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**STRENGTHENING OF PESTICIDE DEVELOPMENT CENTRE**

**DP/IND/89/128**

**INDIA**

**Technical report: Mission to assist in a workshop on pesticide registration  
and regulations organized by the Institute of Pesticide Formulation  
Technology held in New Delhi from 7 to 11 November 1994\***

**Prepared for the Government of India  
by the United Nations Industrial Development Organization,  
acting as executing agency for the United Nations Development Programme**

**Based on the work of Brian B. Watts,  
consultant on pesticide registration and regulations**

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**United Nations Industrial Development Organization  
Vienna**

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\* This document has not been edited.

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## ABSTRACT

This document, prepared for Project DP/IND/89/128/11-69 reports on the Workshop on Pesticide Registration and Regulations organised by the Institute of Pesticide Formulation Technology (IPFT). The Consultant, Mr Brian B. Watts was in India from November 2 - 16 November during which time he delivered 9 lectures to the Workshop on international issues on pesticide registration and control. The Workshop was attended by persons from the Indian pesticide industry, and lasted 5 days which included a ½ day visit to IPFT at Gurgaon. A number of recommendations were made 1) to IPFT for Future workshops and 2) to the Regulatory and Registration Authority. Again of concern as at the previous Workshop was the ease with which second registrations are given under Section 9(4) of the Insecticides Act 1968, and the low fees charged for registration generally. In addition concern was again expressed about the variations between States in their enforcement of the requirements of the Act. A complete list of recommendations is included in the body of this report. The Workshop was voted highly successful by the participants who actively participated in the discussions at every opportunity.

## I. INTRODUCTION

The Consultant, Mr Brian B.Watts visited India arriving in New Delhi on Friday 3 November and departed on Tuesday 15 November 1994. The job description for the Mission is shown as Annex 1.

The main activity undertaken during the visit was to prepare and present a number of lectures to the Workshop on Pesticide Registration and Regulation held in New Delhi from November 7-11 and to prepare a Report of the meeting. Twenty participants from the Indian pesticide industry enrolled for the Workshop but 4 persons were not able to attend. This Workshop was of a similar format to the very successful one held last year. It consisted of 4½ days lectures and discussions and ½ day visit to the Institute of Pesticide Formulation Technology (IPFT) at Gurgaon.

The objective of the Workshop was to provide participants with an update of the requirements for pesticide registration in India as well as to give them with some exposure to the international scene, and in particular to the Asia/Pacific region. In view of the increasing exports of pesticides from India, which are now in excess of US \$70,000,000 per annum, there is a need for the pesticide industry to have an increasing knowledge about registration requirements outside India, and of activities in the International arena.

The Consultant in preparing and delivering 9 lectures and chairing 3 Technical Sessions achieved the objectives of the Mission. In addition a report on the Workshop, prepared by the Consultant was left with the national coordinator at IPFT. A copy of this is attached as Annex 2.

This report which was completed by Brian B.Watts, is unedited and briefly covers the work undertaken as well as setting out the recommendations from the Workshop.

## II. THE WORKSHOP.

### A. General

The Workshop which was organised by the IPFT was designed to suit the needs of the Indian pesticide industry, with special emphasis on data requirements for the registration of pesticides. The programme covered is shown as Annex 2 to the attached report of the meeting. The programme was intended for the executives/product development personnel from the pesticide industry associated with pesticide registration and marketing. Although

20 persons enrolled to take part in the Workshop, four persons could not attend. A registration fee was levied by IPFT.

The Workshop was divided into 8 technical sessions each of which was chaired by a prominent faculty member. The participants were a well balanced group, being people from the pesticide industry involved in technical development, research scientists and registration persons who dealt with pesticide registration within their companies. A list of participants is shown in Annex 2 of the meeting report.

The group was a very active one and was involved in much discussion on most subjects. The Workshop ran to time with no problems. For the closing session the Workshop was privileged to have the Joint Secretary (Chemicals), Department of Chemicals & Petrochemicals, Ministry of Chemicals and Fertilizers, of the Government of India. Mr Vinay Kohli, deliver the Vaedictory address and present the certificates to the participants.

#### B. Pesticide Registration In India

The main thrust of the Workshop was to bring participants up to date with the requirements for pesticide registration and explain the rationale for these requirements. This Workshop was the second of its kind held in India and proved to be a useful experience for the participants as dialogue with appropriate officials can help in sorting out potential problems with registration before they occur. There were a number of officials involved in pesticide registration from the Central Insecticides Board (CIB) the Central Insecticides Laboratory (CIL) and the Registration Committee either presenting lectures or chairing sessions. Of concern to the Workshop was the ease at which a second registration is granted under Section 9(4) of the Insecticides Act 1968, and the low fee charged for such applications of only 100 Rs. Some concern was also voiced by the Workshop of the variations between States in their enforcement of the Insecticides Act.

#### C. International Activities and situation in the Asia/Pacific region

The Consultant prepared and delivered nine lectures on the following subjects:

- The FAO International Code of Conduct on the Distribution and Use of Pesticides.
- "Me-Too" Registration.
- Proprietary Rights and Confidentiality of Data.
- Advertising and the FAO Code of Conduct.
- Mixed Formulations in Asia and the Pacific.

- Prior Informed Consent.
- Harmonisation of Pesticide Residue Requirements in Asia and the Pacific.
- The FAO Series of Guidelines.
- FAO Pictograms

With there being up to 50% more manufacturing capacity than sales in India an increasing amount of pesticide is expected to be exported from India in the future. It is therefore important that pesticide companies have a greater knowledge of both the International activities and individual country requirements for pesticide registration. The importance for industry wishing to export pesticides to determine the requirements of the importing country before export is undertaken was emphasised, as these early discussions could avoid potential problems arising at a later date. The principle of Prior Informed Consent (PIC) is expected to become more relevant to Indian pesticide exporters in view of the anticipated growth in pesticide exports. There will need for an increasingly close liaison between industry and the designated national authority appointed by the Government of India to handle PIC matters in the country. Industry will need to respond to and overcome the challenges which undoubtedly will arise when the new trading regime under the soon to be formed World Trade Organisation, comes into existence.

#### D. Visit to IPFT at Gurgaon

The half day visit to IPFT was very much enjoyed by participants, who were very impressed by the equipment and the expertise at the Institute. Practical demonstrations of some of the work undertaken were given and some in depth technical discussions were entered into with the scientists at Gurgaon. It is expected that more companies may well enter into contracts with IPFT if the comments heard from participants are realised. A number of participants suggested that they would either place some of their company development work with the Institute or that they would recommend to management that this action be taken.

### III. RECOMMENDATIONS FROM THE WORKSHOP

A number of recommendations were made by Workshop participants, and which although included in the Workshop report, are also reproduced again below. They were addressed as follows:

#### A. TO IPFT FOR FUTURE WORKSHOPS

1. More experts from the Registration Committee and the Central Insecticides Laboratory should be involved for discussions as well as more experts from the pesticide industry being asked to contribute.
2. Course papers should be circulated at least one day in advance.
3. Course (Workshop) period should be for 3 days from 8 am to 6 pm and tea should be served in the conference room itself.
4. If the present five day workshop period is continued in the future, the last two days should be directed to "do-it-yourself" exercises to make trainees more conversant with the documentation.
5. A separate course (Workshop) should be arranged for the newer entrants to the industry, ie those not fully conversant with the registration and regulation system.

#### B. TO THE REGULATORY AND REGISTRATION AUTHORITY

1. State pesticide analytical laboratories should be better equipped so that inter laboratory differences of results are minimised.
2. Registration under 9(4) should be granted within a months maximum time and the application fee should be raised to Rs 1000 to limit the number of applicants seeking registration.
3. A reasonable protection period of say five years should be given to the first registrant under section 9(3) and only after this period 9(4) registration should be granted.
4. A shelf-life of 15 months should also be granted after submissions of proper data from the claimant as it would enable the manufacturer to sell his product for three crop seasons.
5. Where chemically and technically feasible, date expired materials should be permitted to be reprocessed as disposal locally is both hazardous and costly.
6. Registration of mixtures (combinations) should be liberalised especially for those cases where tank mixtures are already used by farmers. Detailed guidelines for the registration of combination products should be provided.



