OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

RESTRICTED

DP/ID/SER.A/637
30 September 1985
ENGLISH

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

DP/RAS/82/006

Technical report: The Pesticide Registration Scheme in Sri Lanka*

Prepared for the Government of the Philippines
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 pesticides

United Nations Industrial Development Organization
Vienna

*This document has been reproduced without formal editing.

V.85-31472

ABSTRACT

The Consultant visited Sri Lanka from 17-31 May 1985 to review and evaluate the implementation of the registration process being developed under the Control of Pesticides Act, No. 33 of 1980. A number of field visits were made to areas where pesticides are widely used, visiting Department of Agriculture staff and growers. A meeting was also held with the Pesticide Association of Sri Lanka.

Those persons visited appeared to have a good knowledge of the requirements of the Pesticides Act.

A number of problems were identified, and suggestions are made for solutions. Generally however the Consultant is of the view that excellent progress has been made in the implementation of the pesticide registration scheme, during the two years since the Consultant last visited Sri Lanka. The requirements for data for registration are in general accord with the proposals agreed by the Regional Conference at Baguio City, the Philippines in October 1983, although not as extensive.

Some decisions need to be made on the extent of formulation and residue analyses which Sri Lanka should become engaged in.

TABLE OF CONTENTS

	PAGE
INTRODUCTION	1
ACKNOWLEDGEMENTS	1
1. SUGGESTIONS AND RECOMMENDATIONS	2
2. THE PESTICIDE REGISTRATION SCHEME	4
2.1 Commencement	4
2.2 Actions Taken	4
2.3 Publicity and Training	5
2.4 Authorised Officers	5
2.5 Period of Grace	6
2.6 Regulations	6
2.7 Records	6
3. REGISTRATION	7
3.1 Data Requirements	7
3.2 Action on Data	9
3.3 Phased Registration	10
3.4 Availability of Pesticides	10
3.5 Labelling	11
3.6 Packaging and Storage	11
3.7 Disposal	11
4. PROBLEMS AND POSSIBLE SOLUTIONS	12
4.1 Amendments to the Control of Pesticides Act	12
4.2 Prosecution v Education	16
4.3 Appointment of Staff	16
4.4 Toxicological Evaluations	17
4.5 Library for Registration Office	17
4.6 Distributor Training and Reseller Responsibility	18
4.7 Poisoning with Pesticides	18
4.8 Exemption from Registration	19
5. RESIDUE AND FORMULATION ANALYSIS	19
5.1 Residue Analysis	19
5.2 Formulation Analysis	20
5.3 Facilities Necessary	20
5.4 Laboratory Work Some Options	21
5.5 Which Laboratory To Equip	22

PAGE

ANNEX I	- List of Persons and Organisations Visited	23
ANNEX II	- Control of Pesticides Act, No. 33 of 1980	
ANNEX III	- Gazette Notice 263/17 - Fees	
ANNEX IV	- Licence/Provisional Permit Form	
ANNEX V	- List of Products Registered 1984/5	
ANNEX VI	- Instructions to Authorised Officers	
ANNEX VII	- Gazette Notice 347/7	
ANNEX VIII	- Card Index - Records	
ANNEX IX	- Application for Registration of a Pesticide	
ANNEX X	- Application for Import of a Pesticide	
ANNEX XI	- Model Labels for Pesticides	
ANNEX XII	- Notification of Pesticidal Poisoning	

NOTE: Annex II to XII are not included in this report and can be obtained from the Government of Sri Lanka.

INTRODUCTION

Mr Brian B. Watts of the New Zealand Ministry of Agriculture and Fisheries and Registrar of the New Zealand Pesticides Board visited Sri Lanka from 17-31 May 1985 as a UNIDO Consultant. His terms of reference were to :

1. Evaluate the progress in the registration system.

2. Review all guidelines on data requirements in the light of agreements on harmonisation.

3. Assess any problems encountered in registration and recommend solutions.

4. Review residue monitoring and quality control programmes.

ACKNOWLEDGEMENTS

Special thanks are due to Dr B.A. Baptist the Registrar of Pesticides who developed a programme for a Consultants visit and who gave a Consultant much information on the pesticides registration scheme. Thanks are also due to the many people visited, as shown in Annex I to the report, for their helpful assistance given to the Consultant.

1. SUGGESTIONS AND RECOMMENDATIONS

Although a number of suggestions and recommendation appear throughout the Report, they are summarised here for ease of reference.

1.1 The period of grace to use pesticides which could be legally sold prior to the coming into operation of the Control of Pesticides Act, No. 33 of 1980 should be fairly lenient. (para 2.5).

1.2 Some attention need to be given by the Registration Office to upgrade record keeping (para 2.7).

1.3 It is suggested that the requirement that all pesticides be labelled "Poison" be reviewed particularly for those formulations in WHO Class III (para 3.2).

1.4 It is recommended that final labels be sent to the Registrar for acceptance and that after acceptance no old labels be used on products being packed for sale (para 3.2).

