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20550

DP/ID/SER.A/1690  
11 February 1994  
ORIGINAL: ENGLISH

STRENGTHENING OF PESTICIDE DEVELOPMENT CENTRE

DP/IND/89/128

INDIA

Technical report: Findings and recommendations\*

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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\* This document has not been edited.

V.94 20828

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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 October 26 to 13 November during which time he prepared and delivered 8 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 the Regulatory authority, 2) to IPFT for Future workshops and 3) of a general nature. Of considerable concern to participants was the perceived poor quality of formulations available to Indian farmers, caused it was felt, in part by 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 some concern was expressed about the variations between States in their enforcement of the requirements of the Act. A number of other recommendations are 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 Tuesday October 26 and departed on Saturday 13 November 1993. 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 1-5. Twenty-three participants from the Indian pesticide industry took part, in this Workshop, the first of its kind to be held in India, which 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 that in Asia/Pacific region in particular. In view of the increasing exports of pesticides from India, which for the 12 months ending March 1993 were estimated by one speaker to be worth about US \$33,000,000, there is a need for the pesticide industry to have an increasing knowledge about what is required outside India.

The Consultant in preparing and delivering 8 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 3. The programme was intended for the executives/product development personnel from the pesticide industry associated with pesticide registration and marketing. Although 24 persons enrolled to take part in the Workshop, one person 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 attached as Annex 4.

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 Valedictory 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 first 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. Considerable concern was expressed by the Workshop about the quality of pesticides available to the Indian farmer, particularly those supplied by formulators, often with no or with limited technical know how. Also 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 eight 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.

With pesticide manufacturing plant capacity often being under utilised by sometimes up to 50%, an increasing amount of pesticide is expected to be exported from India in the future. Thus it was timely for there to be an input into the activities in the field of pesticide regulation and control in countries outside India. 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.

#### 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 the Regulatory Authority

1. Concern was expressed on the quality of pesticides, due to the large number of Section 9(4) registrations given. 9(4) should be given only after the sample is cleared and inspection of the proposed premises undertaken. Follow up inspections

should be undertaken and registration revoked if adequate quality control programmes are not being met. Manufacturers license inspections also needs to be strengthened.

2. The application for registration fee should be increased from the present 100 Rs to discourage the widespread 9(4) registrations.
3. There is a problem with the results of analysis for pesticide quality done by the States as, 90% of the samples rejected by the State laboratories are cleared when re-analysed by the Central Insecticides Laboratory.
4. Sampling for product quality should be done at source, ie at the plant, to save costs and as a way of ensuring that regular sampling and analyses are undertaken.
5. As implementation of the Act is weak, there should be more positive action by States and Union Territories.
6. There needs to be a better understanding by some States who should only act within the powers given to them under the Insecticides Act, and not require a type of second clearance.
7. A firm policy on the registration requirements for mixtures of pesticides needs to be established.
8. Steps should be taken to reduce pesticide use on cotton with a coordinated policy being established at national level and implemented by States. It was recognised that some States are addressing the problem through their Cotton Divisions/Sections/Units in the Department of Agriculture.
9. There is an on going difficulty to get users to use pesticide safely and properly, thus there is a need to increase and strengthen the advice given on safe and effective use of pesticides by extension systems.

#### B. To IPET for Future Workshops

1. Future Workshops could be reduced to 3 day by circulating lecture material before hand so the presenter needs only to present a short (15 minute) summary of the paper. This would allow for more discussion.



2. It would be useful to invite experts to answer some practical questions in response to the difficulties being experienced by the pesticide industry during registration.
3. Some repetition of information was experienced at the Workshop and there was therefore need for IPFT to better brief speakers.
4. Officials from the State Governments should be invited to the Workshop, particularly from the important pesticide consuming States as there are many differences between the policy and enforcement of the Insecticides Act between States and Central Government.
5. More discussion should be held at future Workshops, on the actual protocols in the various data packages which are required for registration.
6. More discussion at IPFT on methods of improving the quality of formulations would be useful at future Workshops.
7. Development of a time management strategy for dealing with applications for registration could be a useful subject to include in the future.

