mrs. Gaston in turn asked that the contribution to the transfer of the industry association, the Agricultural Pesticide Institute of the Philippines (APIP) to be recorded.

II. OPENING OF THE MEETING

5. Mrs. Cecilia Gaston, Regional Coordinator, RENPAF, stated that this meeting marked the termination of the initial phase of the Network's operation. Previous meetings, held under the auspices of the TAC had led to a recognition of the need for guidance on the use of the toxicological data for registration of pesticides. She acknowledged the valuable assistance given by participating agencies, WHO, UNIDO, UNDP and by APIP.

6. Mr. Leopoldo Camino, President, APIP, welcomed delegates on behalf of the local pesticide industry and recognized the need for harmonization and clarification of pesticide registration requirements for countries of the region.

7. Mr. B. Sugavanam, Senior Industrial Development Officer, UNIDO, recognized the difficulties to be faced in addressing the wide spectrum of modern pesticide technology, including toxicology. UNIDO appreciated the potential benefits of harmonization of pesticide registration requirements and had provided assistance to some countries of the region in the development of facilities for generation of toxicological data. UNIDO foresaw the role of the Network in bridging the gap between developing and developed countries in pesticide technology, particularly in light of the significant technical advances of the past decade.

8. Dr. J. Copplestone, Chief, Pesticide Development and Safe Use Unit, welcomed delegates on behalf of WHO and recognized the novelty of this meeting dealing with the toxicological aspects of pesticide registration including interpretation of data and its application to national control practices.

9. Dr. J. Copplestone pointed out that pesticides existed solely for the benefit of mankind, namely through improved human health and animal nutrition, prevention of disease, production of fibre for housing and animal feedstuffs and through the mitigation of nuisances caused by pests. He also recognized the inherent capacity for pesticides to produce adverse biological effects and the resultant need for adequate mechanisms for their regulation and control. Most pesticides in use today could no longer be considered as new and that there was considerable information on human exposure under a variety of conditions. In his opinion no other group of chemicals had received such toxicological scrutiny. As toxicology is a relatively new science, often grafted onto older disciplines such as medicine, chemistry, pharmacology and biology, it is understandable that most toxicologists had a particular approach which reflected their basic training. However, it was unfortunate that some individuals sought advancement of personal viewpoints while showing little regard for the practical , responsible use of pesticides. Public confusion over the real or imagined effects of pesticides was evident and there existed a need for training in toxicological assessment and decision making. The present Forum was a first step towards that goal.

10. Mr. Anders Frismark, Resident Representative, UNDP, stated that benefits of pesticides in increasing food production left no doubt as to the justification of their continued use. It has been estimated that pests destroy as much as one third of the world's potential food supply. In 1975, the World Food Agency had recognized the need to facilitate production of pesticides by encouraging their local manufacture through regional cooperation. Recognized difficulties included the complexity of the technology, lack of adequate testing facilities, lack of marketing knowledge and limited opportunity presented by relatively small markets. The Regional Network had been endorsed by UNDP as a means of overcoming these difficulties. The first phase of the Network's activities were nearing completion and provided a good basis for ensuring the continued safe use of pesticides to insure an adequate food supply. UNDP recognized the inherent potential conflict between efficient crop protection and possible adverse effects on the environment, but remained committed to the elimination of hunger through "development without destruction".

11. Mr. Manuel Varquez, Jr., Regional Director, Region I, Ministry of Agriculture and Food of the Philippines, recognized the particular economic contribution that pesticides made by increasing the agricultural productivity of the Philippines. The efficient and safe use of pesticides required training of extension officers and agricultural workers and the practice of Integrated Pest Management. A surveillance and early warning system for the use of pesticides in rice production had proved so successful that it would soon be extended to all major agricultural commodities. Adequate protection of human health and the environment necessitated appropriate systems for the regulation of pesticides using sophisticated toxicological data.

III. ELECTION OF OFFICERS

12. Mrs. Gaston, Regional Coordinator of the Network, was appointed Chairman and Dr. A. L. Black, Consultant, was appointed Rapporteur for the meeting.

IV. ADOPTION OF AGENDA

13. The meeting adopted the agenda as presented in Appendix 2.

14. Dr. Copplestone, WHO, explained that the Forum would focus on methods of assessment of toxicological data rather than on the methology of generation of toxicological data. The latter were reviewed in Environmental Health Criteria No. 6 "Principles and Methods for Evaluating the Toxicity of Chemicals, Part I", published jointly by WHO and UNEP.