1.5 Consideration could be given to combining a permit to import with a trials clearance (para 3.3).

1.6 Further emphasis need be given, particularly to resellers at village level on the need for safe storage and, distributors should be more involved than they appear to be at the moment (para. 3.6).

1.7 Continued publicity need to be given on the need to destroy empty containers (para 3.7)

1.8 Urgency should be given to amendments to the Control of Pesticides Act, No. 33 of 1980 (para 4.1)

1.9 Four further amendments have been identified (para 4.1)

1.9.1 - concentration of solids to be expressed as g/kg.

1.9.2 - remove requirements to list inerts for solid formulations.

1.9.3 - remove requirement for size of lettering for common name.

1.9.4 - query need to publish in the gazette.

1.10 An Assistant Registrar should be appointed as quickly as possible. It is also suggested that the Registrar be appointed under contract for a further 3 years (para. 4.3).

1.11 An endeavour should be made to have someone with a medical/toxicological background review the toxicological data submitted with applications for registration (para 4.4).

1.12 Suggestions are made for some reference books for the Registration Office (para 4.5).

1.13 Industry and Government should co-operate in distributor /reseller training, with Industry taking the lead role (para 4.6).

1.14 All avenues be explored to obtain accurate poisoning records to enable a measurement to be made of the results of publicity on safe use (para 4.7).

1.15 Decisions need to be taken on those types of pesticides which should be exempted from the requirements of registration (para 4.8).

1.16 A suggestion is made that a Consultant with experience in residue analysis should visit Sri Lanka, if it is decided to develop a local analytical capability (para 5.3).

2. THE PESTICIDE REGISTRATION SCHEME

2.1 Commencement

The Control of Pesticides Act, No. 33, of 1980 although passed in 1980 did not come into operation until early 1984. The Consultant visited Sri Lanka in May 1983 and offered suggestions as to how the registration scheme could be implemented. At that time it was suggested that marketers should be advised, and advertisements should be placed in the paper, to the effect that after a certain date all pesticides sold must be registered pursuant to the Act. This action was taken in 1983 when people were advised that no pesticide should be distributed or sold after 29 February 1984 unless such pesticide had been duly registered under the control of Pesticides Act No. 33 of 1980 by the Registrar of Pesticides. The Act is attached as Annex II.

Companies responded by providing the Registrar with the information requested modifying somewhat the forms proposed in the report prepared by the Consultant following the 1983 visit. Fees for registration were set by Regulation 263/77 of 22 September 1983 (Annex III).

2.2 Actions Taken

2.2.1 Clearance

The Registrar has issued licences for a number of products, while provisional permits have also been issued.

Licences have been granted for products for which it is believed there are no problems whereas provisional permits have been issued where, for example, there may be concerns about the hazard of the product e.g. all WHO Class IB formulations have a provisional permit only. The licence/provisional permit form is shown as Annex IV. Where they may be other possible problems such as the possibility of a resurgence of mites following use of the synthetic pyrethoids e.g. permethrin and deltamethrin, provisional permits only have been issued. Other materials about which some questions are still not answered, for example, captan may be held at the provisional permit level. All provisional permits expire at the end of 1985 at which time either upgrading to a licence, cancelling registration or extending the provisional permit would need to be considered. It is proposed that this review will commence shortly, it having already been made clear to the industry that if there is a recommendation by the Department of Agriculture to use a product which is perhaps still under a provisional permit at that time, that favourable consideration to an extension of the permit may be considered.

A list of those products registered is shown in Annex V - those marked with an 'L' being those which have been issued with a licence and those marked with a 'PP' are those with a provisional permit. Where there is a blank a decision is pending.

2.2.2 Restriction on Availability

During 1984 the importation of parathion was stopped with the intention of completely banning the use of this compound. Parathion was widely used throughout Sri Lanka in 1983 when the Consultant last visited the country, as it was cheap and had a wide spectrum of control. Although accurate records are lacking it seemed at that time, as if parathion was the main material involved in suicide cases where pesticide was the causal agent. The Pesticides Formulary Committee which is set up under the control of the Pesticides Act has also decided that formulations which are classified in WHO Class I (either IA or IB) shall not be sold in any container smaller than 200 ml.

2.3 Publicity and Training

A considerable amount of training on the requirements of the Act has been given to Subject Matter Officers (Plant Protection) and other extension workers of the Department of Agriculture. The Registrar and staff have been involved in training sessions as well as the Plant Protection Service of the Extension Division of the Department of Agriculture. This instruction has been largely given at the In-Service Training Centres operated by the Department. Industry too, has been kept fully informed of the requirements of the Act with a number of meetings being held between industry members and the Registrar. It seemed, in the view of the Consultant that there was a good awareness of the fact that the Act was now in operation particularly on the part of industry and officials of the Department, the major distributors and some users.