#### C. General

1. The whole industry is trade driven, it should not be, rather pesticides should be used to assist farmers attain maximum yields and not sold as a merchandising product. - to Industry for consideration
2. List of scientific institutions able to carry out efficacy trials to standards which will meet the requirements of the CIB should be made available to the industry. - to IPFT for consideration.
3. There is a need to train people in application technology. - for IPFT and others.
4. Need for companies to adhere in their recommendations to those uses which are cleared on the label and to follow good advertising practice. Suggest Industry could regulate itself with a Code of Ethics on advertising. - to Industry for consideration.

#### IV. CONCLUSION

The Workshop was considered a success and one which could be repeated in the future, as it 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:** 0.7 m/m
- Date Required:** October/November 1993
- 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 utilizing 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 organizing 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, harmonization 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 ON WORKSHOP ON PESTICIDE REGISTRATION AND REGULATIONS**

**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 1-5, 1993. Twenty three participants from the Indian pesticides industry attended, as shown in Annex 4. The programme consisted of a series of addresses and a visit to IPFT at Gurgaon. The programme is shown in Annex 3, the sessional chairman in Annex 5, the list of speakers in Annex 6 and the support staff and secretariat in Annex 7.
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

**TECHNICAL SESSIONS**

**Technical Session I**

4. The history of the development of IPFT were 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 (Regional Network on Pesticides for Asia and Pacific) member countries.
5. In an overview of the pesticide Industry in India Dr J.S. Verma, a long time industry member and now a private consultant said that the pesticide industry in India had grown up in somewhat of a topsy turvy manner. About 40 years ago, HCH and DDT were being manufactured in India with little interest from the Government of India (GOI). Over the years new pesticides were slowly introduced, and although the long term policy was that India should become self sufficient in pesticide production, this was slow during the early days. There has been a shortage on new molecules coming

into India, but with the move towards opening trade to imports this may well change. 1991 figures show consumption of insecticides accounted for 24,684 tons, fungicides 12,700 tons and fungicides 4,738 tons of the pesticides used. Of the insecticides the biggest was HCH (7,020 tons) followed by monocrotophos (3,226 tons) and endosulfan (3,039 tons). DDT which used to be widely used in agriculture is now allowed only for public health uses which are not included in the above figures. Sulphur (6936 tons) was the most widely used fungicide, while for herbicides, consumption of isoproturon and butachlor were both around 1,500 tons. Use of herbicides is quite small, only 10% of total value of pesticides, which is 15,000 million rupees (approx US \$500,000,000), at user level, with fungicides 10.5% and insecticides 78%. In India 40% of the total pesticide used is on cotton, a figure which tends to indicate excessive use on that crop.

6. 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.
  
7. 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), outlined the development of the Insecticides Act 1968. 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 in 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.

## Technical Session II

8. In his address Dr H.L. Bami, who had been associated with the Registration Committee of the CIB, for a long time, 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. The difference between risk and toxicity was explained. Pesticide use as measured by grams ai/ha is low in India, but pesticides will need to be used more widely to assist increased food production. Over the past few years consumption has been static, a fact that could in part be explained by the introduction of more active molecules which are used at low rates. Most of the references to pesticide problems in India relate to the earlier now prohibited use, of the older pesticides such as DDT and HCH. Two areas for improvement were highlighted

- 1) the need to educate users to use pesticides safely and,
- 2) the need for monitoring to be done at national level to check where abuse is made.

Dr Bami 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.

9. 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 registration authorities had found difficult 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 a period of "exclusive use of data" where a set period of time has been decided by the regulatory authority, during which the second registrant should supply the full information or have agreement from the first registrant to use his data. After that time a lesser amount of data can be supplied 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.

## Technical Session III

10. The Dunkel proposals were prepared to assist Nations in coming to an agreement to the Uruguay Round under GATT, which was due for completion by 31 December 1993. Mr B.K. Keayla dealt with points of concern to India and which could have quite high impact on the pesticides industry if the Round is accepted in its present form. It was stated that a country has the option to accept the final proposals in their entirety or not to accept any of them - it was not possible to accept with conditions. In agriculture the 3 concerns dealt with were

- 1) market access,
- 2) quantitative restrictions and
- 3) input subsidies.