7. Phytotoxicity data for technical/technical concentrate should not be required as it is not demanded in any country.
8. Safety clothing and antidotes should be required to be stocked by pesticide dealers.
9. Single window systems for statutory clearances at State level should be introduced, as presently manufacturers have to run from place to place for different types of statutory clearances for the same product at the same manufacturing site.

#### IV. CONCLUSION

The Workshop was considered a success and one which could be repeated in the future, although one of the recommendations to be considered is to have two Workshops (possibly back to back), one for relatively new entrants to the industry and the second for those more experienced in pesticides registration and control, with different programmes. The Workshop provided a unique opportunity for participants to meet high ranking Government of India officials and also to obtain some exposure to activities in the pesticide field which are taking place outside India. In addition there was considerable benefit to participants in meeting and working with each other.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Job Description

DP/IND/89/128/11-69

**Post Title:** Consultant on Pesticide Registration and Regulations

**Duration:** 0.5 m/m

**Date Required:** 2-16 November 1994

**Duty Station:** New Delhi, with daily travel to project site at Gurgaon, Haryana (around 20 km away from New Delhi)

**Purpose of project** An institution building project, to assist the pesticide industry in India by developing and promoting safer, new generation pesticides formulations and utilising indigenous developed technology for the production of formulation and improving the formulation capabilities of the country.

**Duties:** In order to keep the industrialists, government authorities abreast with registration requirements for pesticides, the consultant is expected to advise and help the national project authorities in organising a workshop on registration of pesticides. Apart from advising the authorities, he/she should participate in the workshop, give lectures on international requirements for registration, re-registration, data required and maintenance of uniformity, harmonisation with regional requirements and also the data needed for new pesticides and their formulations and also for new formulations of commodity pesticides. He/she will elaborate international requirements and FAO Code of Conduct for the distribution and use of pesticides. He/she should also cover registration of pesticide mixtures and bio-pesticides.

He/she is expected to participate in discussions during the workshop and assist in preparing a report of the workshop with recommendations.

**Language:**

English

**Qualifications:**

Chemist, biologist and agricultural chemist with extensive experience in registration of pesticides. Should be familiar with data requirements, FAO Code of Conduct and in re-registration requirements. Experience in the Asia region will be an advantage.

**Background Information:**

The Institute of Pesticide Formulation Technology located at Gurgaon on the outskirts of New Delhi is a national institute, set up by the Government of India with assistance from UNDP/UNIDO. The Institute is devoted to research and training in various aspects of pesticides technology and its safe use and is playing a central role in maintaining contacts and cooperation with other national and international R&D institutions and also in coordinating national activities of the regional network on production, marketing and control of pesticides in Asia and the Pacific.

**REPORT OF**  
**THE**  
**WORKSHOP ON PESTICIDE REGISTRATION**  
**AND REGULATIONS**

**November 7-11, 1994**

**International Youth Centre,  
Chanakyapuri,  
NEW DELHI-110021**

## INTRODUCTION AND OBJECTIVES

1. A Workshop on Pesticide Registration and Regulations, organised by the Institute of Pesticide Formulation Technology (IPFT), was held at the International Youth Centre, Chanakyapuri, New Delhi from November 7-11, 1994. Sixteen participants from the Indian pesticides industry attended, as shown in Annex 1. The programme which is shown as Annex 2, consisted of a series of addresses and a visit to IPFT at Gurgaon. The sessional chairman in Annex 3, the list of speakers in Annex 4 and the support staff and secretariat in Annex 5.
2. The Workshop objectives were:
  - to provide participants from the pesticide industry with the latest information on pesticide registration and regulations in India and,
  - to give participants an overview of the developments in pesticide registration and control in the International area, and in particular in the Asia/Pacific region
3. The report which follows has not been adopted by the Workshop, instead it is a summary of notes taken by the UNIDO Consultant, Mr Brian B. Watts during the Workshop

## INAUGURAL SESSION

4. The participants were welcomed to the Workshop by Dr S. P. Dhua, Chairman of the Institute of Pesticide Formulation Technology. In his welcoming address Dr Dhua spoke about the ever increasing data requirements for pesticide registration, and the need of the pesticide industry to be fully aware of these. The development of the required data is extremely costly and the time taken to obtain full registration of a new pesticide is increasing. In addition patent laws are becoming more complex in many countries, all of which add to registration costs. He pointed out that registration procedures differ from country to country and thus there is a need to be aware of these differing requirements. Dr Dhua in opening the Workshop hoped wished participants a productive and informative week.
5. Brian B. Watts, UNIDO Consultant in his opening remarks stressed the importance for industry to be fully aware of, not only the local country requirements but also the requirements of countries to which they wished to export pesticides. It was important that this information is available at an early stage so that any registration data generated would comply with the data requirements of the importing country. Some considerable progress had been made over the years to harmonise data requirements but still were still considerable variations from country to country. One of the objectives of the

Workshop was to inform participants about pesticide registration developments on both the International and Regional scene.

6. The programme was outlined by Dr Kawal Dhari, the National Project Coordinator of the Institute of Pesticide Formulation Technology. Participants were asked to consider whether there were any subjects other than those in the programme which they would like to have included for discussion.

## **TECHNICAL SESSIONS**

### **Technical Session I**

7. Mr S. C. Mathur, Executive Director of the Pesticides Association of India gave an overview of the pesticide industry in India. It has been estimated that the present food grain production of 180 million metric tonnes (MT) will need to expand to 220 MT by 2000 AD, and in view of the fact that from 20 - 25% of the potential for food production is lost in India due to insect pests, plant pathogens, weeds, rodents birds and in storage the use of pesticide has become essential. Pesticide were first used in India in 1948 when small quantities of DDT and BHC were used for malaria and locust control, with indigenous production beginning with the establishment of a DDT and BHC plant in 1954. Today India is the largest producer of pesticides among the South Asian and African countries next to Japan. Of the 137 different active ingredients in registered formulations 66 are manufactured in India. Production of technical material for 1993/4 is estimated to be 80,000 MT, (value Rs 1500 crore) with imports only 2,400 MT. The pesticide industry has a formulation capacity of about 70,000 MT in terms of technical grade material and it is estimated that there is a similar capacity in the 500 or so small scale units. Future demand predictions are for agriculture use to increase to 97,000 MT by 2000 AD and in public health to 21,000 MT, or an average growth rate of 3%. Export of pesticides in 1993/4 is estimated to be in the order of Rs 211 crores, with exports being now made to USA, France, UK, and Australia and a host of countries of South America, Africa, and Asia. Most of the research and development work is involved with process technology rather than the discovery of new molecules/compounds. Four major challenges for the Industry in the future were identified as a need to:
  - create the right image in the eyes of the public
  - promote a programme for safe and judicious use
  - have the ability to meet more costly and time consuming data requirements
  - put into place good quality management, "good manufacturing practices" and "good laboratory practice"
8. Information on the pesticide database operated by the Regional Network of Pesticides for Asia and the Pacific (RENAPAP) was provided by Dr Y. P. Ramdev. The objective of this data base was to provide extensive, consistent, accurate, timely and relevant information on pesticides from the 15 RENAPAP member countries. Most countries are now contributing data which is being stored on a Foxpro 2 programme at the RENAPAP office. There are 2 main files one being an

Index File of data and the other an Economic File on which is recorded quantities and types of pesticides used and crops on which it is used. Practical problems in collection of data were discussed. It was emphasised that as the data collected are country data, the reliability of the information is very good. Copies of the data which are available either on a disk or as hard copy may be obtained from the RENPAP office at 55 Lodi Estate, New Delhi 110 003, to whom all enquires should be directed.