2.4 Authorised Officers

The Act provides that the Director of Agriculture shall nominate such number of officers of his department as may be necessary to carry out the purposes of the Act, who shall be known as authorised officers, the powers of which are set out (see Section 21 of the Act). The occupational group known as Agricultural Officers (Head quarters), (AO(HQ)), have been appointed as authorised officers. AO(HQ) are experienced advisory officers attached to the headquarters of each of the 25 districts. These people have been given information on the safe use of pesticides and information on their

duties (see Annex VI). Many, if not all, of this group have taken part in training sessions on the Act.

2.5 Period of Grace

Obviously it is desirable to use the old pesticides even those which were not previously registered, on farm land rather than prohibit their use and be faced with a stock disposal problem. Every effort should therefore be made to use these materials, assuming the products are still in a state suitable for use rather, than for the product to remain in store and subsequent disposal. A concerted effort should be made to clear all old stocks out from distributors/resellers shelves as quickly as possible in order to avoid a disposal problem at a later date. The Consultant recommends that a fairly lenient period of grace be given to enable this to be done and that Authorised Officers should be advised accordingly. It is counterproductive for growers who have previously purchased an unregistered pesticide and which is still suitable for use to be told they cannot use the material.

2.6 Regulations

In addition to the regulation on fees (Annex III) a second set of regulations (Annex VII) has just been promulgated. These provide for information on the shelf life or expiry date, the batch number and the date of the formulation of the pesticide to be stamped on the label. Also the minimum type size, other than the common names of the active ingredients, has been set to be characters not smaller in size than 6 point. Provision is also made to classify a pesticide as 'Restricted', such word to appear on the label and a brief reason for such classification is also to appear. Sales of restricted pesticides shall be made only to a dealer who is so authorised by the Authorised Officer and the dealer shall keep a list of pesticides sold together with the names and addresses of the purchasers.

2.7 Records

Records of the registration/clearance status are being kept on a card index system (Annex VIII), where certain information relating to the trade name of the product, the common name, the importing agency, the type and concentration of the formulation, references and the clearance status is recorded. This enables a quick referral to be made of the trade name of the products in the system but there is room for a cross reference by common name and by company. Of use in the future may be a reference system to crops and pests. It is important that a good, accurate system of records should be maintained as this is essential to any registration scheme. There is some room for improvement in this regard.

3. REGISTRATION

3.1 Data Requirements

The industry has been made aware of what information is required to be submitted with an application for registration of a pesticide. Formal guidelines as such have not been prepared but the essential information required is detailed on the application for registration form (Annex IX).

This follows, in broad terms the basic requirements as detailed in the Report of the Regional Consultation on Harmonisation of Pesticide Registration Requirements held at Baguio City, the Philippines, October 1983. In addition there is a proposal that the Control of Pesticides Act No 33 of 1980 should be amended to spell out, amongst other things, the data requirements for registration in more detail.

In summary the data requirements for registration presently required are:

3.1.1 Chemical and Physical Properties

(a) Name and address of the manufacturer of the active ingredient.

Name and address of the applicant.

Name and address of the formulator.

(b) Trade name of the pesticide.

(c) Common name of the active ingredient.

(d) Type of formulation.

(e) Specific detailed composition of the formulated product.

(f) Shelf life of the formulated product.

(g) Method of analysis of the product.

(h) Summary of the chemical and physical properties for both the active ingredient and technical material indicating the page number of the data brochure for details and in particular:

(i) Melting/boiling point of pure active ingredient.

(ii) Melting/boiling point of the technical material.

(i) Nature and percentage of isomers or other impurities in the technical material:

(i) Purity of the technical material.

(ii) Specify the impurities/isomers present with their percentages.

3.1.2 Efficacy and Crop Safety

A summary of efficacy data giving reference to the data submitted including a listing of specific pest control studies is required. There are no set test protocols laid down for efficacy testing and in this regard the protocols being developed by FAO/EPPO for tropical crops will serve a useful purpose. Efficacy trials are carried out by Government or semi-Government institutions, not by industry, although industry may lay down demonstration trials at a later stage in local demonstrations of uses for the pesticide.

3.1.3 Toxicology

A summary of the toxicological data including LD50 oral and dermal values, carcinogenic and mutagenic effects are required indicating the page number of the data brochure for reference to details and in particular:

(a) The LD50 of the active ingredient.

(b) The LD50 of the formulation.

3.1.4 Residues

A summary of the residue data and method of residue analysis with reference to the page of the brochure on which the data are shown is required.

3.1.5 Environmental Impact

A summary of the data on the effects of the pesticide on the environment and wildlife is required.

3.1.6 Other Information

Applicants are required to enclose specimen labels or typed copies of the labels in duplicate as well as specimen containers. They are also required to provide a data brochure which gives information as required by Section 6 of the Act. The application fee must also be supplied.

3.2 Action on the Data

On receipt at the office the registration office staff carry out a check to see if all the data are supplied. The efficacy data will be referred to the appropriate expert within Government for his assessment. He may also be asked to comment on the environmental data.