V. USE OF TOXICOLOGICAL DATA FOR REGISTRATION OF PESTICIDES

15. The goals of toxicological testing is to define adequately the toxicity of a compound so that a firm basis is established for estimation of the risks to man and his environment. Proper decision making in pesticide registration incorporated such an approach. The adequacy of the data

is pre-requisite to its evaluation and interpretation. There is a need to retain flexibility in data generation and interpretation to permit an adequate exploration of the toxicity of individual pesticides and in the assessment of their hazards.

16. As there are no internationally accepted definitions of toxicity, hazard and risk, the meeting agreed to use the terminology employed by WHO.

17. The toxicological significance of impurities in pesticides is important. There is, as yet, no international consensus to the registration of pesticides which may contain variable concentrations of impurities. In practice, toxicological data is often generated on technical pesticides of different purity to that ultimately marketed commercially.

18. It is highly desirable that there be a multi-disciplinary approach in the evaluation of toxicological data on pesticides so that all relevant considerations such as public health, occupational health and environmental effects, were taken into account. WHO could play an important role in fostering this approach.

19. The predictability of interactive effects such as addition, synergism and potentiation is imprecise. Knowledge of mechanisms of action is required and supplementary experimentation may be necessary to define actual hazards. Exposure to a variety of pesticides each at toxicologically insignificant concentrations is unlikely to present particular hazards, especially at very low levels of xposure. Available data is limited but generally supports this view.

20. There is a need to assist developing countries obtain adequate data on pesticides toxicology, especially for highly toxic compounds.

21. In a statement, GIFAP advocated the concept of "product stewardship", especially in countries lacking formal requirements for pesticide registration. It has been in active collaboration with international agencies such as WHO & FAO. The industry association also advocated the adoption of a sound scientific approach to pesticide registration requirements rather than application of a "check-list". GIFAP saw that there is a definite need for research and training of personnel engaged in pesticide registration. It stressed the need for protection of confidentiality of toxicological data on pesticides, and warned of the disadvantage that could result from inappropriate leakage of pesticide registration data. GIFAP expressed concern at use of proprietary data to support the registration of non-proprietary products as it believed that this practice was contrary to the concept of product stewardship. GIFAP was concerned that the considerable investment in proprietary toxicological data required for pesticide registration should be protected. It believed that adequate toxicological data should be submitted on generic products to ensure bio-equivalence with proprietary pesticides.

VI. PRESENTATION OF COUNTRY PAPERS (in order of presentation)

22. Republic of Korea follows the WHO Classification of Pesticide by Hazard and requires the toxicological data specified by FAO* (1982). Acute oral and dermal toxicity data, generated in the Republic of Korea are required for all new pesticide registration. Sub-chronic and chronic data are also required as is documentation of registration status in other countries. Data on persistence in crops and soils and, for pesticide use in rice production, fish toxicity data is required. Simplification of registration procedures within the Network is seen as a suitable topic for the next meeting on harmonization.

23. India requires the toxicological data for pesticide registration as specified by its Pesticide Registration Committee. Data may either be developed in India or abroad in any recognized toxicological institute. There is a requirement for local generation of toxicological data in case the data submitted is found inadequate or unacceptable. Sometimes field data is also required to be generated, depending on the toxicity of the product offered for registration.

24. Pakistan has adopted the FAO* (1982) recommendations as its requirements for pesticide registration toxicological data. The data is processed in the Department of Plant Protection and evaluated by the Technical Committee of the Agricultural Pesticides Advisory Committee. Final approval for registration is granted by the Agricultural Pesticides Technical Advisory Committee after examination of each product on an individual basis.

25. Sri Lanka has also adopted the FAO*(1982) recommendations for toxicological data on pesticides. Data is assessed by the Registrar of Pesticides.

26. The Peoples' Republic of China requires data on the acute, sub-acute and chronic toxicity (including teratogenicity, carcinogenicity and mutagenicity) to mammals and toxicity to aquatic animals such as fish. Data is also required on any impurities composing more than ten percent of the technical product. The data is assessed by the Institute of Public Health.

27. Malaysia usually requires pesticide registration data from acute and short-term toxicological tests, long term tests, mutagenicity, teratogenicity and reproduction studies and pesticide behaviour studies as specified by FAO** (FAO 1980). Pesticide Registration data is evaluated by the Pesticides Board.

