



TOGETHER
for a sustainable future

OCCASION

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



TOGETHER
for a sustainable future

DISCLAIMER

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as “developed”, “industrialized” and “developing” are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

FAIR USE POLICY

Any part of this publication may be quoted and referenced for educational and research purposes without additional permission from UNIDO. However, those who make use of quoting and referencing this publication are requested to follow the Fair Use Policy of giving due credit to UNIDO.

CONTACT

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

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

RESTRICTED

20117

DP/ID/SER.A/1641
26 March 1993
ORIGINAL: ENGLISH

227

REGIONAL NETWORK ON PESTICIDES FOR ASIA AND THE PACIFIC

DP/RAS/88/031

UNION OF MYANMAR

Technical report: Management of quality control in
pesticide formulation using FAO specifications
and CIPAC methods*

Prepared for the Government of the Union of Myanmar
by the United Nations Industrial Development Organization,
acting as Executing Agency for the United Nations Development Programme

Based on the work of Brian Crozier, consultant in
pesticide quality control

Backstopping Officer: B. Sugavanam
Chemical Industries Branch

United Nations Industrial Development Organization
Vienna

* This document has not been edited.

V.93 83456

ABBREVIATIONS AND ACRONYMS USED

Local currency equivalent US \$1 = K5.9

ai	Active Ingredient
CAC	Codex Alimentarius Commission
CIPAC	Collaborative International Pesticides Analytical Council Ltd
EC	Emulsifiable Concentrate
FAO	Food and Agriculture Organisation (of the United Nations)
GIFAP	International Group of National Associations of Agrochemical Manufacturers
GLC	Gas Liquid Chromatograph(y)
GLP	Good Laboratory Practice
HPLC	High Performance Liquid Chromatograph(y)
MAS	Myanma Agriculture Service
MRL	Maximum Residue Limit
PPPF	Pilot Plant for Pesticide Formulation
PRB	Pesticide Registration Board
QC	Quality Control
RENAPAP	Regional Network for Pesticides in Asia and the Pacific
TLC	Thin Layer Chromatography
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organisation
UPS	Uninterruptible Power Supply
UV/VIS	Ultra-violet/Visible Spectrophotometer

ABSTRACT

Title: Consultant in quality control/management

Number: DP/RAS/88/031/11-75

Purpose: To assist the Ministry of Industry and the Ministry of Agriculture to properly manage quality control systems, adhere to FAO specifications and follow CIPAC guidelines.

Duration: Three weeks, 11 February 1993 to 6 March 1993

Conclusion: The Pesticides Analytical Laboratory of the MAS has the responsibility to analyse and test pesticides for the purposes of registration and subsequent checks. The laboratory has been well-equipped by FAO and should be able to cope with the regular demands of a Registration Scheme, although there is the possibility that an initial large number of applications might overwhelm the capability of the laboratory.

Recommendations: Analysis of samples of pesticide formulations supplied for registration should be analysed by recommended CIPAC methods where available, and by manufacturer's supplied methods where not. Products which do not conform to the relevant FAO specification should be refused registration. It is noted that in carrying out analyses of pesticide formulations and for pesticide residues the analysts have to share instruments. It should be an objective that these two functions are separated to prevent cross-contamination.

TABLE OF CONTENTS

Abbreviations and acronyms used	1
Abstract	2
Table of Contents	3
Introduction	4
I Organisation of Registration and Quality Control of Pesticides	6
A. Registration Scheme	6
B. Quality Control	6
II Activities	8
A. Registration of Pesticides	8
B. Training in Pesticide Quality Control	8
C. RENPAP	8
III Findings and Conclusions	9
A. Registration of Pesticides	9
B. Pesticide Quality Control	9
C. RENPAP	10
IV Acknowledgments	11
Recommendations	12
Annexes	
I Job Description	13
II Persons and Institutions contacted	15
III Lectures given to staff of the MAS and PPPF	16
IV Minimum basic Instrumentation and Equipment for a Pesticide Quality Control Laboratory	17
UNIDO comments	22

INTRODUCTION

UNDP, in association with UNIDO, has established the RENPAP to promote the safe development and management of pesticides. The Union of Myanmar has recently joined the Network and is also in the process of setting up a scheme for the registration and control of pesticides in the country. The Government of Myanmar is aiming to maintain its relatively pest-free (compared with neighbouring countries) environment for the production of essential crops and to increase and intensify the cultivation of commodity crops including cotton, rice, pulses, vegetables and citrus for home consumption and export by the judicious use of pesticides. At present there are two main sources of pesticides in the country; import of ready-formulated products and a limited range of essential insecticides produced locally by the PPPF using imported ai and some formulants together with local solvents. The MAS is the main user of these pesticides which are distributed to individual users and groups around the country.