Toxicological data are presently evaluated by the Registrar who takes into account actions reported in the publication "Consolidated Lists of Products Whose Consumption and/or Sale have been Withdrawn, Severely Restricted or Not Approved by Governments". This document is produced by the UN Secretariat in accordance with the General Assembly resolution 37/137. There appears to be no person or group willing or able to evaluate toxicological data in Sri Lanka but if in doubt the Registrar may refer the question to an international or regional authority such as WHO. The Department of Health have virtually no input into the registration process except for a seat on the Pesticide Formulary Committee. They are also the host organisation for the Household Formulary Committee and the Medical Formulary Committee to which applications for pesticides for use in household and in public health work are referred.

The WHO Hazard Classification is followed in as much as all Class I formulations have a skull and crossbones on the label. If however the company elects to put the skull and crossbones on the label of other products this is acceptable. Alternatively the St Andrews Cross may be used on Class II products. All pesticides have to carry the word "Poison". Whilst recognising the desire of the Pesticides Formulary Committee to instil in the minds of the user that all pesticides should be handled carefully the Consultant wonders whether some emphasis should be placed on the degree of hazard and the user be encouraged to treat Class I pesticides in a more careful manner than he would, for example, Class III materials. Over emphasis of the hazard of a product with a relatively low hazard may be counter productive.

The specimen label submitted with the application for registration is studied. The company is advised of the outcome of their application together with any changes required on the label. The company is not asked to send a copy of the final label to the Registrar and thus it is not known for certain whether the required changes have been made. It is recommended that it be made a requirement that two copies of the final label be submitted to the Registrar for checking of the required amendments and if these have been made to his satisfaction a signed copy of the accepted label be sent to the applicant. An additional requirement to be conveyed to the applicant should be that no further packing of pro-

duct for sale should be done unless the approved label is used.

3.3 Phased Registration

There is provision in the Act for two types of clearance:

(a) Register the pesticide and issue a licence.

(b) Register the pesticide and, pending the issue of a licence, issue a provisional permit for limited marketing and use of the pesticide in accordance with the conditions stipulated in the permit.

It is under this section of the Act that the Registrar has acted so far with those products already on the market when the Act came into operation (see para 2.2.1) Applications for registration for pesticides, new to the market, have been made and will also be finally dealt with by either one of the above two actions or by rejecting which is a further option the application in which ease it is necessary to state the reasons for the rejection.

When industry wishes to evaluate a new pesticide in Sri Lanka the applicant must apply to the Registrar for a permit to import, as import is not allowed except with the written approval of the Registrar. A company makes an application on the appropriate form (Annex X).

On receipt of the application the Registrar refers the request to the appropriate Government or Semi-Government research worker and if it is agreed to include the material in the trials programme it will be recommended that the permit be granted. The applicant will be advised of this by the Registrar who will also advise the Controller of Imports. Following acceptable trials the applicant may then apply for registration and either the product could be given a provisional permit or issued with a licence. Following that action the Controller of Imports is notified.

The initial approval to import is a type of trials clearance. It may be desirable to consider changing the procedure to have two types of provisional permits - one for limited sale and, one for trials clearance (not for sale).

3.4 Availability of Pesticides

The importation of parathion has been stopped and the use of this material will be prohibited. Formulations in Class IB are still available but none in category IA. No formulations in Class I (i.e. Class IA and IB) have

been issued with a licence, they have provisional permits only at this stage. Although it has as yet not been finalised it seems that formulations which fall into Class I could be classified as "Restricted" and thus be available to authorised dealers only (see para 2.6). Although, the least hazardous pesticides would be recommended in preference by the Department of Agriculture registration will be granted for the more hazardous ones if their use is necessary to control the pest in question, but, if they fall into WHO Class I it seems that they may be placed into the Restricted category.

There is no specially trained group of applicators in Sri Lanka and thus there is not the possibility of restricting the availability of the more hazardous materials by limiting them to use by trained personnel. Therefore sale by authorised dealers is the only method open to limit the availability of the more hazardous materials except to not agree to registration.

3.5 Labelling

Some labelling guidelines have been issued by the Registrar (Annex XI) which follow in general terms the principles enumerated at the Regional Conference on Harmonisation of Pesticide Registration Requirements. A difficulty exists in getting the required information on the label in three languages as is required under the Act but proposals are in hand to modify this requirement (see para 4.1) and this proposal, if implemented, together with placing a lower limit on the bottle size could largely overcome this difficulty.

3.6 Packaging and Storage

The Registrar is required under the Control of Pesticides Act to approve the type of container to be used. With regard to storage whilst some training is being given to stockists and to Government officials on safe storage practice it seems from discussions that there is considerable room for improvement particularly amongst those stockists at village reseller level. Some added emphasis need be given to this, probably through main distributors who should accept great responsibility for giving advice on safe storage practices to the resellers they supply.

3.7 Disposal

Again a major training effort needs to be continued on the disposal of pesticide containers as empty bottles are quite often a much sought after commodity for subsequent use for a wide range of materials including, it is understood, even medicines. Users must be made aware

of the need to destroy empty containers which previously had pesticides, advice which must be continually emphasised. On-farm disposal of surplus pesticide is a more difficult problem, the best solution to which is to use the pesticide in the recommended manner on the land. Disposal of surplus unwanted stocks of concentrated material which may be held in the trade can be effected by either reformulating or by incineration. In discussions with industry on these aspects it was made clear that there is in an incinerator owned by one of the major companies which is suitable for incineration of concentrates and which may be available for use on a contract basis.