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* FAO (1982) Second Government Consultation on Harmonization of Pesticide Registration Requirements.

** FAO (1980) Environmental Criteria for Registration of Pesticides FAO Plant Protection Bulletin 28: 53-63 (1980)

28. Japan requires comprehensive toxicological data for pesticide registration, namely data on acute toxicity (oral, dermal and inhalational exposure), primary eye and dermal irritancy, dermal sensitisation, acute delayed neurotoxicity, and chronic toxicity, oncogenicity, reproductive toxicity, teratogenicity, mutagenicity, metabolism and pharmacodynamics. Data on subacute toxicity by oral, dermal and inhalational routes, as well as subchronic neurotoxicity studies may be required for registration purposes. Pesticide registration data is evaluated by the Agricultural Chemicals Inspection Station, the Agricultural Chemicals Office, Plant Protection Division, Ministry of Agriculture, Forestry and Fisheries and other related official bodies.

29. Thailand requires acute toxicity data by oral, dermal and inhalational routes of exposure, chronic toxicity data as well as information on signs, symptoms and therapy of human intoxication and environmental toxicity data. The data are reviewed and evaluated by the Division of Agricultural Toxic Substances and Technical Division of the FDA office which submits the results to the sub-committee on pesticide registration for final approval.

30. Philippines applies the recommendations of FAO* (1977) for registration of proprietary pesticides; namely toxicological data on acute toxicity (oral, percutaneous or dermal, inhalational and intraperitoneal), dermal and eye irritancy, short term toxicity, allergic sensitisation, toxicity of active metabolites, metabolism, carcinogenicity, neurotoxicity, reproduction, teratogenicity, mutagenicity and potentiation. In addition, data on human observation, diagnosis and management of poisoning are required.

    For commodity pesticides the following toxicological data are required: acute toxicity (oral, dermal or percutaneous, inhalational), dermal and eye irritancy, short term toxicity (oral and dermal), observations in man (direct and indirect) and information on diagnosis and treatment of poisoning.

    For household products, toxicological data is required on acute toxicity (oral, dermal, inhalational), skin and eye irritancy, allergic sensitisation and mutagenicity. The required toxicological data is evaluated by the Subcommittee on Toxicology of the Pesticide Technical Advisory Committee using a multidisciplinary approach. The Pesticide Technical Advisory Committee advises the management of the Fertilizer and Pesticide Authority.

31. Nepal requires toxicological data consistent with those required by India. Pesticides are regulated by the Pesticides Board.

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* FAO (1977) Report of the Ad Hoc Government Consultation on International Standardisation of Pesticide Registration Requirements.

32. Papua New Guinea has no pesticide legislation, and hence, no specific requirements for toxicological data on pesticides. Of the South Pacific countries only Fiji, Tonga, and Solomon Islands currently have their own requirements by law, though territories/countries in association with U.S. or France share the legislation of those countries and some have additional requirements.

33. Indonesia requires acute oral and dermal toxicity data of the formulated product for all pesticide registrations in rat and rabbit. Acute inhalational toxicity data may be required if indicated. Supplementary acute toxicity by subcutaneous, intramuscular or intraperitoneal routes of administration also may be acceptable. Data on skin and eye irritancy and dermal sensitisation are also required. Subchronic and chronic toxicity data, including carcinogenesis are required as is carcinogenicity, teratogenicity and mutagenicity. Medical data, including information on symptoms of poisoning, first aid measures, antidotes and medical treatment in cases of poisoning is also required. Evaluation of the data is conducted by the Interdepartmental Pesticide Committee.

35. In summary, the Chairman noted that of the 12 countries represented, all but Papua New Guinea and the South Pacific group had their own legislation for pesticides. There was general agreement on the need for transferability of toxicological data and that data in conformity with WHO and FAO guidelines was acceptable for registration purposes. There are, differences in the data requirements for registration of commodity products and of formulated products.

VII. CLASSIFICATION OF PESTICIDES BY HAZARD

36. The WHO Recommended Classification of Pesticides by Hazard, and the Guidelines which lists over 500 technical products are now being used by many countries in both the developing and developed world. Guidelines have to remain flexible and are therefore re-issued periodically, and some countries have made adaptations to meet their particular needs. Nevertheless, the Classification is probably the most useful and used tool for harmonization in the toxicological area.