The PPPF has been producing EC formulations of five insecticides (cypermethrin, diazinon, endosulfan, fenitrothion and phenthoate) since June 1990 and this output provides a significant proportion of the needs of the MAS. The PPPF was previously under the control of the Ministry of Industry No 1 but as from December 1992 responsibility for the PPPF was taken over by the MAS. This is obviously more suitable since it will mean a faster response time between supplier and user when required. Representation of the Union of Myanmar in the RENPAP organisation still resides with the Ministry of Industry No 1 but it would be more practical if this representation were also with the MAS.

This report has been written by Brian Crozier, Consultant in Pesticide Quality Control, based on the Job Description in Annex I.

The mission had two main objectives, namely group training and assistance with pesticide QC procedures and advice on long-term management of the

use of pesticides in Myanmar.

The Consultant had, immediately before this mission, been on a mission relating to QC at the PPPF [see report DP/MYA/80/011, dated February 1993] and some of the training, particularly the lectures on various aspects of pesticide analysis and registration, were held jointly with staff from both the MAS and the PPPF.

I. ORGANISATION OF REGISTRATION AND QUALITY CONTROL OF PESTICIDES

A. Registration Scheme

The Pesticide Law was enacted in May 1990 and the detailed Regulations and Procedures are being developed and it is expected that applications for registration of pesticide formulations will begin to be received soon.

The PRB, whose Chairman is the Managing Director of the MAS and Secretary the Head of the Plant Protection Service, is made up from a number of specialists in several areas, ie., Plant Protection, Pesticide Residues and Formulation Analysis, Toxicology, Occupational and Public Health, Animal Health, Aquatic Environment, Stored Products Protection and Pesticide Trade. In the area of pesticide analysis, the PRB has set up two Sub-Committees; the Pesticide Technical Sub-Committee and the Bioefficacy Sub-Committee whose main concerns are the analysis of pesticide formulations and the analysis for pesticide residues respectively.

The Registration Scheme has been modelled on other well-founded schemes so that information required from manufacturers is similar to that demanded by other countries.

B. Quality Control

The Pesticide Analytical Laboratory of the MAS has the responsibility to analyse and test pesticide formulations before registration and to carry out subsequent checks on the quality of available formulations. It is also planned to carry out analyses for pesticide residues on crops and commodities for comparison with Codex MRLs and as a check on the correct usage of pesticide formulations.

The PAL has a total complement of nine graduate analysts (4 for formulation analysis and 5 for pesticide residues) and at present has three main laboratories - one each for the preparation of samples for formulation analysis and residue analysis and a shared instrumentation laboratory. The laboratories are basically well-equipped with few major requirements

needed and the instrumentation (three GLC, one HPLC and one Atomic Absorption Spectrophotometer) is adequate. Problems have been experienced with one of the Nitrox nitrogen and air generators and also with power supplies.

II. ACTIVITIES

A. Registration of Pesticides

Information was given on the basic principles, purposes and procedures of a Pesticide Registration Scheme and the information required to be provided to enable sound decisions to be made on the registration of pesticide formulations. Emphasis was placed on the need to ensure that the quality of the pesticide formulation complies with the relevant published FAO specification.

B. Training in Pesticide Quality Control

1. Good Laboratory Practice

A lecture on GLP and its application to pesticide analysis was given to staff and the need for complete, permanent notes and records to be made. The purpose behind the practice of GLP was explained and information given on the requirements necessary from management and staff to ensure working practices adhered to GLP principles.

2. Analytical Techniques

Several lectures on various aspects of pesticide analysis were given (see Annex III). Staff of the PPPF have recently had a two month consultancy in QC including much practical work but constraints on time meant that there was no opportunity for practical work at the PAL of the MAS. Discussions with the section leaders indicated that training from previous consultants engaged through FAO had given them a sound basis of pesticide analytical chemistry.

C. RENPAP

A discussion took place with the Myanmar representative on the RENPAP to identify areas of need and requirements for the future.

III. FINDINGS AND CONCLUSIONS

A. Registration of Pesticides

The Registration Scheme as designed is sound, based on successful schemes in other countries and there is no reason why it should not carry out its purpose of ensuring safety in all aspects of the use of pesticides in Myanmar. In order to avoid too great a burden on the facilities it is recommended that thought be given to harmonisation of the scheme with those in action in other countries in the RENPAP organisation, so reducing the need for duplication of analyses.