4. PROBLEMS AND POSSIBLE SOLUTIONS

4.1 Amendments to the Control of Pesticides Act

A number of changes are proposed to this Act. These will be of benefit to the operation of the registration scheme and every effort should be pursued to have these brought into operation as quickly as possible as they will assist the Registrar in the registration process. A brief outline of these changes follows.

Section	Change Recommended
Description of Act	Replace the word 'formulary' by the word 'advisory'.
Section 2(a)	Delete the word 'and' after the word 'adjuvants' and add the words 'as defined in section 27 of the Act'.
Section 2(b)	Delete the whole section.
Section 3(1)	Add after the words 'Registrar of Pesticides' the words 'and at least one Assistant Registrar'.
Section 4(1)	Replace the word 'formulary' by 'advisory'.
Section 4(2)(b)	Replace the number '8' by '10'.
Section 6(2)(b)	Revise to read 'The name and address of the manufacturer or producer of the technical grade of the active ingredient in the pesticide formulation in respect of which such application is made'.
Section 6(f)	Revise to read 'A statement of the claim made by the manufacturer or

	producer of such pesticide as to its uses, potency, stability and storage and date of expiry of usage, and, a statement with regard to its efficacy and crop safety supported by the submission of data on trials carried out'.
Section 6(g)	Revise to read 'A statement of the composition of such pesticide, its chemical identity, including the chemical and physical properties of the technical grade material from which the pesticide formulation is prepared, its net weight and the identity and amount of isomer impurities and other byproducts'.
Section 6(h)	Revise by adding after the word "antidote" words 'to show that when used as recommended the product would not cause ill effects to those applying it or the consumers of treated crops'.
Section 6(i)	Add after the words 'compound' the words 'with the result of any determination obtained'.
Section 6(j)	Add after the word 'pesticide' the words 'in food and feed after application as directed with the results of determination obtained'.
Section 7(1)(a)	Add after the word 'licence' the words 'for a period not exceeding 3 years'.
Section 7(1)(b)	Add after the word 'pesticide' the word 'provisionally' and after the word 'pending' the words 'or in lieu of' and replacing the word 'limited' by 'restricted'. Also add after the words 'provisional permit' the words 'for a period not exceeding 12 months'.
Section 8(1)	Revise by adding the words 'at least' before the words 'in the Sinhala' and removing the words 'and English' in the fourth line.
Section 8(1)(a)	Revise by adding after the words 'the trade name' the words 'and pesticide type'.

Section 8(1)(c)	Revise to read 'a statement of the composition of the pesticide with, in the case of solid formulations, the active ingredient expressed on a weight by weight percentage basis together with the percentage of all other materials present, and in the liquid formulations the active ingredient expressed as grams per litre'.
Section 8(1)(f)	Revise by adding after the word 'information' the words 'supplemented when necessary by the inclusion of a leaflet in the package giving detailed instructions in Sinhala, Tamil and English'.
Section 8(1)(g)	Replace the word 'statement' by 'word' and delete the words 'under the control of the Pesticides Act 1980'.
Section 21(2)(b)	To be amended to read 'request any pesticide offered for sale which has not been registered under the Control of Pesticides Act to be held "in bond", having first compiled a list of the pesticides and giving a copy of the seller or his agent, copy of which shall also be delivered to the Registrar and to the Police'.
Section 24(1)	Add after the words '2 years' the words 'and/or a fine not exceeding Rs10,000'.
Section 24(3)	A new section to say 'when a person or a body of person is seen or found to be committing an offence under this Act any officer nominated under the Act or any Police Officer may apprehend and prosecute such a party and institute legal proceedings'.
Section 26(1)(vi)	Amend by adding before the words 'use' the words 'the sale and'.
Section 27(1)	Include another item for making regulations which would be '(vii) Including or excluding pests or pesticides on account of their significance or insignificance for public health or health'.

Section 27 para 3	Add after the words 'Assistant Government Analyst' the words 'the Chemist of the Central Agricultural Research Institute, Gannoruwa, an Analyst of the Ceylon Institute of Scientific and Industrial Research, an Analyst of the Sri Lanka Standards Institution'.
Section 27 para 4	Delete the words 'and ectoparasites' in the eighth line.
Section 27 para 5	Revise by adding after the words 'formulations' the words 'other than any particular pesticide formulations which may be specifically excluded by regulation'.
Section 27 para 6	Revise by adding after the words 'under the Act' the words 'but excluding pheromones'.

These proposals for amendment to the Act have been recommended by the Pesticides Formulary Committee and are now in the hands of the Ministry of Agriculture Development and Research for consideration.