- 9 The development of the Indian pesticide registration scheme was outlined by Dr Kawal Dhari. The main impelling force for the development of the scheme were cases of pesticide poisoning in Madras in 1958. The Insecticide Act became law in 1968 and Rules were gazetted in 1971 with amendments being made in 1993. Lists of pesticides which are not allowed have been published as have lists of pesticides which have been banned or restricted. These are shown in Annex 6. The publication of an "environmentally friendly" list of pesticides is being considered by the Ministry of Agriculture following a request from the Ministry of the Environment for "eco-typing", but has not been proceeded with. An expert committee has reviewed the use of insecticides banned or restricted in other countries considering 31 pesticides. These reports have been published, and appropriate actions taken. In addition there are another 17 pesticides currently under review. The Air (Prevention and Control of Pollution ) Act 1981 and the Water (Prevention and Pollution) Act 1974 also impact on the pesticide industry. There are 40 laboratories in India which have the capacity to carry out tests on some 45,000 samples of pesticides annually for quality control. Quality control analyses are mostly done by the States who have the responsibility of enforcing the Act. The Central Insecticide Laboratory serves as the reference laboratory.
- 10 The FAO International Code of Conduct on the Distribution and Use of Pesticides as adopted unanimously by the FAO Conference in 1985 and as amended in 1989 was introduced. Mr Watts explained the various Articles and stressed that the Code was intended to set forth responsibilities and establish voluntary standards for all public and private entities engaged in or affecting the distribution and use of pesticides, particularly where there is no or inadequate national law to regulate pesticides. The responsibilities of the various sectors addressed in the Code were highlighted. The Code was intended to serve as a point of reference and to be of benefit to the international community and to serve to increase international confidence in the availability, regulation, marketing and use of pesticides for the improvement of agriculture, public health and personal comfort. The Code is a comprehensive and a very useful document on many aspects of pesticides.

## **Technical Session II**

- 11 Before asking the speakers in this session to give their papers, the Sessional Chairman Dr M. L. Saini, for many years Secretary of the Central Insecticides Board (CIB), and also Secretary of the Registration Committee, and now a Joint Director in the Central Insecticides Laboratory (CIL), discussed the Insecticides Act 1968 very briefly. When the Insecticide Rules were introduced in 1971, the Act came into operation to cover all of India - prior to that time its coverage had

been limited Policy on pesticides and their control is made by Central Government, (The Central Insecticides Board (CIB)), with State Governments responsible for carrying out enforcement measures. In the case on any dispute Central Government is the arbiter. Before a pesticide is able to be registered it must be first added to the schedule to the Insecticides Act. The CIB is required to deal with an application for registration of a pesticide 18 months after receiving the application but an extension can be sought. Cancellation of a registration can only be made by the Government of India and cannot be made by CIB, acting alone although it would give advice to GOI. There are three types of registration:

- 9(3b)- Provisional registration - for 2 years only, no sale but to allow the development of full data
- 9(3)- Full registration - no time limit,
- 9(4)- Subsequent registration which must be given as required under the Act.

Maximum Residue Limits (MRLs) are not established under the Act but may be set under the Food Adulteration Act

- 12 In his address Dr H.L. Bani, emphasised that as pesticides are designed to kill pests, their use is always subject to intense attention and often misinformed information. They must be used in such a way so the goals intended from their use are met with minimal harm to the environment. Pesticide use, as measured by grams ai/ha is low in India, but in his view, pesticides will need to be used more widely to assist increased food production. Four States use 80% of the total pesticides consumed in India, and 45% of the total consumption is used on one crop and nearly 30% on another crop. Of the 75000 MT used per year 55,000 MT (made up of 137 active ingredients) are used in agriculture. Although DDT and BHC have been prohibited in agriculture for many years some 20,000 MT of DDT and BHC are still used in public health. While these compounds are still being used there will continue to be significant residues of these organochlorines detected in the environment. Much more attention needs to be given to publicity on the need to use pesticides safely and there is a need for monitoring to be done at national level to check where abuse is made. Dr Bani made the point that problems with pesticide residues on food following the use of pesticides, although often emotive in nature, are of limited concern to health especially as much residue is lost during the preparation of the food prior to consumption.
- 13 The subject of "me-too" or second registration was introduced by Mr Watts. The question of the amount of data to be submitted by the second registrant was a difficult one, and one which has been a problem to registration authorities over the years. The two extreme scenarios were covered, from no data to full data requirements, and a proposal was put forward for a practical approach somewhere in between the two. For the proposal to operate there should be an "exclusive time period" where a set period of time had been decided by the regulatory authority, during which time the second registrant applying for registration should supply the full information or have agreement from the first registrant to use his data. After the exclusive time period expired a lesser amount of data could be acceptable in support of the second applicant than was required for the first, the nature and type being determined according to the pesticide in question. It was noted that this system was in operation in some countries in the Asia/Pacific



region and had been endorsed at a Regional Workshop held under the FAO Regional Project on the Implementation of the International Code of Conduct on the Distribution and Use of Pesticides in Beijing 1990.

- 14 Mr E.N. Sunder, who has had long experience with the Bureau of Indian Standards (BIS), until his retirement explained how the original standards, initially DDT and then BHC were based on overseas standards, but how, gradually over the years, although still formulated similarly to WHO and FAO specifications, there has been more flexibility in developing standards for locally manufactured pesticides. BIS standards are developed as a result of a long dialogue with industry, government and others. Standards are always subject to review and this is being done as required to meet the needs of modern technology. ISO TC 81 on Common names is accepted by BIS. In addition to standards for pesticides BIS has also set standards for treatment of pesticide poisoning, packaging standards and standards for packages. A number of production units have now been granted ISO 9000 registration.

### **Technical Session III**

- 15 The final Act of the Uruguay round and the Trips (Trade Related Intellectual Property Rights) proposal was discussed by Mr B K Keayla. The Uruguay round was the 8th round since 1948 when GATT was founded with 23 members, one of which was India. It was clear that this round was one of the most difficult in GATT's history. The round was finally signed in 1993 some 3 years after the expected date following the submission and agreement of the so called Dunkel agreement which was put forward by Dunkel as a proposal in which it was hoped to avert an impasse. During the discussions considerable reservations were expressed by developing countries as to the adverse effect such an agreement would have on them. The proposals could even adversely affect constitutional issues and impair the Federal structure. Individual States may also complain about not being consulted on the agreement. The 21 agreements under the Round are now to go before individual countries for ratification, with the proviso that a country should accept all the agreements or none. At the moment India does not accept product patents on pharmaceuticals or pesticides but the proposals requires product patents to be put into place after a set down transitional period. It was suggested that by agreeing to this the Indian pesticide industry who generally do not synthesis molecules, could be adversely affected and also the farmer who may be charged more for pesticides because of the possibility of monopolies. Product patents would be valid for 20 years from the date of filing and need not be commercialised, which implies that a multinational company could patent a product in India simply to prevent Indian companies synthesising the product and yet not market the pesticide.
- 16 The differences between confidentiality of data and the protection of proprietary rights to that data was explained by Mr Watts. Most countries in the Asia/Pacific region treat registration data as confidential and many respect proprietary rights, that is that the data belongs to the proprietor or applicant for registration.

provided he shows that it has either been generated by him or he has authority from the original developer to use it. It is generally recognised that health and safety data should be available for public viewing provided certain conditions are established to enable this to be undertaken, and the proprietary nature of the data to be protected. Some countries are allowing third parties to view the health and safety data subject to there being adequate safeguards in place to ensure there is no unauthorised use of it.

- 17 Mr N. R. Subbaram, who is the Adviser (Patents) of the Council of Scientific and Industrial Research outlined the intellectual property right protection in India. Intellectual Property includes patents, design, trade marks and copyright. A patent is granted by the Government for the disclosure of an invention for a limited period of time. The principle of a patent is to give the inventor exclusive rights and to stimulate the technical process. If an invention is novel and has utility it is patentable, but to be successful with a patent the application must be filed at an early stage and in all countries. Compared with some 30,000,000 patents filed world wide very few are filed in India. Some inventions are not patentable for example scientific principles, mere mixtures, treatment of humans, animal or plants. The products of biotechnology are patentable as are microorganisms. In India there are no product patents being given for chemicals at the moment, but instead there are process patents only. This will change when the agreements entered into under the Dunkel agreement come into force and there are differing views on what effects this will have on the chemical industry. Mr Subbaram was of the view that changes to allow product patents could in the long view be beneficial as Indian expertise is available, what is often missing is financing, and this change could result in worthwhile association with overseas companies to the ultimate betterment of the Indian chemical industry.