It is necessary that the MAS is kept up-to-date with published FAO specifications and obtains all possible information from CAC for MRLs in relevant produce.

It is suggested that a rolling programme of analysis for pesticide residues in appropriate commodities be started in order to be able to provide information to Codex, to be alerted to any possible misuse of pesticides and as part of a requirement for international trade.

B. Pesticide Quality Control

The complement of analysts should be adequate to cope with the normal day-to-day requirements of the Registration Scheme. It is possible that when the Scheme is started up there may be an initial surge of samples for analysis and in order to prevent too great a back-log it is suggested that products submitted for registration from reputable manufacturers should not be subjected to a full analysis.

It was noted earlier that whilst the Formulation Analysis and Residue Analysis Sections have separate laboratories for sample preparation, they both use the same instrumentation. It would be preferable if each section could be self-contained in the future and this will obviously entail the purchase of additional instrumentation.

The safety facilities in the laboratories are just adequate, a separate ventilated store for storage of solvents and bulk chemicals and a room for retained samples should be built. Because of the nature of the work with materials, some of which are extremely toxic, it is recommended that all the analysts receive a Hazardous Working Allowance. Thought must be given to possible recruitment and retention problems to ensure that there are adequate numbers of suitably trained staff available.

The PAL should take part in relevant CIPAC collaborative analyses whenever possible.

It was hoped that the provision of three UPS systems would overcome problems with power black-outs and brownings, however there appears to be a similar problem with all three units, although not all purchased at the same time, and it is recommended that these be examined by a fully qualified serviceman as soon as possible.

C. RENPAP

The Myanmar representative on the RENPAF is employed by the Ministry of Industry No 1 as a legacy of the time that the Ministry had control of the PPPF, the major producer of pesticide formulations in the country. Since the MAS took over the management of the PPPF in December 1992, it is suggested that the position of RENPAP co-ordinator should also be transferred to the MAS.

It is noted that Governmental and Organisational procedures sometimes mean that nominations of candidates for training courses and meetings cannot be made in time due to the short notice given. It is requested that the RENPAP organisation send out notifications of meetings and requests for nominations allowing an adequate period for responses to be made.

Myanmar has an interest in the production of biological pesticides from local materials such as neem and tobacco and would like the assistance of the RENPAP in this area.

IV. ACKNOWLEDGMENTS

The Consultant would like to thank and acknowledge the help and advice received from all persons with whom he came into contact which helped to make the mission enjoyable.

The contacts with U Maung Maung Tin and MAS staff, although brief were fruitful, and U Win Kyi and staff of the PPPF were never failing in the provision of transport and hospitality.

RECOMMENDATIONS

1. The MAS to consider the harmonisation of registration requirements with other countries in the RENPAP organisation to prevent unnecessary duplication of work.
2. The MAS to continue and foster contacts with FAO and Codex to ensure receipt of up-to-date information.
3. The PAL of the MAS to begin a regular rolling programme of pesticide residue analyses.
4. The MAS to consider building a separate solvent and retained samples store.
5. The MAS to consider separating Pesticide Formulation and Pesticide Residue analysis sections to prevent cross-contamination.
6. Analytical staff at the PAL to receive a Hazardous Working Allowance.
7. The PAL to take part in appropriate CIPAC collaborative trials to widen their experience.
8. The PAL to arrange for the UPS system to be examined by a qualified serviceman.
9. The position of Myanmar representative on the RENPAP to be transferred to the MAS.
10. RENPAP to note the procedural requirements for nominations and to allow adequate time for such procedures.

ANNEX 1

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

JOB DESCRIPTION

DP/RAS/88/031/11-75

- Post title:** Consultant in quality control/management
- Duration:** 0.7 m/m (three weeks)
- Date required:** January 1993
- Duty station:** Yangon including travel within the country
- Purpose of the project:** To assist the Ministry of Industry and the Ministry of Agriculture to properly manage quality control systems, adhere to FAO specifications and follow CIPAC guidelines.
- Duties:** The consultant is expected to provide advisory assistance and group training in various aspects related to pesticide quality control, good laboratory practice, maintenance of records, analysis of new type of formulations, maintaining secondary reference materials and how quality management could be organized between producer and regulatory ends.
- In this he will bring together counterparts from pesticide industry and the regulatory authorities and assign certain protocols to be followed for long term quality control/management of pesticides in Myanmar.
- Qualifications:** Highly qualified analytical chemist with experience in industry or institution dealing with quality control of pesticides. Should be familiar with the international practice in running of a quality control laboratory. Experience in a developing country would be an advantage.