As stated above, amendments to the Act should assist the Registrar in the registration process. There is one proposal however which should in the Consultants view be changed and that relates to Section 8(1)(c). The internationally accepted method of expressing concentrations of solid formulations is on a gram per kilogram basis. This should then be the preferred term and the weight by weight percentage basis should be not required. Also the Consultant can see no valid reason for having the percentage of all other materials present in a solid formulation to be specified on the label. This requirement only exacerbates the difficulties of getting the required information on labels. The Consultant therefore suggests that the amendment to Section 8(1)(c) be revised to read 'A statement of the composition of the pesticide with, in the case of solid formulations the active ingredient expressed in grams per kilogram, and, in liquid formulations as grams per litre'.

In addition there are two further possible changes which are worthy, in the Consultants view, for consideration. The first being Section 8(1)(b), where the requirement is that the names of the active ingredients be not smaller in size than half of the size of that used for the trade name. As long as the active ingredient is in a position directly below the trade name and is in type size of minimum of 6 point the Consultant can see no reason for the requirement as spelt out in 8(1)(b).

Of more significance however is the requirement of Section 9 where the Registrar is obliged to declare any pesticide for which a licence has been issued as an approved pesticide such declaration to be approved by the Minister and published in the gazette. To date no approved pesticides have been gazetted. The Consultant can see no valid reason for this requirement in the Act and believes it not to be necessary. The Registrar is given specific powers of registration in other sections of the Act and the onus to publish in the gazette adds, what is in the Consultants view, a unnecessary requirement. In particular confusion could result unless there is a system in operation to enable publication in the gazette to be made immediately after or within a very short time of a licence being issued. It has been suggested that the gazette, being the official publication is required by the Controller of Imports. This may be a reason for retaining this section. In the event that the sighting of a gazette notice is not required then the Consultant recommends that Section 9 be deleted.

4.2 Prosecution v Education

In discussion with some Department of Agriculture field staff the Consultant was given the view that certain field staff favoured prosecution as the answer to those persons who were not following the letter of the law with regard to the Control of Pesticides Act. Whilst there is power to take prosecutions under the Act the question must be asked whether the objective, namely of promoting the safe and effective use of pesticides, will be achieved by this approach. Whilst recognising that there will be times when a prosecution will be essential the Consultant is of the view that, at least in the initial stages of the scheme, a more positive result would be achieved by field staff following the approach involving education to obtain the understanding of users towards the requirements of the Act. In the Consultants experience most people respect the advice of inspectors such as Authorised Officers, and in the event of users not following this advice then the final action could well be prosecution.

4.3 Appointment of Staff

It seems important that there should be an Assistant Registrar appointed at an early stage. A major duty of an assistant would be field visits to check on the implementation of the Act and to keep abreast of what is happening in the field. The Assistant could also take a lead role in any prosecutions should it be decided that these are necessary (see para 4.2). Also the added responsibility for the operation and overseeing of the records within the registration system (see para 2.7) could be given to the Assistant Registrar as well as other technical matters.

Consideration should be given to appointing the Registrar on a contract basis for a further 3 years during which time he would adequately train the Assistant Registrar in the many facets of pesticides and pesticide control and also continue to build and consolidate the framework of the registration scheme to enable his successor to inherit a well run system when the contract term expires.

4.4 Toxicological Evaluations

In the Consultants view the toxicological data should at least by sighted by a medically qualified person or a toxicologist as it seems unwise to leave the consideration of toxicological data solely in the hands of the Registrar. Whilst agreeing that the Registrar has an input, the evaluation of the data should be done by someone with expertise in a medical/toxicological field. A difficulty arises in that suitably trained and qualified people may be limited but nevertheless some effort should be made to find some body or organisation to study toxicological data particularly when new pesticides are submitted for registration.

4.5. Library for Registration Office

It is useful and desirable for the Registration Office to have ready access to some reference books on pesticides both for the purposes of identification and to keep up to date with new developments. The Office in Sri Lanka is not well equiped in this regard and the following books are suggested as being a nucleus on which to build.

The Pesticides Manual - Editor C.R. Worthing
Published by the B.C.P.C. Publications, 74 London Road, Croydon, CR0 2TB, UK

ISBN 0-901436-44-5

(Updated by replacement volumes every year or so.)

Farm Chemicals Handbook
Published by Farm Chemicals, Willowghby, Ohio 44094 USA

(Updated by replacement volumes every year or so.)

Pesticides - Theory and Application - George Ware
Published by W.H. Freeman and company, San Francisco
ISBN 0-7167-1416-7

Pesticide Application Methods - G.A. Matthews.
Published by Longman Group - London
ISBN 0-582-46054-9

4.6. Distributor Training and Reseller Responsibility

There is, in the Consultants view still a need for training the above people. While some companies in industry provide a considerable amount of distributor training a number do little or no training of distributors. It seemed from discussions that some resellers are not aware of the nature of the products that they are selling. Some distributors supply leaflets on the product to the reseller but it seems more should be done to ensure at least that pesticides are stored safety at village level and that the right type of pesticide is offered when asked for. Farmers appear to have a reasonable knowledge of what pesticides they want and in this regard the Department of Agriculture extension personnel are doing a good, on-going job. Where the farmer is in doubt he may seek advice from the distributors/reseller who should be in a position to be able to provide good advice. The Consultant is of the opinion that industry could perhaps be doing more in training distributors/ resellers and there may be room for a joint approach with the Department of Agriculture in some instances. It is however recognised that the Department of Agriculture Personnel are already fairly well commited in grower training programmes.