#### Technical Session IV

- 18 In outlining the Indian requirements for efficacy and residue data for pesticide registration Mr S. P. Yadav made the point that unless a pesticide will control the pest with no adverse effect on the crop, registration would not be considered. In order to assess the efficacy of a pesticide trials must be carried out under practical conditions of use. Trial protocols should be discussed and agreed on and in particular the method of reporting results is clearly established as it is very important. In addition to the efficacy testing, observations should also be made and recorded on any phytotoxicity effects on the treated plant. Dose rates of 2 and 4 times higher than that intended to be used in normal use should also be tested to assess any phytotoxicity. Residue trials should also be undertaken and samples may be taken from the efficacy trials or from specially laid down trials. Mr Yadav emphasised the absolute necessity to report the results correctly and in full. He presented a summary of the trials data required by the Central Insecticides Board for the various registration classes of registration in India, which is shown in Annex 7.

19 The most publicised botanical pesticide at the moment is neem, an extract from the seeds of the Neem tree, (*Azadirachta indica*) which grows freely in India. Dr N R. Srinatheshwar in presenting his address said that several formulations of neem are registered in India and that two standards were being developed on different formulation types. In addition to neem there are nicotinoids, rotenoids and pyrethrum based botanical pesticides in use in many countries including India. CIB has recently liberalised registration requirements for botanical pesticides and has developed a new set of registration requirements for neem in particular and other botanicals in general, but there are still some unresolved matters. Some of the disadvantages with neem are it is

- slow in action, it acting mainly as an antifeedant
- there is a variability in the quality of the neem seeds,
- there is a seasonality in seed production and,
- methods of analysis of the active ingredient can be difficult

There is considered to be a good future for neem based botanical pesticides although there is still a lot of development work to do to show how it can best fit into the pest control arena. In addition extracts from other plants are being studied at IPFT to see if they can be developed into botanical agents and some promising avenues are being explored. Botanical pesticides possess a number of advantages over chemical pesticides such as

- no development of resistance,
- no residue problems, and,
- no known environmental hazards

20 The Pesticide Industry has the potential to be a major polluter of the environment and Mr N. R. Babu of the Central Pollution Control Board outlined some of the problems and solutions to overcome this. Of the 57 plants manufacturing some 53 different technical materials and 21 large formulating plants in India, 80% are in Gujarat and Maharashtra. Although the Central Pollution Board has the legislative power to require actions to be taken under the various Statutes it has elected to achieve the objective of controlling pollution by discussion and cooperation with the Industry. Due to the diversity of the products produced and the often complex manufacturing procedures it was considered absolutely essential to obtain the cooperation of the Industry at an early stage. Several meetings have been held with the Pesticides Association of India and as a result of these, guidelines have been prepared and training sessions have been held on steps to take. Waste disposal standards have been established and studies undertaken for the development of emission standards. In addition studies have been undertaken at a number of plants and flow diagrams of areas where waste is generated being developed. Discussions are taking place about the installation of a chemical incineration facility and in some areas common storage and disposal areas are being considered. Guidelines for Environmental audit have been developed with emphasis being placed on waste reduction to reduce the amount of waste requiring treatment. Finally Mr Babu covered some technical aspects about waste disposal and concluded by saying that the pesticide industry was very much aware of the need to adequately manage waste treatment and was achieving this.

- 21 Harmonisation of pesticide registration requirements in Asia and the Pacific was discussed by Mr Watts, who outlined the concept behind harmonisation of these requirements. When generating data it was always desirable to do this using accepted methods, the results of which should be as transportable as possible. Although a considerable degree of harmonisation in the region had been achieved as reflected in the responses to the Beijing Workshop Report in May 1990, there was still a long way to go before complete harmonisation was reached. It was emphasised that before a final decision on export is taken, the registration requirements should be ascertained from the regulatory authority in the country to which export is intended at an early so the data needs are known well before exports are scheduled to commence.

#### Technical Session V

- 22 The chemical and physical data required for pesticide registration in India were outlined by Dr S. Y. Pandey and are shown in Annex 7. Differing requirements for the various registration types and whether or not the product was for export or for local consumption were explained. Data requirements were very similar to that suggested by FAO. Any data produced were fully transportable and data produced in an overseas country would be accepted in India.
- 23 In establishing the expiry date requirements for pesticides, four categories had been determined, and in the absence of data to the contrary the CIB required manufacturing and minimum expiry dates for the specified pesticides to be placed on labels in accordance with these parameters. If an expiry date longer than the minimum set by the CIB, is required, the registrant may on the submission of supporting data request a re-evaluation of the decision. Labelling requirements, particularly for small packs is of concern as it is mostly not possible to get all the required information on these small containers. In this instance the use of leaflets is allowed provided some minimum information is on the label and the leaflet is attached to, or sold with the container. Er V.C. Bhargava in explaining these requirements also outlined briefly the requirements of IS 819 (Parts I to IV), which is the Bureau of Indian Standard set for packages. The average distance a package containing a pesticide travels in India prior to its use is estimated to be 3000 km and during that time it would be handled 60 times. Thus packages should be strong and durable. Water soluble packages are not allowed neither is glass because of its fragility.
- 24 Dr N. Ramakrishnan said that biological pest control agents, unlike chemical pesticides were naturally occurring materials and were usually safer both to man and the environment than chemical pesticides. Different testing procedures than those applicable to chemical materials to establish safety were required for biological pesticides. The best known biological pest control agent is *Bacillus thuringiensis* and related strains which were now used quite widely in many parts of the world and quite possibly would be used increasingly in India in the future, although at the moment it has provisional registration only due mainly to concerns about adverse effects on the silkworm. Parasites and predators are now marketed and while technically they could be considered to be biological pesticides they are

not subject to registration. Parasites of eggs are perhaps the best form of biological control, but predators which tolerate pesticides are now being developed. Transgenic plants, that is plants in which genes have been biologically engineered and introduced to make them resistant to insect attack are now available. In addition there was now considerable interest in the development of formulations of *Baculoviruses* which have been used to successfully control *Heliothis*, *Spodoptera*, *Chilo* spp and Rhinoceros beetle. Another type of biological pest control agent is the use of fungi eg *Trichoderma* spp to suppress harmful soil fungi, or to inoculate fruit trees to keep pathogenic fungi at low levels. Estimates for the offtake of these materials have been made and by the year 2000 significant offtake is foreseen. CIB have set guidelines for registration requirements of some of these agents. Generally biological pesticides are quite costly to produce and although environmentally preferred are sometimes not commercially viable.

- 25 The FAO International Code of Conduct on the Distribution and Use of Pesticides places considerable responsibility on the pesticides industry as far as advertising is concerned. Mr Watts in outlining these responsibilities pointed out that very often the public judged an industry by its advertising and suggested it could be useful for the industry to develop a Code of Ethics on pesticide advertising. A large amount of the public sector controversy on pesticides had been fuelled by extravagant advertising or by the presentation of unsafe practices during advertising. In a survey done by FAO on Government responses to the implementation of the Code many countries felt that the Article on advertising was not being well observed by industry in their country. It was noted that apart from the disallowed use of certain words there is no power under the Insecticides Act 1968 to control misleading or extravagant advertising.