Language: English

Background Information: Asia region is going through an accelerated industrial growth during the last 10-15 years and the both per capita chemical production and use have risen enormously. Unfortunately the corresponding awareness and actions to deal with the chemical contamination in the environment has been very limited in many countries due to lack of facilities and expertise. UNDP in association with UNIDO has established a Regional Network on Pesticides for Asia and the Pacific (RENPAF) to promote safe development and management of pesticides. In the network there are 14 member countries covering almost half of the world's population. Some selected countries have taken up specific areas to provide assistance to the region and UNIDO is providing technical assistance to increase the capacity of these countries in the chosen topics by linking with other national projects. The following topics are covered:

- Formulation Technology - India
- Quality Control - Rep. of Korea
- Bio-botanical Pesticides)
- Residue Analysis) - Thailand
- Occupational Safety - Philippines
- Operational Safety)
- Waste Management)
- Environment Safety) - Thailand
- Application Technology - Malaysia
- Data collection/Dissemination - India
- Ecotoxicology - Pakistan

At present UNIDO, supported by Denmark government, is providing adequate support to Pakistan to establish an ecotoxicology centre which would provide the necessary assistance not only to Pakistan but also to the region. With this it is planned to have a workshop in 1993 in Pakistan on ecotoxicology for the benefit of the Asia region. This regional project is intended to assist Pakistan in organizing the workshop and handle topics relevant to the region especially with regards to pesticides.

ANNEX II

PERSONS AND INSTITUTIONS CONTACTED

United Nations Personnel

U Htin Aung Programme officer

Myanma Agriculture Service

U Maung Maung Tin Dy GM, Head Plant Protection Service

Analytical Staff

U Than Aye Head, Pesticide Residues Analysis Section

U Saw Say Paw Head, Pesticide Formulation Analysis Section

U Aung Myint Oo Residues Analysis Section

Daw Tin Tin Shine Residues Analysis Section

Daw Mu Mu Aye Residues Analysis Section

U Tun Zaw Win Formulation Analysis Section

U Tin Win Formulation Analysis Section

Daw Thida Than Formulation Analysis Section

PPPF Staff

U Win Kyi National Project Director

U Saw Mooler Laboratory Manager

U Mon Tin Win Dy Laboratory Manager

U Myint Htay Analyst

Ministry of Industry Number 1

U Myoe Lwin RENPAP Co-ordinator

ANNEX III

LECTURES GIVEN TO STAFF OF THE MAS AND THE PPPF

1. Good Laboratory Practice
2. Trends in Pesticide Formulation
3. Chromatography
 - General Introduction and Overview
 - Maintenance
 - Troubleshooting
4. High Performance Liquid Chromatography
 - Equipment
 - Methods
 - Developments
5. Gas Liquid Chromatography
 - Introduction: Components of the System
 - Stationary Phases
 - Special Techniques
6. Registration of Pesticides
 - Need, Objectives, Responsibilities
 - Data Requirements
 - Trials
 - Assessment
 - Post-Registration Activities
 - ADI and MRL
7. Specifications for Pesticides
 - Description
 - Physical Requirments
 - Tolerances

ANNEX IV

MINIMUM BASIC INSTRUMENTATION AND EQUIPMENT FOR A PESTICIDE QUALITY CONTROL LABORATORY

Main items listed together with suggested spares and consumables1. Major Instrumentation with Accessories and Spares

Gas Liquid Chromatograph, fitted with packed and capillary injectors,
FID and other suitable detector

Gas supplies, Nitrox generator with maintenance kit

Gas filters for oxygen and moisture

Gas supply of hydrogen

Glass columns, ready packed or empty together with suitable liquid
phases and support materials

Capillary columns, bonded phase

Injection port liners

Septa, silanised glass wool, O rings, syringes, ferrules, copper
tubing, Swagelock fittings, chart paper

Manufacturer's recommended service kit

High Performance Liquid Chromatograph, with variable wavelength UV
detector

Selection of columns of various lengths and packings

Guard columns

Degasser/debubbler for solvents

Syringes, injection loops

Swagelock fittings and connectors, ferrules, stainless steel and
PTFE tubing, chart paper