4.7. Poisoning With Pesticides

The Ministry of Health have now finalised the preparation of a report form on pesticide poisoning. It will be a requirement for Doctors to complete the details in the notification form (Annex XII) for all patients who are treated for pesticide poisoning. This should enable more precise records to be developed although it will still be somewhat subjective as far as determining the number of cases which were suicides and those which were accidents or from occupational exposure. An unsuccessful suicide attempt would probably be recorded as an accident.

There may be an opportunity for the Department of Agriculture to develop some statistics on pesticide poisoning giving emphasis in the first instance to areas of high use, such as, for example Nuwara Eliya. It is understood, that at village level, there is an official known as a Cultivation Officer, who moves within the community and who knows what it going on in the area. It could be that the Subject Matter Officer (Plant Protection) in the area should follow this up to see whether the more meaningful data on pesticide poisoning could be collected.

It is important in the Consultants view that good realiable data are obtained to make decisions as to which, if any pesticides should be classified as Restricted (See para 3.4)

The Consultant is under the impression that there are perhaps, fewer cases of suicides now, than there were two years ago during the earlier visit. There was no firm evidence for this but this impression was gained during discussions.

4.8. Exemption From Registration

The definition of a pest in the Control of Pesticides Act No. 33 of 1980 is quite wide. That of a pesticide is also quite wide. There are a number of products such as insect repellents, air fresheners and disinfectants which should probably be registered in view of the definition of pesticides in the Act but there could be some doubt about this. Registration has already been sought for some products falling into these categories. It will be necessary for the Pesticide Formulatory Committee to decide at an early stage whether or not these products need to be registered and if not to have available the machinery to exempt them. There is an amendment proposed to the Act (see para 4.1) and it will be necessary to have this made as soon as possible so that the Registrar can deal with those applications already in the office.

In the Consultants view the following types of products should be considered for exemption in so far as registration is concerned

Insect Repellents	- both for human and industrial use.
Bactericides	- in disinfectants and for other purposes unless used for horticultural/agriculture.
Slimicides	- for use in water cooling towers.
Air Fresheners	- in aerosol or solution form.
Fungicides	- in paint and emulsions unless recommended for fungicidal use.

5. RESIDUE AND FORMULATION ANALYSIS

5.1. Residue Analysis

There is no laboratory in Sri Lanka routinely carrying out residue analysis on food. This lack of capability is being given as one of the reasons for the Ministry of Health not yet establishing maximum residue limits. Some concern has been expressed about the possibility of excessive pesticide residues on vegetables, in view of the high use of pesticides on leafy vegetables in particular. The laboratories at the Central Agricultural

Research Institute at Gannoruwa, is not equipped to carry out routine residue analyses and would require a considerable input to make it so (see para 5.3). The Government Analyst laboratory has technical expertise but again that laboratory is not yet set up for this work but if work was r quired, it is understood that it could be done.

5.2. Formulation Analysis

A similar comment applies as in para 5.1. Analysts at the Central Agricultural Institute are asked by the Department of Agriculture field staff from time to time whether formulations which have been in stock for some time are still suitable for use. The chemist who make these assessments in part make his decision on a physical examination but has the capability of doing some chemical analysis. The Government Analyst laboratory does little pesticide work involving formulations apart from diagnosing the pesticides used in suicide cases.

5.3 Facilities Necessary

A policy decision is required as to how well to equip a laboratory/laboratories in Sri Lanka to carry out pesticide work. There is some responsibility under the Control of Pesticides Act No. 33 of 1980 both for the government to be involved both in residue analysis (section 20), and in pesticides formulations (section 21 and 22).

The Consultant in his last report in 1983 stated "although desirable to be able to analyse for residues and for active ingredients in the formulations in the long term, the present inability to do so on a large scale should not be an impediment to the registration scheme. Such capabilities for analysis should be developed in due course"

The person who was under training in analytical techniques overseas, in 1983, did not return to Sri Lanka after training. A chemist presently employed in the Central Agricultural Research Institute Laboratory at Gannoruwa has participated in the RENPAP workshop held in Thailand in January of this year.

There needs to be a considerable input into equipment and chemicals to make the residue laboratory and the formulation laboratory operational. It was estimated, in 1983 this could be in the order of $35,000 US for the residue laboratories and $15,000 US, for the laboratory to check formulations and no doubt those estimates will have escalated since that time.

The Consultant has limited expertise in this field and it is therefore suggested that a visit be made by a

Consultant with the appropriate expertise if it is decided that Sri Lanka should have analytical capability. Also it may be desirable for an expert to spend some time in the laboratory helping to set up facilities, processes and give training to staff.

