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ENGLISH

REGIONAL NETWORK ON PESTICIDES
FOR ASIA AND THE PACIFIC

DP RAS/85/023

THAILAND

Technical report: Quality Control and Specifications for Pesticides in Thailand*

Prepared for the Government of Thailand
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 Control Specifications

Backstopping officer: B. Sugavanam, Chemical Industries Branch

United Nations Industrial Development Organization
Vienna

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ABBREVIATIONS AND ACRONYMS USED

a.i.	Active ingredient
ARD	Agricultural Regulatory Division
ASS	Analytical Services Sub-Division
ATSD	Agricultural Toxic Substances Division
CIF	Cost, Insurance, Freight
CIPAC	Collaborative International Pesticides Analytical Council
DOAE	Department of Agricultural Extension
e.g.	exempli gratia = for example
FAO	Food and Agriculture Organisation (of UN)
GIFAP	International Group of National Associations of Manufacturers of Agrochemical Products
i.e.	id est = that is
LD50	Dose required to kill 50% of test animals
MOA	Ministry of Agriculture
MOI	Ministry of Industry
MPH	Ministry of Public Health
PAA	Poisonous Articles Act, 1967, amended 1973
PFAS	Pesticide Formulation Analysis Section
PRS	Pesticides Regulatory Sub-Division
RENPAF	Regional Network on Pesticides for Asia and the Pacific
TPA	Thai Pesticides Association
UNIDO	United Nations Industrial Development Organisation.

ABSTRACT

Title: Consultant Quality Control/Specifications

Number: DP/RAS/85/023/11-53

Purpose: To provide technical assistance to Asia and the Pacific Region in the safe development and use of pesticides.

Duration of Mission: One month from 17 June 1987.

The existing system for the *registration* of *pesticides* is reviewed and recommendations are made for strengthening the *legislation* and *information requirements* from *producers*.

Improvements to the procedure for checking the *quality* of *pesticide formulations* submitted for registration and available for purchase are proposed.

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Appendices

INTRODUCTION

The Regional Network was established in 1982 through a project executed by UNIDO. The initial phase attempts to develop a co-operative system in Asia involving Government institutions and bodies dealing with pesticides. Registration of pesticides for sale and use and quality control of available products are important areas in this initial phase.

Imports of pesticides into Thailand in 1985 amounted to a value of US$M57(CIF). These imports are almost wholly technical grade material for local formulation or finished formulations for repacking; only one active ingredient, paraquat, is manufactured locally by two producers. The majority of major manufacturing companies belong to the Thai Pesticides Association, associated to GIFAP, the international organisation, but the smaller firms do not belong, having broken away last year. Both groups are represented on a Working Group, together with Government authorities, set up to consider a new scheme for registration of pesticides.

Pesticides are distributed by both government, mainly through the Department of Agricultural Extension (DOAE), and private sector, through Co-operatives and agro-chemical dealers. It is thought that there are over 2000 points of distribution in the private sector.

The control of pesticides in Thailand is achieved by the Poisonous Articles Act (PAA) of 1967 as amended in 1973, which classifies poisonous articles into two groups: highly poisonous and ordinarily poisonous, based on a figure of 50

mg/kg bodyweight for the acute oral LD50. Not all pesticides have been classified as poisonous articles, in particular new compounds or newly introduced pesticides are not included and therefore can be imported and sold without restriction until they are added to the list. Three Ministries, those of Agriculture (MOA), Industry (MOI), and Public Health (MPH) administer the enforcement of the PAA such that any poisonous article must be registered before, import, manufacture or distribution. The registration of pesticides in Thailand is the responsibility of the Pesticides Regulatory Subdivision (PRS) of the Agricultural Regulatory Division (ARD). The PRS issues permits for the import, manufacture or stocking for sales and produces guidelines on the Registration Procedure which requires fairly general information. Section 12.3 of the amended PAA requires, *inter alia* , 'amount of poisonous article' and 'detail on properties' and in effect this has meant that in general only the active ingredient content has been checked. Most analysis of pesticide formulations is the responsibility of part of the Analytical Service Section (ASS) of the Agricultural Toxic Substances Division (ATSD) [See Appendix I for the relationship between Divisions etc]. The Pesticide Formulation Analysis Section (PFAS) of ASS receives samples for analysis from a number of sources:

1. DOAE - samples of materials prior to purchase for use
2. PRS - samples of materials for registration
   - samples collected by PRS Inspectors
3. Samples collected by PFAS staff
4. Samples from farmers (through DOAE)
5. Samples from manufacturers
6. Other Government Departments
7. Thai Industrial Standards Institute - mainly mosquito coils for consumer protection.