#### Technical Session VI

- 26 Dr (Ms) S Kulshrestha, in introducing her talk on the toxicological data requirements for registration indicated that the original emphasis given to the Insecticides Act was for the protection of health and safety. Two reports of expert committees, named after the chairmen, the Gaitonde and the Kasyap report form the basis of the requirements for the toxicological package to be submitted in support of applications for registration. The former report deals with requirements for chemical pesticides while the latter covers biological pest control agents. The requirements are outlined in tabular form as shown in Annex 7. For import of technicals and formulations under 9(4) no toxicological data are required. The requirements for household pesticides were given. The toxicity classification, which is based on the active ingredient, determines the type of labelling requirements for colour coding of the formulation.
- 27 In 14 countries which responded to the ARSAP/ESCAP survey in 1990, some 33% of the active ingredients were available as formulated mixtures usually containing 2 active ingredients. The reasons for the use of mixtures was explained by Mr Watts, and suggestions made on the amount and type of data to be supplied in support of their registration. It was to be understood that the smaller amount of

data generally required for mixtures than for a new active ingredient was based on the premise that the individual actives were already registered as formulations

28. Dr J. C. Majumder, saw a need for mixtures of herbicides to be used increasingly in India, as few herbicides were able to control the weed spectrum present when used alone. He discussed the advantages and disadvantages of mixtures. The results of some German work on toxicity, reporting that in trials work done, the chronic toxicity of mixtures was usually no worse than an additive effect of the various ingredients. He did not foresee a need to do long term tests on mixtures. There are only 4 combination products registered in India for use in agriculture. There were no controls able to be enforced over farmer use of either tank mixing or of sequential applications, two alternatives used by farmers to increase the pest control spectrum. Potential problems with these two increasingly common practices were discussed. Difficulties in developing a suitable method of analysis was given as a reason for not having more mixtures registered.

#### Technical Session VII

29. It was well known that pesticides are important for the continuing production of food and fibre and much work has been done over the years in developing these. It was very important that pesticides were able to be applied so that they would reach the target. Mr S.L. Patel, in presenting his paper made the point that not as much research had been given to application equipment as had been given to pesticides. Mr Patel discussed the various types of application equipment which was being marketed in India and outlined some of the new developments with controlled droplet application (CDA), as well as with air assisted sprayers. He discussed the way to select application equipment for the particular situation which depends on a number of factors including target pest, pesticides formulation, type and characteristic of the formulation and the evaporation and drift properties, the latter being influenced also by the weather. He demonstrated the relationship between droplet size and spray coverage pointing out that the finer the spray the better the coverage in ideal conditions but the greater the potential for drift. A balance had to be struck between these two. The importance of good calibration of the spray equipment was stressed.
30. The requirements for registration of pesticides for export and import of pesticides in India were presented by Dr Kawal Dhari. There is high production capacity in India with perhaps only half of which is utilised. Pesticide exports are increasing in value being now in the order of \$70,000,000, with imports being around 20-25% of this value. Of the 137 pesticide active ingredients registered, only 70 or so are actively used. The registration requirements for the various categories of pesticides were outlined and is shown in Annex 7.
31. The history of the development of the FAO series of pictograms was outlined by Mr Watts. Pictograms are pictures without words and are intended to be used on labels to assist farmers and particularly those who may be illiterate to be able to follow safety directions. It was emphasised that the pictograms are not intended to replace any written word but rather they are intended to supplement it. It was

noted that pictograms are being used on labels in India and that the Registration Committee is encouraging their use.

### **Technical Session VIII**

32. The symptoms of, and treatment for poisoning from the various types of pesticides were very briefly outlined by Dr V.L. Patil, who made the point that the toxicity of a pesticide towards a target was a reflection of the dose absorbed by that target. The value of the information on the label is not to be underestimated and the information on the label, as required by Rule 19 of the Insecticides Act should be followed at all times. The leaflet which is considered as part of the label is also an important document carrying amongst other things instructions for use in various local languages. Public conceptions on the fears of pesticides as a killer are not borne out by statistics on the listed causes of death according to figures from a survey done in USA. Also the concept that anything that is natural is safe is a myth as some of the most toxic compounds are naturally occurring toxins. However as pesticides are designed to kill living organisms they should be used carefully and responsibly at all times.
33. The Bureau of Indian Standards (BIS) started standardisation work in pesticides in 1955 and now has published over 270 standards on pesticides covering products, the methods of testing, common names, packaging, sampling and guidance for treatment of poisoning. After registration is granted, the standard is developed following consultation with all interested parties and standards are developed for all pesticides that are registered. A problem now facing BIS is the request from the Ministry of the Environment for "eco-marking" of pesticides but this is still being considered by the Ministry of Agriculture. Standards for biological pesticides are being developed as are 2 standards for neem based products. There are 25 or so standards for pesticides application equipment, covering the product, test methods, calibration, a glossary of terms and a code of practice for the operation and maintenance of the equipment. In addition to setting standards BIS certifies the product under the standard following receipt of satisfactory test results.
34. The principle of Prior Informed Consent (PIC) was outlined by Mr Watts. The history of the development of the principle was explained and a detailed explanation of how the system was working was given. India which is a participating country has nominated a Designated National Authority for pesticides, in the Ministry of Agriculture. With an increased export potential PIC is expected to become more applicable to the Indian pesticide industry in the future.
35. The FAO Guidelines were discussed and an outline given of the contents of those which are published. It was pointed out that FAO had provided these for guidance, mainly to Government officials concerned with the regulation, registration and control of pesticides. They were well accepted by countries in the Asia/Pacific region as was reflected unanimously at the Beijing Workshop.

## **VISIT TO IPFT GURGAON**

- 36 A visit was made to IPFT at Gurgaon on the afternoon of November 4. The history of the development of IPFT was given by the National Project Coordinator, Dr Kawal Dhari. The Project originally started in 1981 as a joint UNDP/UNIDO project implemented by Hindustan Insecticides Limited (HIL) called the Pesticide Development Programme of India. The name was changed in 1988, to the Pesticide Development Centre and later to the current name, the Institute of Pesticide Formulation Technology (IPFT). IPFT is a Registered Society under the Societies Act 1860, and is moving towards being a stand alone entity. A highly technical staff of about 30 scientists and technicians working in four Divisions,- Biosciences, Analytical, Formulation and Pilot Plant, as well as Administration and Finance makes up IPFT. The Institute is available to undertake projects under contact to local Industry as well as to train Industry personnel from India and from RENPAP member countries.
37. The participants broke into two groups and took part in a very useful and informative visit to the four Divisions during which time they were able to see, first hand the type of work being undertaken at the Institute. These demonstrations and explanations were most beneficial to all the visitors who were impressed with both the facilities and the expertise at the Institute.

## **RECOMMENDATIONS**

38. Recommendations were put forward for future workshops, and for transmission to the relevant officials in the GOI.

### **ADDRESSED TO IPFT**

1. More experts from the Registration Committee and the Central Insecticides Laboratory should be involved for discussions as well as more experts from the pesticide industry being asked to contribute.
2. Course papers should be circulated at least one day in advance.
3. Course (Workshop) period should be for 3 days from 8 am to 6 pm and tea should be served in the conference room itself.
4. If the present five day workshop period is continued in the future, the last two days should be directed to "do-it-yourself" exercises to make trainees more conversant with the documentation.
5. A separate course (Workshop) should be arranged for the newer entrants to the industry, ie those not fully conversant with the registration and regulation system



## **ADDRESSED TO REGULATORY AND REGISTRATION AUTHORITY**

1. State pesticide analytical laboratories should be better equipped so that inter laboratory differences of results are minimised.
2. Registration under 9(4) should be granted within a months maximum time and the application fee should be raised to Rs 1000 to limit the number of applicants seeking registration.
3. A reasonable protection period of say five years should be given to the first registrant under section 9(3) and only after this period 9(4) registration should be granted.
4. A shelf-life of 15 months should also be granted after submissions of proper data from the claimant as it would enable the manufacturer to sell his product for three crop seasons.
5. Where chemically and technically feasible, date expired materials should be permitted to be reprocessed as disposal locally is both hazardous and costly..
6. Registration of mixtures (combinations) should be liberalised especially for those cases where tank mixtures are already used by farmers. Detailed guidelines for the registration of combination products should be provided.
7. Phytotoxicity data for technical/technical concentrate should not be required as it is not demanded in any country.
8. Safety clothing and antidotes should be required to be stocked by pesticide dealers.
9. Single window systems for statutory clearances at State level should be introduced, as presently manufacturers have to run from place to place for different types of statutory clearances for the same product at the same manufacturing site.