5.4. Laboratory Work - Some Options

5.4.1 Residue Laboratory

This laboratory could be supplied with analytical standards by companies seeking registration and thus should be in a position to analyse for residues for pesticides on food stuffs following trials for efficacy carried out by research workers. By carrying out these analyses on a regular basis the Registrar could establish withholding periods based on Sri Lankan conditions and the laboratory would be kept up to date with analytical methods for newer pesticides. It is not envisaged that lengthy residue trials would need to be carried out, but simply there be enough analysis residues done to show that the levels found in Sri Lanka are the same or similar to those found overseas following a similar use pattern.

In addition the laboratory could do, from time to time, residue monitoring on food crops on which significant amounts of pesticide has been used, for example vegetables. Residue analysis on exports such as tea could also be done from time to time.

5.4.2 Formulation Laboratory

Samples of each pesticide for which registration or a request to import a quantity for trials, could be lodged with the formulation laboratory for analysis. The laboratory could also be available to answer any enquires such as whether a pesticide which has been stored for sometime is still suitable for use. Also it would be in a position to check on pesticides which may be adulterated or suspected of being off specification. There would also be an opportunity to do research work to develop, for example, the possible use of locally available inert ingredients or other adjuvants.

5.4.3 Use Of Laboratory Overseas

FAO is providing substantial funds towards the development of a regional pesticides laboratory in Thailand. This laboratory while primarily a training laboratory will also, it is understood, be able to do some analyses on samples taken within the region, quite probably on a commercial bases. It may be feasible for some analyses to be done by this laboratory. This option could be explored.

5.5 Which Laboratory To Equip

If it is decided to proceed with the equipping and operation of a laboratory for pesticides the Consultant is of the view that it will be necessary that only one laboratory be so equipped, the question is which one?

The Government Analyst has a responsibility for servicing the Food Act, the Police, the Customs and other Departments which do not have their own analytical facilities. The laboratory has expertise in identification of pesticides used in suicides. At the moment they have inadequate premises but a new building may be in the offing. The Government Analyst is listed in the Control of the Pesticides Act No. 33 of 1980 as an "Authorised Analyst".

The Central Agricultural Research Insititute at Gannoruwa has a laboratory housed in good buildings but does not have adequate equipment and chemicals at this time. The laboratory is part of a research institution and may not be best suited to participate in possible prosecutions under the Pesticides Act or in routine monitoring acitivies. Although not presently included as an Authorized Analyst under the Control of Pesticides Act it is proposed that the chemist of the Central Agricultural Research Institute at Gannoruwa be included (see para 4.1). The two institutions the Ceylon Institute of Scientific and Industrial Research and the Sri Lankan Standards Association are not mentioned presently in the Act as Authorised Analysts but it is proposed that an analyst from both organizations will be so defined (see para 4.1). The Consultant did not have the opportunity to visit either of these two institutions.

If local facilities are developed it must be recognised that the operation of an analytical laboratory is an ongoing commitment involving considerable running expenses by a way of reagents and chemicals and regular upgrading of equipment plus the retention of trained staff.

ANNEX I

LIST OF PERSONS AND ORGANISATIONS VISITED

Ministry Of Agriculture, Development and Research - Colombo

Mr D. Nilaweera	-	Additional Secretary (Development)
Mr W. Weeraratne	-	Deputy Director (Development)

Department Of Agriculture - Peradeniya

Dr G.W. Fernando	-	Director Of Agriculture
Dr B.A. Baptist	-	Registrar of Pesticides
Mr de Mel	-	Additional Director (Education and Training)

Plant Protection Service - Gannoruwa

Mr H.E. Senanayake	-	Chief

Central Agricultural Research Institute - Gannoruwa

Dr S.N. Senewiratne	-	Deputy Director, Research
Dr S.L. Amarasiri	-	Chief, Residue Laboratory

Research Station - Maha Illuppallama

Dr J. Fernando	-	Deputy Director Research
Dr Amarasingher	-	Weed Scientist
Mr Gunewarder	-	Economist
Mr Wijeratne	-	Ent ogist

Department Of Agriculture - Anuradhapura

Mr Ratnayake	-	Additional Director, Agriculture (Extension)

Department Of Agriculture - Mahawele - Region H

Mr Karunatikaka	-	Deputy Regional Project Manager (Agriculture)

Department Of Agriculture - Nuwara Eliya

Mr W. Wickramatunga	-	Additional Director, Agriculture (Extension)

Mr Waranesekara	-	Subject Matter Officer (Plant Protection)
Mr Jayawarna	-	Agricultural Officer (Headquarters)

Tea Research Institute - Talawakelle

Dr Sivapalan	-	Director
Dr Kuasegaram	-	Deputy Direct (Research)
Dr Aurulpragasam	-	Plant Pathologist

Ministry Of Health - Colombo

Dr M. Rodrigo	-	
Dr Herath	-	

Office Of The Government Analyst - Colombo

Dr T. Kandasamy	-	Government Analyst

Pesticides Association Of Sri Lanka - Colombo

Member of the Association.