It was established that countries still had the right to set their own sanitary and phytosanitary standards, but of concern was that these could conceivably be set at such a high level so as to preclude imports from third countries, and thus be an artificial trade barrier. Countries will need to review plant variety rights (as well as other patents) within 5 years after acceptance. A matter of concern to India is the situation with farmers saving their own seed for subsequent re-sowing. In addition there are also concerns about TRIMS (Trade Related Investment Matters) and changes proposed to the Service sector, with the required opening up to international financial institutions and insurance companies, with a limited possibility to impose conditions upon them locally. With regard to the present patent law in India, this is more related to the process, not the product and this law which is considered to be good for developing countries has encouraged local production of pesticides. Under the Dunkel text all technology is able to be patented which means that the Indian patent law would need to be changed to enable this to be done and to give the required years of protection. The problem for Indian innovators would be the cost of developing the technology and the need to patent that in other countries to protect their investment. India too would be required to give patent protection to International companies, and the overall result as seen by the speaker could become a monopolistic situation with increased costs, to India.

11. Dr Kawal Dhari, in discussing the subject of efficacy requirements for pesticide registration asked the question why is this required. In India, as in many other countries, it was considered essential for the registrant to supply data to show that the pesticide worked, when used according to label directions. Trials are normally required for 2 years in more than one climatic zone. There have been 15 agro-ecological zones established in the whole country. It was noted that label recommendations should be for individual crops and no crop grouping. Registrants, should initially obtain clearance for one crop then add crops one by one, rather than dilute efforts by applying for registration on several crops at once. The importance of following international test protocols was emphasised as results from tests developed by these methods would be transportable to other countries to a considerable degree, where similar crop/pest combinations were present. Dr Dhari mentioned efficacy trials work could be undertaken at the IPFT. With regard to residue requirements in India, there are virtually none at this time although a number of MRLs have been established.
12. In the case of fungicides, efficacy testing was also required and some of the measurements for these tests were outlined by Dr M.S. Chatrath who discussed some of the standard techniques developed for laboratory work, and in the case of soil fungi of different techniques to enable measurement of fungicide movement in the soil. He then covered greenhouse testing procedures and referred to the fact that the Indian Phytopathological Society was to publish some information on this. He dealt briefly with reporting procedures for the results from such tests. In the case of field tests, procedures were similar to those for insecticides except that the methods of evaluation was obviously different.



#### Technical Session IV

13. Dr N. Ramakrishnan said that the naturally occurring materials which he was covering should be known as biological pest control agents, not biocides as they were sometimes referred to, as the term biocides would include chemical pesticides. 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 was required for biological pesticides. The best known biological pest control agent was *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. In addition there was now considerable interest in the development of formulations of *Baculoviruses* which have been used to successfully control *Heliopsis*, *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. In India there had been serious concerns initially about the side effects of *Bacillus thuringiensis* on sericulture resulting in slow development but products containing *B.t.* are now registered and there is a considerable renewed interest in biological pest control agents.
14. 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 and has been called the "wonder tree of India". Dr N.R. Bhatishwar in presenting his address said that several formulations of neem are registered in India. 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. Some of the disadvantages with neem are it is
- 1) slow in action,
  - 2) there is a variability in the quality of the neem seeds,
  - 3) there is a seasonality in seed production and,
  - 4) methods of analysis of the active ingredient can be difficult.
- Adequate quality control procedures are essential during commercial production. There is considered to be a good future for neem based botanical pesticides. In addition extracts from other plants which are not attacked by pests are being studied at IPFT to see if they can be developed into botanical agents. Dr Bhatishwar emphasised that botanical pesticides should prove really effective in developing integrated pest management programmes. Botanical pesticides possess a number of advantages over chemical pesticides such as
- 1) no development of resistance,
  - 2) no residue problems, and,
  - 3) no known environmental hazards.

## Technical Session V

15. Dr R.C. Gupta who, until his retirement was a member of the Registration Committee outlined the requirements for the chemical and physical properties to be submitted for registration, stating that they were in general the same or very similar to those suggested by FAO. There should be minimal variations between national and international requirements as chemical and physical properties were the most transportable of all the registration packages. Attention was drawn to increasing difficulties in obtaining standards for the chemical itself and its impurities which were of concern. The desirability of maintaining the requirement for accelerated storage tests at  $54^{\circ} \pm 2^{\circ} \text{C}$  for 14 days rather than reduce the period of the test was stressed, as clear parameters for setting the shelf life had been established on the 14 day period.
16. In establishing the expiry date requirements for pesticides, four categories of pesticides had been determined, and in the absence of data to the contrary the CIB required manufacturing and minimum expiry dates 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. Glass is not allowed because of its fragility. In the case of processing, guidelines have been prepared and are available to applications for registration.
17. The differences between confidentiality and the protection of proprietary rights to 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.
18. 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