The Consultant was attached to this Section for the period of his stay in Thailand, 21 June - 16 July 1987; the objectives of the stay are given by the duties in the job description [Appendix II]. A programme of activities was drawn up for the duration of the stay [Appendix III] and all items in the programme were completed. The two main areas were in connection with the registration and specification of pesticides and the laboratory work connected with the quality control of pesticides.

RECOMMENDATIONS

	Action
1. Strengthen the Registration procedure for pesticides:	
a) Amend Poisonous Articles Act if necessary	MOA
b) Define 'pesticide'	MOI
c) Use WHO classification for toxicity categories	MPH
d) Restrict availability of the most toxic pesticides (Grades Ia and Ib)	
2. Manufacturers to provide information on their products in line with FAO Specifications	MOA
3. Manufacturers to provide samples on application for registration:	MOA
a) Analytical grade material	
b) Formulation	
c) Internal standard or other unusual chemical	
4. Strengthen quality control of pesticides:	MOA
a) Increase staff	
b) PFAS to analyse formulations submitted for registration and retail samples obtained by Inspectors	
c) Amalgamate PRS laboratory facility into PFAS	
5. Widen analytical capability of PFAS by purchase of further equipment	MOA UNIDO
6. Increase confidence of PFAS analysts by taking part in international collaborative exercises	MOA
7. Further training in instrument servicing and computer use and programming.	UNIDO

I REGISTRATION

The Pesticide Registration Section employs 5 persons - both technical and administrative and associated with it as part of the PRS are 10 Inspectors, 2 Inspectors at Customs, 4 to deal with permits and 1 concerned with the analysis of samples.

Only materials gazetted as 'poisonous articles' need to be registered and have a permit for import and therefore some control over their manufacture, marketing and use. After registration inspectors visit markets and retail outlets to check conditions of storage and correctness of labelling. They may also take samples to check the formulation - usually only for active ingredient content. Inspectors at Customs take samples of imported material for analysis; the small laboratory at the PRS (only one Gas Chromatograph and very limited other facilities) was set up in order that results of the analyses of these samples could be carried out quickly so that imports were not held up. It had been found on occasions that the PFAS was overloaded with work from other sources and so analyses took some time. In addition the PRS and PFAS are physically separated and are controlled by separate Directors.

Visits were made to several manufacturers to see the quality control facilities and to discuss registration requirements [Appendix IV]. The facilities varied as would be expected depending on the nature of the analyses required and there was general agreement that the registration of pesticides in Thailand could be strengthened. Note that all organisations visited belong to the Thai Pesticide Association (TPA), non members may have other views.

In order to have greater control over the use of pesticides in Thailand a definition of 'pesticide' should be agreed, e.g. a chemical substance (and certain micro-organisms) prepared or used to destroy pests or other creatures, plants or other organisms. This will encompass herbicides and fungicides as well as insecticides. Coupled with the requirement that all pesticides (as defined) should be registered and that import, sale or use of a non-registered pesticide should be an offence this will enable faster control of pesticides. For this purpose each formulation is considered as a separate case and must be registered as such; registration numbers must continue to be displayed on the label as part of the registration requirements.

It would be advisable to use the WHO classification of pesticides [Appendix V] and to restrict the sale and use of pesticides in categories Ia and Ib to authorised users.

The information required from applicants for registration should be more detailed, particularly with respect to the chemical composition and physical properties of the formulation. Advice and information on suggested requirements is available from FAO (copies left with PRS) and such requirements have the support of GIFAP [Appendix VI]. Note that the RENPAF meeting on Quality Control of Pesticides in May 1984 recommended that member countries adopt specifications based on FAO standards wherever possible. The changes outlined above would make an advance towards harmonization of the registration requirements in Thailand with those in other RENPAF countries.

Discussion between the PRS and pesticide manufacturers in Thailand (both TPA and non-TPA) have already taken place and this Working Group is expected to reach agreement regarding a new scheme for 1988. The proposal is that all

new pesticides and patented products would be included in this scheme but that formulations based on commodity products would continue under the present system which includes a review of the registration of each pesticide every five years. Phased or stepwise registration is available while results of manufacturer's tests under local conditions (for example efficacy testing and toxicological information particularly on fish, shrimps etc) are obtained.