37. Some difficulties have arisen because it is sometimes applied only to technical products and not to formulations. Methods are being devised to facilitate classification of formulations. Use experience has shown that the hazard classes, can reflect the actual hazard in both use and often in misuse of pesticides. The Classification can only be a tool but the tendency is for international meetings to use it more to make recommendations on many aspects of pesticide control.

VIII. MODE OF ACTION AND REGISTRATION

38. The mode of action of a pesticide can influence its toxicity, its hazards and hence ultimately its registration. The nature and degree of toxic effects, their duration and reversibility have to be taken into account. Knowledge of mode of action can influence decisions made on permitted uses, restrictions on availability, packaging and labelling, first-aid and safety directions and the need for appropriate

use of preventive or protective measures. These decisions may require revision in the light of experience in use. Several relevant examples were discussed.

IX. ACUTE AND SUB-CHRONIC TOXICOLOGY

39. Pesticides are responsible for many thousands of acute intoxications annually. Their oral, dermal and inhalational hazards can be reliably estimated by acute toxicity studies in animals. Acute toxicity data provides a basis for classification of pesticide by hazard. It should be appreciated that expressions such as LD50 or LC50 are merely convenient statistical terms to quantify a lethal response.

40. Sub-chronic toxicity tests, usually conducted over about 12 weeks, provide data under non-lethal condition on the potential of a pesticide to impair normal physiological functions or pathological changes. Importantly, such studies can also provide data on the reversibility of toxicity. Consequently, sub-chronic toxicity data can provide a valuable basis for assessing the hazard of pesticides and for their interim registration.

X. LONG TERM TOXICOLOGICAL STUDIES

41. Long term toxicity studies are intended to produce data about toxic effects by repeated administration to pesticides,their reversibility and to establish a level of exposure which produces no toxic manifestations. Such studies include carcinogenicity studies using appropriate methods. Threshold values for a wide variety of toxic manifestations can usually be defined from consideration of appropriate toxicological end points. Sometimes the toxicological no-effect level is codified for purposes of regulation e.g. as threshold limit values or acceptable daily intakes.

42. Assessment of data from carcinogenic studies is controversial. Difficulties arise with sensitivity of the testing methodology and from the interpretation of the dose-response relationship. The actual existence of a true toxicological threshold is uncertain and a true toxicological end point can be difficult to define. A threshold may exist theoretically but have little significance in itself when accurate knowledge of the threshold of reference in humans remain unknown.

43. Interpretation of pathology in rodents, particularly in the mouse, is also controversial and includes the evaluation of spontaneous lesions, the time of onset, the localization of tumors, the degree of malignancy, etc. Guidelines for such interpretation are provided by the International Agency for Research on Cancer.

44. The scientific certainties in chemical carcinogenicity are few but opinions are legion. Appropriate judgments and evaluations require logical deductive reasoning and not emotional extrapolation.

XI. DELAYED NEUROTOXICITY

45. Some organophosphates, but not all, can produce this kind of toxicity which is unrelated to the anticholinesterase properties of pesticides. The mechanism of action of organophosphate-induced delayed neuropathy is now understood and certain structure-activity relationship rules are well defined (e.g. carbamates do not require testing because they do not cause such toxicity.

46. The availability of biochemical tests allows an evaluation of the degree of the response, extrapolations from in vitro to in vivo data, and extrapolations from the experimental animal to man. Furthermore mechanistic studies on this neuropathy represents examples of the practical benefits which can be derived from the understanding of the mode of action of pesticides.

XII. TERATOGENICITY AND REPRODUCTION

47. Protocols incorporating both types of study exist but the toxicological end-points are quite distinct. Mechanisms of teratogenicity are usually unknown but the period of particular sensitivity to a true teratogen is well known for several test species and dose-response relationships may be defined. However species- and even strain-variations in the teratogenic response necessitates caution in extrapolation of the data. Data from more than one species improves the likelihood of detection of a teratogen significantly.

48. Reproduction studies are designed to determine the overall toxicity of a pesticide to the process of reproduction. Again, the mechanism of action is usually unknown and caution in extrapolation is therefore required. The potential irreversibility of the action of reproductive toxins should be kept in mind.