## **VALEDICTORY SESSION**

39. Dr S.P Dhua welcomed the Joint Secretary of the Ministry of Chemicals and Fertilisers, and the National Project Director, Mr Vinay Kohli to the Workshop. He said he had heard good reports of the progress of the Workshop and that he considered the subject of registration requirements was a very important one and he hoped that participants had gained additional useful knowledge from the weeks activities.
40. Mr Brian B.Watts, the UNIDO Consultant stated how much he had enjoyed working with members of the Workshop, and how he saw a major part of the value of Workshops of this nature from meeting Government officials and fellow participants. It was timely that developments in the International area were introduced into the programme particularly as there was likely to be an increasing amount of pesticide exported from India in the future. It was therefore very important that the Industry was aware of the need to understand the requirements of importing countries well before export was contemplated.
41. Dr Kawal Dhari outlined some of the recommendations from the group and indicated to the guests that the group had been a very participative one, freely entering into discussion on the various topics discussed. He was most pleased with the outcome of the Workshop and hoped to arrange another one in the next 12 months or so.
42. Before presenting the Certificates to the participants, Mr Vinay Kohli said in his valedictory address that there was a need to use pesticides carefully for the betterment of man and the environment. Today the use of pesticides was under very close scrutiny from a number of organisations and a careful responsible attitude by Industry was absolutely essential if the Industry was to prosper and survive as indeed it must in order to continue the much needed pesticide input into crop production. A report of the Joint Secretary's address is given as Annex 8.
43. Dr R D Kapoor, passed a vote of thanks on behalf of the participants for efforts put in by all parties to make this Workshop the success it was.

## **PRESENTATION OF CERTIFICATES AND CONCLUSION OF WORKSHOP.**

44. The certificates and mementoes were presented by Mr Vinay Kohli to the participants of the Workshop
45. The Workshop concluded with a vote of thanks passed by Dr N.R. Bhatেশwar on behalf of the National Project Coordinator and his colleagues. A copy of the vote of thanks presented by Dr Bhatेशwar is given as Annex 9

**WORKSHOP ON PESTICIDE REGISTRATION AND REGULATIONS**

**NOVEMBER 7 -11 , 1994**

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**WORKSHOP ON PESTICIDE REGISTRATION AND REGULATIONS**

**November 7-11, 1994  
PROGRAMME**

**Monday, November 7, 1994.**

0900 Registration

**Inaugural Session**

0930 Welcome Address: *Dr S. P. Dhua*, Chairman IPFT  
Introduction of Programme: *Dr Kawal Dhari*, NPC  
Keynote Address: *Mr I. S. Malhi*, JS (PPT& AC)<sup>1</sup>  
Vote of Thanks: *Dr Kawal Dhari*, NPC

10.15 Tea/coffee

**Technical Session I**

**Chairman:** *Dr S. P. Dhua*

- 1045 The Pesticide Industry in India - an overview  
*Mr. S. C. Mathur*
- 1115 Pesticide Database  
*Dr. Y. P. Ramdev*
- 1145 Pesticide Registration and Regulations - an overview  
*Dr A. D. Pawar*<sup>2</sup>
- 1215 Pesticide Regulations in India  
*Dr. Kawal Dhari*
- 12.45 The FAO International Code of Conduct on the Distribution and Use of  
Pesticides  
*Mr. Brian B. Watts*
- 1330 Lunch

**Technical Session II**

**Chairman:** *Dr. M. L. Saini*

- 1430 Environmental Issues arising from Pesticide Use  
*Dr. H. L. Bami*
- 1515 Tea/coffee
- 1530 "Me-Too" Registrations  
*Mr. Brian B. Watts*

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<sup>1</sup> Could not attend because of prior commitments

<sup>2</sup> Could not attend because of ill health

- 1615 Indian Standards and Quality Systems Application in the Pesticide Industry  
*Mr E. N. Sunder*
- 1700 Close

**Tuesday, November 8, 1994**

**Technical Session III**

**Chairman: Mr Brian B. Watts<sup>3</sup>**

- 0900 Uruguay Round - Final Act 1994 - Trips Agreement: Impact of new Patent Regime on Pharmaceuticals, Pesticides and Seeds.  
*Mr. B. K. Keayla*
- 1030 Tea/coffee
- 1045 Protection of Proprietary Rights and Confidentiality of Data  
*Mr. Brian B. Watts*
- 1145 Intellectual Property Protection in India  
*Dr. N. R. Subbaram*
- 1300 Lunch

**Technical Session IV**

**Chairman: Mr Brian B. Watts**

- 1400 Efficacy and Residue Data Requirements for Registration of Pesticides  
*Mr S. P. Yadav*
- 1445 Requirements for Registration of Botanical Pesticides in India.  
*Dr. N. R. Bhateshwar*
- 1530 Tea/coffee
- 1545 Pollution and its Prevention in the Pesticide Industry  
*Mr N.R. Babu*
- 1630 Harmonisation of Pesticide Residue Requirements in Asia and the Pacific  
*Mr. Brian B. Watts*
- 1715 Close

**Wednesday, November 9, 1994.**

**Technical Session V**

**Chairman: Mr. Brian B. Watts**

- 0930 Chemical Data Requirements for Registration of Pesticides  
*Dr. S. Y. Pandey*
- 1015 Processing, Packaging and Shelf Life Requirements of Pesticides for Registration  
*Er. V. C. Bhargava*
- 1100 Tea/coffee
- 1115 Efficacy and Residue Data Requirements of Biological Pest Control Agents  
*Dr N. Ramakrishnan*

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<sup>3</sup> Originally to be chaired by Mr Keayla but he was unable to because of other commitments

- 1200 Advertising and the FAO Code of Conduct  
*Mr. Brian B. Watts*
- 1300 Lunch

**Technical Session VI**

**Chairman:** *Dr. D. Kanungo*

- 1400 Toxicological Data Requirements for registration of Pesticides  
*Dr. (Mrs) S. Kulshreshtha*
- 1445 Mixed Formulations in Asia and the Pacific  
*Mr. Brian B. Watts*
- 1530 Tea/coffee
- 1545 Mixed Formulation : Its scope in India  
*Dr J. C. Majumder*
- 1630 Discussion and film on Pesticide Safety
- 1700 Close

**Thursday, November 10, 1994**

**Technical Session VII**

**Chairman:** *Dr. V. Raghunathan*

- 0930 Pesticide Application Techniques  
*Sri. S. L. Patel*
- 1015 Tea/coffee
- 1030 Data Requirements for Import and export of Pesticides in India  
*Dr. Kawal Dhari*
- 1100 FAO Pictograms  
*Brian B. Watts*
- 1215 Open Discussion
- 1300 Lunch
- 1400 Visit to the Institute of Pesticide Formulation Technology, Gurgaon
- 1715 Back to Delhi

**Friday, November 11, 1994**

**Technical Session VIII**

**Chairman:** *Dr. B. P. Srivastava*

- 0930 Pesticides Safety : Toxicity, Poisoning, First Aid Treatment, Labels and Leaflets  
*Dr. V. L. Patil*
- 1015 Pest Control Products and Equipment - an overview of Indian Standards  
*Mr. R. N. Sharma*
- 1100 Tea/coffee
- 1115 Prior Informed Consent  
*Mr. Brian B. Watts*

- 1215 The FAO Series of Guidelines  
*Mr. Brian B. Watts*
- 1300 Lunch

**Plenary Session**

- 1400 Evaluation of Workshop and Discussion on Recommendations  
Moderator, *Dr Kawal Dhari*
- 1515 Break

**Valedictory Session**

- 1530 Valedictory Function  
Address : *Dr S. P. Dhua*, Chairman, IPFT  
Valedictory Address: *Mr Vinay Kohli*, Joint Secretary (Chem)  
Distribution of Certificates by *Mr Vinay Kohli*, Joint Secretary (Chem)  
Vote of Thanks: *Dr.N. R Bhatashwar*, NPC.
- 1630 Tea/coffee



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#### **Technical Session V**

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Er. V.C. Bhargava,  
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#### **Technical Session VI**

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### **Technical Session VII**

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### **Technical Session VIII**

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Dr. P.K. Ramadas,  
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**LIST OF PESTICIDES WHICH ARE BANNED, RESTRICTED OR UNDER REVIEW IN INDIA AS AT 31/12/92**