19. Dr (Ms) S. Kulshrestha, in introducing her talk 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 which are freely available were outlined in tabular form. 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.
20. The symptoms of, and treatment for poisoning 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 it should be followed at all times. 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 must be used carefully and responsibly at all times, a seemingly almost impossible goal to reach.
21. 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. Dr J. C. Majumdar, who was present by special invitation to give his views on the subject of mixtures, 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.

### Technical Session VII

22. Although there had been many developments in the types of pesticides available over the years, not much change had taken place with application methods and techniques. Dr Y.P. Ramdev identified three factors on which successful application depended as
  - 1) quality of equipment,
  - 2) correct timing of application, and
  - 3) the accuracy of the spray.He pointed out that studies had shown that in the case of insecticides applied by a knapsack sprayer, only 1% of the spray actually hit the target. In the case of herbicides the figure was around 30%. The importance of droplet size, and target type was explained as well as the effect of temperature, humidity and wind on droplet size. There is a considerable variation in droplet size from knapsacks, with varying sized

droplets having different characteristics. A practical problem is that most knapsack sprayers do not have pressure gauges. Dr Ramdev outlined some of the newer systems at present available and to be tested at IPFT including controlled solution applicators, air assisted sprayers, weed wipers and controlled oil droplet applicators.

23. The history of pesticide use in India was outlined by Dr S.N. Deshmukh. In 1951 all pesticides were imported whereas now India produces 95% of its pesticide requirements. There is high production capacity in India with perhaps only half of which is utilised. Of the 180 pesticide active ingredients registered, only 70 or so are actively used. For the year ending March 1993, import of pesticides was worth 750 million rupees or (approx US \$25 million), whilst export was worth about 1000 million rupees (approx US \$33.3 million). The registration requirements for the various categories of pesticides were outlined.
24. Dr Kailash C. Gautam put the losses to Indian agriculture due to weeds, pests and diseases at 600 million rupees (approx US \$20 million), of which he estimated 33% was due to weeds, yet herbicides are not widely used, as in the past hand weeding was quite inexpensive. Labour is more costly today, but also important is the fact that by the time hand weeding is done much of the crop yield loss will have been determined due to competition by the weed seedlings for moisture, reduced germination and interplant competition. With higher fertiliser and water inputs needed for the higher yielding varieties, the conditions for weed growth are also improved. There was a need to have herbicides which were effective on the major weeds of the major crops, did not harm the crop, and would not have carry over effects to following crops in a rotation. Until farmers become more aware how to use more selective, weed and crop specific materials this was the favoured approach. Trials on some of the newer materials and also mixtures were being undertaken.

#### **Technical Session VIII**

25. 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, in the Department of Agriculture and Cooperation of the Ministry of Agriculture. With an increased export potential PIC is expected to become more applicable to the Indian pesticide industry in the future.
26. Mr E.N. Sunder, who, until his retirement had long experience with the Bureau of Indian Standards (BIS), explained how the original standards, initially DDT and then HCH 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.

27. Harmonisation of pesticide registration requirements in Asia and the Pacific was discussed by Mr Watts, who outlined the concept behind harmonisation of pesticide registration requirements. When generating data it was always desirable to do this using methods, the results of which are 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 final decisions on export are taken, the registration requirements should be ascertained from the regulatory authority in the country to which export is intended so the data needs are well known.
28. 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.**

29. A visit was made to IPFT at Gurgaon on the afternoon of November 4. An overview of the work of the Institute was given after which 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**

30. Recommendations were put forward for future workshops, for transmission to the relevant officials in the GOI, and of a general nature.

##### **(a) For Future Workshops**

1. Future Workshops could be reduced to 3 day by circulating lecture material before hand so the presenter needs only to present a short (15 minute) summary of the paper.
2. It would be useful to invite experts to answer some practical questions in response to the difficulties being experienced by industry during registration.
3. Some repetition of information was experienced and there was therefore need for IPFT to better brief speakers.
4. Officials from the State Governments should be invited to the Workshop, particularly the important pesticide consuming States as there are many differences in policy and working of the Insecticides Act between States and Central Government.