XIII. MUTAGENICITY

49. Genotoxicity tests are aimed at protecting humans from the potential risk of genetically mediated diseases and of cancer. Tests are available both in vivo and in vitro to explore different aspects of the potential effects of pesticides on genetic material. However more than one test are needed for evaluation of potential genotoxicity. The possibility of false positives and negatives should be kept in mind.

50. Furthermore a number of assumptions are implied when these tests are used in attempts to predict potential hazards to man, including the assumption that environmental mutagens can cause significant mutagenic effects in man and that removal of such agents would ameliorate any such influences in comparison to existing mutagenic hazards, e.g., those posed by ionising radiation and naturally occuring chemical mutagens. Therefore, at this time, short-term tests for genotoxicity should be considered as indicators of potential hazard which may require elucidation.

XIV. STUDIES ON HUMAN EXPOSURE

51. Relevant information can be derived from studies in humans, provided some basic requirements are fulfilled. Both acute poisoning and occupational exposure data, when available, are of paramount relevance for comparison with animals and validation of the experimental models used for extrapolation. Data of acute poisonings include clinical records, analytical chemistry, clinical toxicology data and pathology, where fatalities occur.

52. Data on occupational exposures should include measurements of the dose of the pesticides to which workers are exposed, either by measurement of environmental exposure or preferably by measurement of the concentration of the pesticide itself and/or metabolites in body fluids. Tests proposed for measuring effects should be specific for the type of biological adverse effect to be monitored (e.g. acetylcholinesterase activity in red blood cells for exposures to organophosphates). The use of these tests require several assumptions which should be considered where a critical evaluation of such data is performed. Basic criteria for diagnosis and treatment of pesticide poisoning should be made known to medical professionals, as well as basic information about availability of specific therapy.

53. To assist in the collection of valid human data a protocol for designing field surveys for estimation of human exposure to pesticides is available from WHO Pesticide Development and Safe Use Unit*. A code of good manufacturing practice could do much to identify and alleviate occupational hazards in pesticide formulation plants.

XV. TRANSFERABILITY OF TOXICOLOGICAL DATA

54. Modern toxicological data on pesticides is technically sophisticated and economically valuable. Data for pesticide registration purposes should be beyond doubt with respect to experimental design, execution and reporting; its quality can be assured by good laboratory practice**. (see FAO(1982)).

55. Because of the reproducible conditions under which it is generated, modern toxicological data is suitable for transfer across national boundaries. Its interpretation can give a reliable estimation of toxicity. However evaluation of potential hazards of the pesticides should be conducted according to local conditions of use.

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* Field Surveys of Exposure to Pesticides. Standard Protocol VBC/82.1 (1982)

** Good laboratory practice means that , as a minimum, the personnel engaged in the supervision of toxicological investigations have the education, training and experience to carry out the work effectively; that the testing facilities and equipment are suitable and are maintained to a satisfatory standard; that the test protocol and operating procedures are observed so as to assure the Registration Authority that the work is adequately supervised and that full records of all procedures and data are kept and accurately reported.

56. Modern toxicological data on pesticides is costly to generate and is also technologically valuable. For these reasons, Pesticide Registration Authorities have traditionally accepted the need to protect the confidentiality of toxicological data submitted for pesticide registration purposes. Confidential handling of pesticide registration data promotes its international transferability and encourages innovation to develop new pesticides.

57. Special problems can arise in the registration of so called commodity pesticides for which any original period of patent protection has lapsed. Some governments elect to recognize the proprietary value of toxicological data by reserving its use to the original applicant.

58. There is a growing awareness of the need to provide adequate health and safety on pesticides to the community. Adequate information should be provided for every pesticide to permit identification and control or elimination of its hazards.

XVI. HARMONIZATION OF TOXICOLOGICAL DATA REQUIREMENTS

59. A significant number of countries of the Network have already adopted the FAO recommendations on Toxicological data requirements for pesticide registration. (FAO (1982)). However, there are differences in the data requirements for formulated products. Some countries require local generation of at least some data on each formulation to be marketed.

60. Understandable difficulties are to be envisaged in automatic acceptance of regulatory decision of other countries. However, there is a need for exchange of information on registration status and particularly of restrictions imposed due to toxicological concerns.

XVII. LABELLING

61. Regardless of any other labelling requirements, priority must be given, without exception, to essential information on the safe handling of pesticides. The possibility of a separate safety label merits serious consideration.