**LIST OF PESTICIDES NOT APPROVED FOR USE IN INDIA  
( as at 31/12/92)**

1	calcium arsonate	10	azinphos-ethyl
2	EPN	11	binapacryl
3	azinphos-methyl	12	dicrotophos
4	lead arsenate	13	thiodemeton/disulfoton
5	mevinphos	14	fentin acetate
6	2,4,5-T	15	fentin hydroxide
7	carbophenothion	16	chinomethionate
8	vamidothion	17	ammonium sulphamate
9	mephosfolan	18	leptophos

**LIST OF BANNED PESTICIDES IN INDIA  
(as at 31/12/92)**

1	dibromochloropropane (DBCP)	7	chlordan
2	endrin	8	heptachlor
3	pentachloronitrobenzene (PCNB)	9	aldrin (w.e.f 1/1/94)
4	pentachlorophenol (PCP)	10	paraquat
5	toxaphene	11	nitrofen
6	parathion-ethyl	12	tetradifon

**LIST OF PESTICIDES WHICH ARE UNDER REVIEW BY THE GOVERNMENT OF INDIA  
(as at 31/12/92)**

1	alachlor	10	sodium methane arsonate
2	benomyl	11	calcium cyanide
3	copper acetoarsenite	12	phosphamidon
4	diuron	13	thiometon
5	ethyl mercury chloride	14	triazophos
6	fenarimol	15	tridemorph
7	menazon	16	ziram
8	methomyl	17	monocrotophos
9	oxyflurofen		

**LIST OF PESTICIDES RESTRICTED FOR USE IN INDIA  
(as at 31/12/92)**

1	aluminium phosphide	sold to Government and to be used under the strict supervision of Government expert of Pest Control Operators whose expertise is approved by the plant protection Adviser
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2	BHC	banned for use on vegetables, fruits, oilseed crops and for the preservation of food grains
3	chlorbenzilate	banned in agriculture but special formulations in strip form can be imported by Government and prepared for sale to beekeepers for controlling mites of honeybees
4	captafol,	foliar spray banned but can be used as a seed dressing
5	DDT	use in agriculture is banned but in very special circumstances the State Government can purchase directly from Hindustan Insecticides to be used under expert Government supervision. The use of DDT for public health programme up to 10,000 MT per annum is allowed.
6	dieldrin	use restricted for locust control in desert areas by the plant protection Adviser to the Government of India
7	ethylene dibromide (EDB)	use restricted to a fumigant for food grains through Government and State food grain warehouses and by pest control operators approved by the plant protection Adviser
8	methyl bromide	as for aluminium phosphide
9	sodium cyanide	for fumigation of cotton bales only by plant protection under expert supervision
10	phenyl mercury acetate (PMA)	banned in India but may be produced only for Export
11	lindane	use indoors as a smoke generator is prohibited, but it may be used outdoors for control of insects of field crops
12	nicotine sulphate	use in India prohibited but it may be produced for Export

**DATA REQUIREMENTS FOR REGISTRATION OF PESTICIDES UNDER  
VARIOUS CATEGORIES FOR CONSUMPTION AND EXPORT AS AT 1/1/93**

(R: Required, NR: Not Required)

Sl No	Data Requirements	Home Consumption									Export				
		Technical					Formulation				Technical		Formulation		
		9(3b) Import	9(3) Import Ind.		9(4) Import Ind.		9(3b) Ind.	9(3) Ind.	9(4) Ind.	9(3b) Unreg. Insectii. for imp.	9(4) Reg Insect for imp	9(3b) unreg form	9(3) unreg stren	9(4) regd form	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
<b>A CHEMISTRY</b>															
1	Source of supply	R	R	NR	R	NR	NR	NR	NR	R	R	NR	NR	NR	
2	Chemical composition	R	R	R	R	R	R	R	R	R	R	R	R	R	
3	Chemical identity	R	R	R	R	R	R	R	R	R	R	R	R	R	
4	Physico-chemical properties	R	R	R	R	R	R	R	R	R	R	R	R	R	
5	Technical bulletin	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
6	Specification	R	R	R	R	R	R	R	R	R	R	R	R	R	
7	Method of Analysis	R	R	R	R	R	R	R	R	R	R	R	R	R	
8	Analytical test report	R	R	R	NR	R	R	R	NR	NR	NR	NR	NR	NR	
9	Identification & quantification of identifiable	R	R	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	
10	(a) Shelf life claim	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR	
	(b) Shelf life data	NR	NR	R	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	
11	Establishment of chemical equivalence	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	
12	Process of manufacture														
	(a) Information about raw materials used	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	
	(b) Their source of supply	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	
	(c) Stepwise manufacturing process	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	
	(d) with chemical equation	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	



SI No	Data Requirements	Home Consumption									Export				
		Technical				Formulation					Technical		Formulation		
		9(3b) Import	9(3) Import Ind.		9(4) Import Ind.		9(3b) Ind.	9(3) Ind.	9(4) Ind.	9(3b) Unreg. Insect. for imp.	9(4) Reg Insec for imp	9(3b) unreg form	9(3) unreg stren	9(4) regd form	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
	(c) Formula	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR
	(f) Flow sheet diagram of process of manufacture	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR
	(g) Effluent method of treatment	NR	NR	R	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR
13	Sample (a) Date & place from where in-process sample could be drawn	NR	NR	NR	NR	R	NR	NR	R	NR	NR	NR	NR	NR	NR
<b>B. BIO- EFFICACY &amp; RESIDUES</b>															
14	Bio-effectiveness	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	NR	NR	NR
15	Phytotoxicity	NR	NR	NR	NR	R	R	R	NR	NR	NR	NR	NR	NR	NR
16	Translocation within plants being treated	R	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
17	Metabolism in soil	R	R	R	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR
18	Metabolism in water	R	R	R	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR
19	Metabolism in plant	R	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
20	Persistence in soil	R	R	R	NR	NR	NR	R	NR	NR	R	NR	NR	NR	NR
21	Persistence in water	R	R	R	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR
22	Persistence in plant	R	R	R	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR
23	Compatibility with other chemicals	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR
24	Residue s in plant	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	NR	NR	NR
25	Residues in soil	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	NR	NR	NR
26	Residue tolerance limits	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	NR	NR	NR
27	Purpose for import/manufacture	R	R	R	R	R	R	R	R	R	R	R	R	R	R
28	Directions concerning usages	NR	NR	NR	NR	NR	R	R	R	R	NR	NR	NR	NR	NR
29	Time of application	NR	NR	NR	NR	NR	R	R	R	R	NR	NR	NR	NR	NR
30	Application equipment	NR	NR	NR	NR	NR	R	R	R	R	NR	NR	NR	NR	NR
31	Waiting period	NR	NR	NR	NR	NR	R	R	R	R	NR	NR	NR	NR	NR
32	Information regarding registration status in other countries	R	R	R	NR	NR	R	R	NR	NR	NR	NR	NR	NR	NR