There is obviously a need for the PRS to have, or have access to, analytical facilities for checking pesticide formulations. The present facility was set up to provide rapid results on samples taken from stocks awaiting import permits but only a limited number of types of analyses can be carried out and the absence of any fume extraction facility makes working in the room hazardous. The plan for a new laboratory for the whole of the ARD, to encompass testing of pesticides, fertilizers and seeds should overcome this but there is still liable to be some duplication of effort between PRS and PFAS. In the present circumstances, where analysis of toxic pesticides has to be undertaken, the expedient solution would be for the PRS chromatograph to be re-located to the PFAS laboratory in the ATSD until the new laboratory is functioning. The analyst attached to the PRS (Mrs Suwapee) would be based in this laboratory, using all the facilities, but her priority is analyses for the PRS. As the two sections concerned are in different Divisions, agreement of both Directors would be needed.

II QUALITY CONTROL

The Pesticide Formulation Analysis Section, headed by Mrs Chiraporn Sriplakich, has the responsibility for the chemical and physical analysis of pesticides used in both agriculture and public health. The analysis is done as a quality control measure to determine the percentage of active ingredient of toxic chemicals and has been undertaken as a service for both government and private sectors in order to serve the registration of pesticides under the Poisonous Articles Act.

Mrs Chiraporn has a total staff of 10, 5 qualified and experienced, 2 qualified and 3 assistants.

The major items of analytical equipment specifically for the PFAS and also available to it are given in Appendix VII.

Samples for analysis come from several sources

1. DOAE - samples before purchase and from farmers
2. PRS - samples for registration and retail samples
3. PFAS - samples collected by staff
4. Manufacturers without suitable quality control facilities
5. Other Government departments
6. Thai Industrial Standards Institute (TISI)

are given priorities by Mrs Chiraporn and assigned to staff members for analysis on the basis of their qualifications and experience.

The vast majority of requests for analysis are purely concerned with active ingredient content and little relevance has been attached to a consideration of the physical properties of formulations. Investigations by the Section however on several samples have shown that the majority would have failed the relevant FAO Specification for emulsion stability or suspensibility. This is obviously cause for great concern and adds weight to the argument that there should be a strengthening of information required for registration and subsequent quality control of formulations. The manufacturers visited [Appendix IV] all have satisfactory quality control facilities for monitoring their production, however there are many other formulation plants which do not check quality. This coupled with the fact that anyone may import any formulation for sale with little control over its composition or performance, means that the PFAS should be carrying out many more checks to support a strengthened Registration Scheme.

Assuming such a Registration Scheme requiring formulation analysis for registration and quality control at point of sale the present PFAS would need strengthening. A report by Mr G L Baldit, Expert in Pesticide Manufacturing Technology [UC/THA/83/116, December 1984] envisaged analyses on 2500 samples per year, i.e. of the order of 10 samples per working day. Methods for physical properties can be carried out by competent school-leavers but with greater emphasis placed on identification and determination of (possibly) toxic impurities graduate analytical chemists are necessary. A turnover of the level above would require six graduates each with two assistants. In order to assist Mrs Chiraporn to regulate the demands on the PFAS for quality control checks it is recommended that there should be some forward planning between PRS and the PFAS to target the number and types of formulations to be routinely analysed. A programme of sampling for 3-6 months ahead would

enable the inspectors to prepare their schedules and also allow for any staff absences on training courses or annual leave [The FDA have such arrangements for their routine analysis].

The major items of equipment in the PFAS are manufactured by Tracor. Servicing of the instruments has been carried out by one of the chemists (Mr Vinai) who has benefited from attending a specialised course arranged by Tracor. The servicing of the sophisticated equipment in a modern laboratory needs special skills and knowledge and although analysts are often able to locate the area in which a fault has occurred they may not be able to rectify it. Further training on instrument maintenance for several members of the ATSD should be sought and, if the range of manufacturers is widened, consideration to employing a specialist electronic engineer should be given. Training in the use of, and programming for the Apple computers available in the ATSD is necessary. There is no suitable, compatible Thai software available.

If the GC belonging to the PRS is installed in the PFAS, one further Shimadzu GC would fully equip the laboratory. It would be necessary for the GC to be either a dedicated capilliary GC or to have the capability of use with capilliary columns, i.e. a total of 4 gas chromatographs, one with the facility of capilliary GC analyses. There are a few items of general laboratory equipment which are necessary and some accessories which would fully equip the laboratory [See Appendix VIII for suggested purchases]

One of the major problems of a quality control laboratory associated with a Regulatory Scheme is that multi-national manufacturers often recommend methods of analysis using the most up-to-date techniques and often using unusual chemicals as internal standards. Government laboratories do not have the resources immediately available for e.g. capilliary gas chromatography nor to purchase special chemicals. One solution would be for applications for registration to be accompanied by samples of analytical grade material, the formulation and recommended internal standard.