62. Pesticide labels should include unequivocal information on identity of the pesticide through use of its approved name, potential health hazards and relevant medical management and therapeutic measures in case of poisoning. The need for well-balanced, standardised phraseology is apparent. The advantages of symbols and pictograms remains to be established. Some countries favour colour coding. The value of inclusion of date of manufacture as a means of promotion of stock rotation is appreciable. There is a clear need for legal prohibitions of false or misleading label statements.

XVIII. DISTRIBUTION AND USE

63. Complimentary to the decision of pesticide registration, toxicological data are essential for the classification and recognition of the hazards of the use of a pesticide.

64. Protective measures can only be determined properly on the basis of toxicological information such as acute toxicity, mode of action, route of absorption, and rates of metabolism, distribution and excretion. In classifying hazards, it should be appreciated that diluted formulations generally pose less hazard than concentrates. In situations where appropriate regulations cannot be enforced, consideration should be given to withdrawal of hazardous pesticides.

XIX. TOXICITY AND EDUCATION IN THE SAFE USE OF PESTICIDES

65. While a good knowledge of the toxic potential of a pesticide permits reasonable, sound and enforceable protective measures to be applied, these measures must be adapted to the level of risk incurred in actual use. For example, the need for different types of protective clothing or equipment will vary depending on the class of active ingredient, the type of formulation - granules, emulsifiable concentrate, etc. - the concentration of active ingredient in the formulation, the type of application - spray, dusting, etc. Attempts at overprotection can be as unproductive in terms of safety as its opposite. Therefore, toxicology tests and their results have a direct bearing on the education and training in safe use and handling for pesticide users. It is necessary for users to have a realistic understanding of the actual risks to understand the necessity for safety precautions. Industry should promote a good understanding of potential hazards and safe use of its product amongst its own staff and, through them, its customers.

66. Similarly, the general public, since it is also exposed to many kinds of household and horticultural products, among them pesticides, must receive a correct but appropriately modified education in their safe handling. This education is based on the knowledge of the toxic potential of the products they use, with particular emphasis on the risk and consequences of misuse or careless handling, and the necessity of precautionary measures to prevent accidental poisoning. At the same time, a more informed understanding of toxic risks, and the knowledge of the benefits brought by pesticides should promote in the general public a more rational view of pesticides and their uses, and should improve an all-too-common fear biased by ignorance.

XX. RECOMMENDATIONS

67. The following recommendations were unanimously agreed by the Forum:

A. ASSESSMENT OF TOXICOLOGICAL DATA

Recognizing the multidisciplinary nature of pesticide toxicology, the Forum

Recommends that the evaluation of toxicological data on pesticides should be undertaken by a multidisciplinary team, with relevant expertise in medicine, chemistry, and associated medical and agricultural sciences.

B. TRAINING IN TOXICOLOGICAL ASSESSMENT

Recognizing the need for training on toxicological assessment within the countries of the Region, the Forum
Recommends -

a. That a course on toxicological assessment of two to three months duration should be established within the Region. It should be practical and be repeated as required both for those newly engaged in assessment activities and as a refresher course for those already engaged in assessment of toxicological data.

b. That exchanges between staff of regulatory authorities in the Network and their counterparts in developed countries should be encouraged as a means of sharing practical experience in pesticide registration.

c. That the Regional Coordinator should arrange a study on manpower needs for toxicological assessment within the Region, both for training as in (a) above and as a basis for promotion of training in toxicology

d. A future meeting of the Network should review courses on safe use of pesticides available from international and other bodies with a view to deciding those considered appropriate for the Region.

C. NOTIFICATION OF REGULATORY DECISIONS

Recognizing the need for an increase in harmonisation of registration decisions in the Region, the Forum

Recommends -

a. That all registration authorities in the Region should inform the Regional Coordinator of regulatory decisions, especially those of severe restrictions for toxicological reasons, and brief reasons for these.

b. That the Regional Coordinator should communicate these details to all the registration authorities in the Region.

D. ACCESS TO INFORMATION

Recognizing that there is a true need for better access by regulatory authorities to information on the toxicity of pesticides published by international organizations, the Forum

Recommends to WHO, FAO, UNIDO, UNEP (IRPTC) and other bodies that they arrange to supply registration authorities in the Region directly with all relevant published information.