SI No	Data Requirements	Home Consumption									Export				
		Technical				Formulation					Technical		Formulation		
		9(3b) Import	9(3) Import Ind.		9(4) Import Ind.		9(3b) Ind.	9(3) Ind.	9(4) Ind.	9(3b) Unreg. Insecti. for imp.	9(4) Reg Insec for imp	9(3b) unreg form	9(3) unreg stren	9(4) regd form	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
<b>C. TOXICITY</b>															
33	Acute oral in rat & mice	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR
34	Acute dermal	R	R	R	NR	R	R	R	R	NR	R	NR	R	NR	NR
35	Acute inhalation	R	R	R	NR	NR	R	R	R	NR	R	NR	R	NR	NR
36	Primary skin irritation	R	R	R	NR	NR/R	R	R	R	NR	R	NR	R	NR	NR
37	Irritation to mucous membrane	R	R	R	NR	NR/R	R	R	R	NR	R	NR	R	NR	NR
38	Sub-acute oral in rat & dog	R	R	R	NR	NR	NR/R	NR/R	NR/R	NR	R	NR	NR	NR	NR
39	Sub-acute dermal	R	R	R	NR	NR	NR/R	NR/R	NR/R	NR	R	NR	NR	NR	NR
40	Sub-acute inhalation	R	R	R	NR	NR	NR/R	NR/R	NR/R	NR	NR	NR	NR	NR	NR
41	Neuro-toxicity	NR	R	R	NR	NR	NR	NR/R	NR	NR	NR	NR	NR	NR	NR
42	Synergism & potentiation	NR	R	R	NR	NR	NR	NR/R	NR	NR	NR	NR	NR	NR	NR
43	Teratogenicity	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
44	Effect on reproduction	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
45	Carcinogenicity	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
46	Metabolism	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
47	Mutagenicity	NR	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
48	Toxicity to birds	R	R	R	NR	NR	R	R	R	NR	NR	NR	NR	NR	NR
49	Toxicity to fish	R	R	R	NR	NR	R	R	R	NR	NR	NR	NR	NR	NR
50	Toxicity to honey bees	R	R	R	NR	NR	R	R	R	NR	NR	NR	NR	NR	NR
51	Toxicity to livestock	R	R	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
52	Medical data	R	R	R	NR	NR	R	R	R	NR	NR	NR	NR	NR	NR
53	Human toxicity information from foreign countries	R	NR	NR	NR	NR	R	NR	R	NR	R	NR	NR	NR	NR
54	Observations in man (health records of spray operators)	NR	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	NR	NR

Sl No	Data Requirements	Home Consumption									Export				
		Technical						Formulation			Technical		Formulation		
		9(3b) Import	9(3) Import Ind.		9(4) Import Ind.		9(3b) Ind.	9(3) Ind.	9(4) Ind.	9(3b) Unreg. Insecti. for imp.	9(4) Reg Insec for imp	9(3b) unreg form	9(3) unreg stren	9(4) regd form	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
55	Health records of industrial workers	NR	R	R	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR
56	Toxicity to livestock (field trial & observation)	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR
57	International report carcinogenicity & carcinogenicity status	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR
58	Labels & leaflets as per IR-1971 existing norms	R	R	R	R	R	R	R	R	R	R	R	R	R	R
59	Type of packing (packaging material+ compatibility with content)	R	R	R	R	R	R	R	R	R	R	R	R	R	R
60	Manner of packaging	R	R	R	R	R	R	R	R	R	R	R	R	R	R
61	Specification for primary packaging	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
62	Specification for secondary packaging	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
63	Specification for transport packaging	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
64	Manner of labelling	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
65	Instructions for storage, use etc.	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
66	Information regarding disposal of used packages	R	R	R	R	R	R	R	R	R	NR	NR	NR	NR	NR
67	Process of manufacturing	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR

NOTE For export only labels are required.

Explanation.

- 1 For getting registration under 9(3) for export the data are required to be submitted as per column no 4, 5 or 9 as the case may be.
- 2 Information based on International Organisations/Institutions on (i) carcinogenicity, (ii) mutagenicity and (i) carcinogenicity, (ii) mutagenicity and (iii) health records of factory workers/spray operators is required in case of insecticide/its formulation to be registered for the first time in the country under the Act
- 3 For registration of pesticides for export an undertaking is required to the effect that the insecticide shall be packed as per the requirements of the importing country

**VALEDICTORY ADDRESS**

**VINAY KOHLI**  
**National Project Director and**  
**Joint Secretary (Chemicals)**  
**MINISTRY OF CHEMICALS AND FERTILIZERS,**  
**GOVERNMENT OF INDIA**

**on the concluding day of the Workshop on**  
**Pesticide Registration and Regulations, November. 7 - 11, 1994,**  
**at International Youth Centre, New Delhi.**

1. I am pleased to be here at the final session of your week long Workshop, and to hear that you had a such an informative and productive week. The recommendations which you have submitted are based on your practical experience and I can assure you that I will be diligently considering them and where appropriate taking action or pass them to my colleagues for their attention.
2. I plan to ask IPFT to call together a working group consisting of persons from Industry, the Ministry of Agriculture and private scientists to thoroughly discuss and evaluate the amount and types of data required to be submitted to the pesticide registration authority, in support of the registration application. One of the main complaints I constantly receive from Industry is in regard to the pesticide registration data requirements with a common complaint being that the information requested is sometimes in their view not necessary nor relevant in order to arrive at a decision on whether or not the pesticides should be registered.
3. There is a need of course to fully evaluate the pesticide before it can be sold and used, as are pesticides by their very nature designed to control pests, which are living organisms and therefor their properties must be fully considered, particularly effects on human health and the environment.
4. I am pleased to see from your programme that you discussed the registration requirements in some other countries in the Region as it is very important that you recognise the challenges we are to face in the future with the changing in trade and services under the Uruguay round of GATT. These changes will have to be faced and the challenges which they will undoubtedly bring will have to be met and overcome for the industry to progress.
5. The recommendation that more use be made of Industry pesticide registration experts with considerable practical experience for future workshops is an excellent one as to meet and overcome challenges a good practical knowledge is essential.

- 6 The success of a training workshop of this nature can be judged in part by the interaction among the participants and the resource people and I am delighted to hear that participation of this group was at such a high level
  
- 7 Finally I hope you have happy memories of your time in Delhi and I wish you all the best in your future endeavours in your chosen occupation

## VOTE OF THANKS

**Dr N.R. Bhatেশwar**

Respected Mr. Vinay Kohli, Dr S. P Dhua, Mr. Brian B.Watts, Mr Wilhelm Zsifkovits,, dear participants of the Workshop, my colleagues and friends

It is my great privilege to propose this vote of thanks

Dear Mr. Kohli, I on behalf of the Chairman, IPFT, the National Project Director, myself and my colleagues express a great sense of gratitude to you for kindly gracing this occasion in spite of your busy schedule.

Sir, this is the second Workshop of this kind and we have received an overwhelming response from the pesticide industry. We are sincerely grateful to the management of the pesticide industry who sponsored the participants.

Mr Brian B. Watts was instrumental to make the first workshop a great success. With the same hopes, he was again invited for this Workshop where he has delivered a very useful nine lectures on various aspects of pesticide registration requirements. We are sincerely grateful to Mr Watts for his untiring efforts and contributions.

Our faculty and Chairmen of the Technical sessions comprised of very eminent scientists who had been dealing with various aspects of pesticide registration, including the scientists from CIL and CIB. We are sincerely thankful to all the faculty members and the Chairmen who, even at very short notice have made great contributions and delivered very useful and lucid lectures.

The participants of the Workshop both from multinational as well as small scale pesticide industry are the Managers and senior executives who are directly or indirectly involved in pesticide registration. We have found every participant very enthusiastic to learn as well as taking very keen interest and participation in really constructive discussions during the entire course of the Workshop. We are sincerely thankful to every participant.

I will fail in my duties if I do not thank the Chairman, IPFT, the National Project Coordinator and my colleagues who have worked day and night to make this Workshop a great success. My heartfelt thanks to Dr S. P. Dhua, Dr. Kawal Dhari, NPC and my colleagues, Dr. Ramdev, Mr. Yadev, Mr. Degra, Mr. Singh and Mr. Mandal.

My sincere thanks to my colleagues of IPFT who had helped in many ways.

Once again I thank you all and invite you for a cup of tea down stairs.

UNIDO'S COMMENTS

This report gives a detailed account of the pesticide registrations procedures that are widely adopted in the developed countries and how they would relate to India in the wake of GATT treaty. In this, the report is very timely to provide necessary views on India's policy towards pesticide registration.

From the level of participants from industry and the government it clearly indicates the importance given to the topic. The deliberations and the recommendations made in the meeting will have a wider implication for pesticide production and use in India. The consequence would be globalization of the Indian market which in the long run would benefit the industry, consumers and the environment.

The meeting also makes reference to bio-botanical pesticides and mixture formulation. Introduction of these types of pesticides and formulations will drastically change the pesticide industry and the market. In addition, the global market on food crops (export oriented) would depend on registration of pesticides in each country (both exporting and importing).

In this Indian experience in novel registration approach would be valuable to the region.