5. More discussion should be held at future Workshops, on the actual protocols in the various data packages required for registration.
6. More discussion at IPFT on methods of improving the quality of formulations would be useful at future Workshops.
7. Development of a time management strategy for dealing with applications for registration could be a useful subject to include in the future.

**(b) Regulatory Authority**

1. A firm policy on the registration requirements for mixtures needs to be established.
2. As implementation of the Act is weak, there should be more positive action by States and Union Territories.
3. There is a problem with the results of analysis for pesticide quality done by the States as, 90% of the samples rejected by the State laboratories are cleared when re-analysed by the Central Insecticides Laboratory.
4. There needs to be a better understanding by some States who should only act within the powers given to them under the Insecticides Act, and not require a type of second clearance.
5. Concern was expressed on the quality of pesticides, due to the large number of 9(4) registrations given. 9(4) should be given only after the sample is cleared and inspection of the proposed premises undertaken. Follow up inspections should be undertaken and registration revoked if adequate quality control programmes are not being met. Manufacturers license also needs to be strengthened.
6. The application for registration fee should be increased from the present 100 Rs to discourage the widespread 9(4) registrations.
7. Sampling for product quality should be done at source, ie at the plant, to save costs and as a way of ensuring that regular sampling and analyses are undertaken.
8. Steps should be taken to reduce pesticide use on cotton with a coordinated policy being established at national level and implemented by States. It was recognised that some States are addressing the problem through their Cotton Divisions in the Department of Agriculture.
9. On going difficulties to get users to use pesticide safely and properly, thus there is a need to increase and strengthen the advice given on safe and effective use of pesticides by extension systems.

**(c) General**

1. The whole industry is trade driven, it should not be, rather pesticides should be used to assist farmers attain maximum yields and not sold as a merchandising product.
2. List of scientific institutions able to carry out efficacy trials to standards which will meet the requirements of the CIB should be made available to the industry.
3. There is a need to train people in application technology.
4. Need for companies to adhere in their recommendations to those uses which are cleared on the label and to follow good advertising practice. Suggest Industry could regulate itself with a Code of Ethics on advertising.

**VALEDICTORY SESSION**

31. Dr Kawal Dhari, welcomed the Joint Secretary of the Ministry of Chemicals and Fertilizers, Mr Vinay Kohli, and Deputy Secretary Mr K Gurtu, to the Workshop. He 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.
32. 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 made.
33. Before presenting the Certificates to the participants, Mr Vinay Kohli said in his valedictory address that there was a need to use pesticides carefully and to 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 copy of the Joint Secretary's address is given as Annex 8.
34. Dr T.P.S. Teotia, 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.**

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



**WORKSHOP ON  
PESTICIDE REGISTRATION AND REGULATIONS**

**November 1-5, 1993  
PROGRAMME**

**Monday, November 1.**

**0900 Registration**

**Technical Session I**

**Chairman: Mr. Brian B. Watts, UNIDO Consultant**

**0930 Welcome and Introduction of Programme**

*Dr. Kawal Dhari*

**1015 The Pesticide Industry in India - an overview**

*Dr. J. S. Verma*

**1100 Tea/coffee**

**1120 The FAO International Code of Conduct on the Distribution and Use of Pesticides**

*Mr. Brian B. Watts*

**1210 Pesticide Registration Policies in India**

*Dr. M. L. Saini*

**1300 Lunch**

**Technical Session II**

**Chairman: Er. V. C. Bhargava**

**1400 Environmental Issues arising from Pesticide Use**

*Dr. H. L. Bami*

**1530 Tea/coffee**

**1550 "Me-Too" Registrations**

*Mr. Brian B. Watts*

**1700 Close**

**Tuesday, November 2.**

**Technical Session III**

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

**0930 Pesticide Industry, Impact of Global Patent Regime Proposed in the Dunkel Report**

*Mr. B. K. Keayla*

**1100 Tea/coffee**

**1120 Bioefficacy and Residue Data Requirements for Registration of Insecticides**

*Dr. Kawal Dhari*

**12.10 Bioefficacy and Residue Data Requirements for Registration of Fungicides**

*Dr. M. S. Chatrath*

**1300 Lunch**

**Technical Session IV**

**Chairman: Dr. V. Ragunathan**

- 1400 Bioefficacy and Residue Data Requirements for Registration of Biological Pest Control Agents  
*Dr. N. Ramakrishnan*
- 1445 Requirements for Registration of Botanical Pesticides and Data Requirements in India.  
*Dr. N. R. Bhatেশwar*
- 1530 Tea/coffee
- 1550 Open discussion and film on pesticide safety
- 1700 Close