E. TOXICOLOGICAL REQUIREMENTS

Recognizing the acceptance by the countries of the Network of toxicological requirements for pesticide registration purposes during the Regional Consultation on the Harmonization of Registration Requirements;
Requests countries who have not yet done so to adopt these requirements.

F. LABELLING

Recognizing the need for harmonization of pesticide labelling in the Region, the Forum

Recommends -

a. That the Regional Coordinator arrange a study on current labelling practices in the Region which will collate and analyze those elements that could be harmonized successfully and that the study be circulated to countries of the Network.

b. The acceptance of the offer of the GIFAP Delegation to discuss with its Asia Working Group their participation in this study.

G. PROTECTION OF WORKERS IN FORMULATION PLANTS

Recognizing the need for adequate protection of workers in formulation plants, the Forum

Recommends that pesticide regulatory authorities should form links with authorities regulating such plants with a view to exchanging information and agreement on the measures needed to protect workers from the adverse effects of pesticides.

H. TRAINING OF USERS

Recognizing that the basic objective of generating and evaluating toxicological data on pesticides is to determine their potential hazards and thereon decide to allow the use of such products, the Forum

Recommends

a. That the countries of the Region who do not already do so should undertake specific training programmes in the safe and judicious use of pesticides by farmers, pesticide applicators, retailers and users.

b. ESCAP* (through the ARSAP** or equivalent programme) be requested to assist countries in this matter.

I. HUMAN POISONING BY PESTICIDES

Recognizing the need for prompt and correct management of people acutely intoxicated by pesticides and the need for better understanding of the toxicology of pesticides, the Forum

Recommends -

a. The introduction of training in occupational medicine and toxicology of pesticides into the undergraduate medical curricula of all medical schools in the Region;
b. The establishment of poison control centers in localities where they do not exist; the extension of the services of existing centers to agricultural regions;
c. The collection of appropriate information on the incidence of poisoning by pesticides, including the identity and formulation of the toxicant, the nature and degree of exposure, the circumstances under which poisoning occured, and the outcome of the incident.

XXI. PESTICIDE CONTROL IN THE PACIFIC AREA

68. The Meeting notes the particular needs of the countries and territories in the Pacific and supports any requests by governments or intergovernment organisations for the establishment of a Pesticide Information Center or other bodies contributing to pesticide safe use and control.

XXII. CLOSING OF THE MEETING

69. After adoption of the Recommendations, the presentation of statements by UNIDO, WHO and the exchange of courtesies, the Meeting was closed by the Chairman, Mrs. C. Gaston.

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* Economic and Social Commission for Asia and the Pacific.

** Agricultural Requisite Scheme for Asia and the Pacific.

APPENDIX 1

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APPENDIX 2

REGIONAL FORUM ON PESTICIDE TOXICOLOGY

of the

Regional Network for the Production, Marketing and Control of Pesticides in Asia and the Pacific

Baguio, Philippines, 22-26 April 1985

A G E N D A

Monday, 22 April 1985

Session 1: a) Opening
b) Appointment of Session Chairman and Rapporteur

Session 2: a) Use of toxicology data for registration purposes
Dr. A. L. Black

Session 3 and 4: Country Reports on

a) Sources of toxicological information
b) Assessment procedures
c) Standards applied
d) Practical implications for registration

Tuesday, 23 April 1985

Session 1: Acute and short-term toxicological tests
Dr. R. Plestina

Session 2: Long-term toxicological tests
Dr. M. Lotti

Session 3: Other toxicological tests, mutagenicity, teratogenicity reproduction studies.
Dr. M. Lotti

Session 4: Classification of pesticides based on toxicological tests
Dr. J. F. Copplestone

Wednesday, 24 April 1985

Session 1: Influence of mode of action on registration
Dr. A. Black

Session 2: Influence of toxicology tests on distribution and use of pesticides

Dr. R. Plestina

Session 3: Studies on human exposure to pesticides

Dr. M. Lotti

Session 4: a) Influence of toxicology tests on labelling

Dr. R. Plestina

b) Influence of toxicology tests on education in safe use of pesticides, including education of the public

Dr. J. F. Copplestone and
Dr. A. F. Pelfrene

Thursday, 25 April 1985

Session 1: Transferability of toxicological information

Dr. A. L. Black

Session 2: Harmonization of toxicological requirements w ıin the Network

Discussion

Session 3: Preparation of recommendations

Friday, 26 April 1985

Approval of Report and closure.