Solvents

Manufacturer's recommended service kit

UV/Visible Spectrophotometer, scanning range 200 to 1100 nm

Spectrophotometer cells, various sizes

Spare deuterium and tungsten bulbs

Chart paper

Manufacturer's recommended service kit

Infrared recording spectrophotometer, double beam

Sodium chloride cells, various path lengths

Chart paper

Manufacturer's recommended service kit

2. Laboratory Apparatus and Small Instruments

Balance, analytical, 200g X 0.1mg, with tare

Balance, laboratory, 2kg X 0.1g, with tare

pH meter/potentiometric titrator

electrodes, buffer powders

Karl Fischer titration apparatus

solvents, reagents

Deioniser, spare cartridges or resins

Melting point apparatus, tubes

Flash point apparatus

Ultrasonic bath

Microwave oven

Centrifuge

assorted tubes and 100ml IP75 tubes

Sieve shaker and range of sieves

Laboratory ovens X 2

Furnace with crucibles and tongs

Steam bath, thermostatted water bath, cooled bath, water bath for

emulsion stability test

Refrigerator/ deep freezer

Liquidizer/ homogenizer/ blender

Vegetable/fruit chopper

Tissue grinder

Hotplate/magnetic stirrer with fleas

Rotary shaker

Orbital shaker

Ball grinding mill with containers and balls
Rotary evaporator with spare clips and flasks
Heating mantles of various sizes
Vacuum pump/compressor
Water vacuum pump
Whirlimix
Desiccators
Stirrer motors and rods with varying lengths and paddles
Hair dryer
Viscometer, or range of viscometer tubes
TLC plate maker (or plates), tanks, sprayer etc
UV lamp
Stop clock, stop watch, interval timer
Thermometers, general and melting point

3. Glassware etc

Volumetric flasks and stoppers to fit
1,5,10,20,25,50,100,200,250,500,1000 ml
Graduated cylinders, lipped and stoppered
5,10,25,50,100,200,250,500,1000 ml
250 ml for suspensibility test
tap density cylinders
Pipettes, bulb and graduated
1,2,5,10,20,25,50 ml
pipette fillers
Pasteur pipettes and teats
Burettes
10,25,50 ml
Beakers, squat and tall form
10,25,50,100,250,500,1000 ml

Quickfit glassware

Adaptors, condensers, distillation columns, flasks (round bottomed, one and two necked, 50,100,250,500 ml), still heads, splash heads, chromatography columns, separating funnels, thermometers, gas adsorption apparatus, Dean and Stark fittings, Soxhlet extractor with thimbles, conical flasks (25,50,100,250,500 ml), iodine flasks (250 ml), range of stoppers

Reagent bottles, labelled, 500,1000 ml

Buchner flasks and funnels with range of papers

Sintered glass funnels, range of porosities

Filter funnels, varying sizes, range of papers to fit

Test tubes and racks

Mortars and pestles, various sizes

Polythene squeeze bottles

Tubing: glass, polythene, rubber, vacuum and tubing clips

Glass rods

Weighing bottles and funnels; disposable weighing boats

Glass vials, varying sizes with screw caps

Glass jars, varying sizes with screw caps

4. General Equipment

Spatulas, palette knives, scoops, spoons

Forceps

Scissors

Bowls and buckets, polythene

Cleaning brushes (bottles, burette, stiff, bristle, soft)

Paint brushes, various sizes

Aluminium foil

Cotton wool

Glass wool

Cork rings

Paper tissues

Butane burner with cartridges, tripods and gauzes

Vials, caps and liners

Crimper/decapper

Retort stands, clamps (various), bosses, rings

Scaffold rods

Laboratory jacks

Multimeter

Assorted tools

Knives

Self-seal polybags or polybags and sealer

5. Safety and disposable items

First aid kits

Eye wash bottles

Safety glasses and goggles

Safety shields

Dust masks

Ear defenders

Laboratory coats

Protective gloves (nitrile, polythene, heat resistant)

Solvent store cupboard

Acid store cupboard

6. Special chemicals etc.

GC phases and supports

Silylating agents

Aluminium oxide, silica gel (various grades)

CVS solutions

Indicator papers, pH papers

UNIDO COMMENTS

The report gives a clear analysis of the interaction that should be maintained between the producers of pesticides and the users of pesticides so that clear understanding of the requirement according to national or international standards is achieved.

The expert who went on both national project and regional project has brought the necessary linkages that should be kept between the two sections of the MAS (now that the pesticide plant belongs to MAS) to serve the country's demand in pesticides.

Such an interaction between the two sections of MAS would make it easier to keep common spare parts for the analytical laboratory, reference standards thereby reducing the overall expenditure.