**Wednesday, November 3.**

**Technical Session V**

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

- 0930 Chemical Data Requirements for Registration of Pesticides  
*Dr. R. C. Gupta*
- 1015 Processing, Packaging and Shelf Life Requirements of Pesticides for Registration  
*Er. V. C. Bhargava*
- 1100 Tea/coffee
- 1120 Protection of Proprietary Rights and Confidentiality of Data  
*Mr. Brian B. Watts*
- 1205 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. (Ms) S. Kulshrestha*
- 1445 Pesticides Safety : Toxicity, Poisoning, First Aid Treatment, Labels and Leaflets  
*Dr. V. L. Patil*
- 1530 Tea/coffee
- 1550 Mixed Formulations in Asia and the Pacific  
*Mr. Brian B. Watts*
- 1700 Close

**Thursday, November 4.**

**Technical Session VII**

**Chairman: *Dr. V. Ragunathan***

- 0930 Pesticide Application Techniques  
*Dr. Y. P. Ramdev*
- 1050 Tea/coffee
- 1110 Data Requirements for Import and export of Pesticides in India  
*Dr. S. N. Deshmukh*
- 1210 Evaluation of the Bioefficacy of Herbicides and their Mixtures  
*Dr. Kailash Gautam*
- 1300 Lunch
- 1400 Visit to the Institute of Pesticide Formulation Technology, Gurgaon

**Friday, November 5**

**Technical Session VIII**

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

- 0930 Prior Informed Consent  
*Mr. Brian B. Watts*
- 1015 Indian Standards on Pest Control Products including Application Equipment and Residue Analysis  
*Mr. E. N. Sunder*
- 1100 Tea/coffee
- 1120 Harmonisation of Pesticide Residue Requirements in Asia and the Pacific  
*Mr. Brian B. Watts*
- 1215 The FAO Series of Guidelines  
*Mr. Brian B. Watts*
- 1300 Lunch

**Penultimate Session**

**Chairman: *Dr. Kawal Dhari***

- 1400 Evaluation of Workshop and Discussion on Recommendations

**Valedictory Session**

- 1530 Valedictory Function  
Distribution of Certificates

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**Penultimate and Valedictory Session**

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Dr. P.K. Ramadas,  
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Mr. T.R. Sarin,  
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Mr. D. Khemani,  
Finance Officer,  
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**SECRETARIAT**

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Chief, Biosciences Division,  
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Mr. S.P. Yadav,  
Junior Entomologist, Biosciences Division,  
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Dr. Y.P. Ramdev,  
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Mr. J.P. Degra,  
Field Supervisor, Biosciences Division,  
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Mr. Y. Singh,  
J.S.A., Biosciences Division,  
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Mr. B.C. Mandal,  
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**VALEDICTORY ADDRESS**

**VINAK KOHLI**  
**National Project Director and**  
**Joint Secretary (Chemicals)**  
**Department of Chemicals & Petrochemicals,**  
**MINISTRY OF CHEMICALS AND FERTILIZERS,**  
**GOVERNMENT OF INDIA**

**on the concluding day of Workshop on**  
**Pesticide Registration and Regulations, November. 1 - 5, 1993,**  
**at International Youth Centre, New Delhi.**

1. In a highly inter-related, inter-dependent world of modern technology and trade, the challenge of protecting crops, livestock and human health without hazard to people, animals or their environment requires the combined and sustained efforts of scientists, technicians, administrators, producers, processors, distributors, pesticide industry and of nations working together to establish and administer sound, acceptable standards of food safety and environmental quality. We need pesticides, but reckless and careless use either agricultural or industrial is to be stopped through proper legislation and efficient regulations.
2. The wholesomeness of any food supply depends on the quality of the total environment; the soil, water, and air in which food is grown, processed and consumed. Acute contamination of these basic natural resources by pesticide residues can affect, not only the safety of food products, but also other environmental values such as water supplies, wildlife preservation, and outdoor recreation. In order to give effect to laws and policies it is necessary to develop criteria and protocols that are effective and workable. It should be the objective to achieve goals with minimum dislocation of production and trade, but under no circumstances should adverse affects on people or the environment be countenanced to serve economic goals.
3. Increasing complexity, potency and applications of pesticides has developed an increasing but understandable concern about the safety of these chemicals to users, livestock, wildlife, the environment, and especially to consumers of food produced with their assistance. This public concern has made it necessary for the Indian government to review the standards and procedures for evaluation and acceptance for pesticides. Pesticide registration under increasing environmental concerns is to become stringent, diverse and more responsible, in the future.
4. The term "registration" used for pesticides should not be compared with the registration of a motor vehicle or a trade mark. In each of these cases the procedure simply involves the recording in a register of a few salient details which establish ownership, evidence of which is then provided by a document for which the registrant pays a designated fee. Such an operation entails the minimum of time, expense or documentation. In the case of pesticides, registration follows the evaluation and acceptance by a Statutory Authority of extensive documented proof submitted in support of all claims for efficacy and safety made for the proposed product.

Registration implies a number of different controls among which evaluation is the most important. For a pesticide to be adequately assessed for registration purposes extensive scientific information is to be developed by the manufacturer on many aspects of the product, particularly its properties and performance. The purpose of registration is to ensure that pesticides, when used according to registered label directions, will be effective and efficient for the purposes claimed, and safe. Misused, pesticides can certainly be harmful. Properly handled, they form an essential tool in the production of food, fibre and to protect human health from vector borne diseases.

5. We are in the process of working out more regulatory procedures to control trade practices and the production and use of pesticides and trying to enforce it in our country as soon as possible. This is the reason now that some pesticides have been put on restricted use. The elaborate regulatory procedures are strengthened by a comprehensive enforcement system. Such a system and the regulatory procedures, designed to enforce, make demands on available resources which developing countries will often find difficult to meet.
6. We should design regulatory procedures suited to our specific needs, and not attempt to adopt all the elements of regulatory schemes used in developed countries. The standards for acceptance of a pesticide in one country, such as an industrial food-exporting country with a temperate climate, an abundance of fertile land available and advanced agricultural technology, would not necessarily be applied in another country with different agricultural practices, a different climate or economy.

I feel, the use of a pesticide should be permitted only if the benefits outweigh the risks involved. The balance between risk and benefit will differ greatly under different socioeconomic conditions and it is important to study our own priorities when deciding which pesticides may be used. It should not be influenced too much by decisions made elsewhere.

7. I am pleased to learn that you had a very fruitful discussion during these five days and your recommendations are worth consideration. We will try to implement these recommendations through appropriate registration and regulatory authorities of pesticides in our country.

## VOTE OF THANKS

**Dr N.R. Bhatshwar**

Respected Mr. Vinay Kohli, Mr. Brian B.Watts, Dr. Kawal Dhari, dear participants of the Workshop, my colleagues and friends, it is my great privilege to propose a vote of thanks.

Dear Mr. Kohli, I on behalf of the National Project Coordinator, 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 first 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. As per the Project objectives and commitments, we have been receiving consultants and experts in different fields. But this time we have not only received a consultant but also an adviser, an organiser and a very sincere knowledgeable faculty member who has delivered as many as 8 useful lectures on different aspects of pesticide registration and regulation. We are sincerely grateful to Mr. Brian B.Watts for his untiring efforts and contributions.

Our faculty and Chairmen of 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 National Project Coordinator and my colleagues who have worked day and night to make this Workshop a great success. My heartfelt thanks to 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,

Thank you.

UNIDO Comments

The report of the consultant gives a summary of the workshop on Pesticide Registration and Regulations. The topic is of great relevance to India with the opening up of the market for introducing new and more active compounds. This would mean that Indian industry and regulatory mechanism should tune in to international understandings and norms in registration of pesticides. This is clearly reflected in the response from senior representative of industries and regulatory departments who attended to attend the meeting. Such a workshop will give greater credibility to IPFT and also provide a focal point to industry for consultation regarding introduction of new products and formulations.