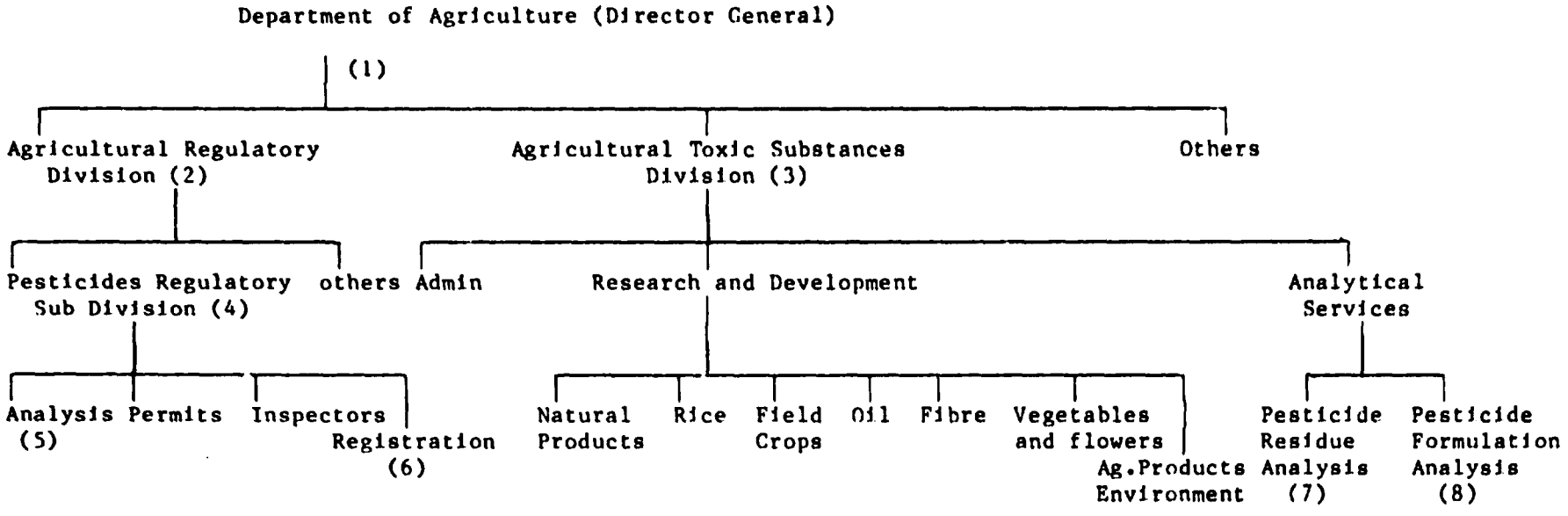
The RENPAF meeting on Quality Control of Pesticides in May 1984 recommended that the regional network should take steps to initiate collaborative studies in coordination with CIPAC. The cost of organising pilot trials and full collaborative studies probably makes this recommendation out of reach at present but in order to gain confidence in the analysis of the new pesticides the PFAS should take part in as many collaborative studies as possible. Notifications of such studies are circulated by the Secretary of CIPAC.

III ACKNOWLEDGEMENTS

The author would like to express his sincere thanks for the assistance given to him by those persons and organisations mentioned in Appendix IV. The unfailing kindness and courtesy shown by everyone, within and without the laboratory, has made a lasting impression.

APPENDIX I

Organisation of Relevant Areas of the Department of Agriculture



(1) Dr Riksh Syamananda, Deputy Director-General (one of three)
(2) Mr Boonchob Bhatraruji, Director ARD
(3) Mr Adul Woravisithumrong, Director, ATSD
(4) Mr Patanan Sangkatawat, Chief, PRSD
(5) Mrs Suwapee Patarawimol
(6) Mr Sukhum Wong-Ek
(7) Mrs Supranee Impithuksa
(8) Mrs Chiraporn Sriplakich

APPENDIX II

JOB DESCRIPTION

DP/RAS/85/023/11-53

Post Title	Consultant Qualtiy Control/Specifications
Duration:	One month
Date required	January 1987
Duty Station	Bangkok, Thailand
Purpose of project	To provide technical assistance to Asia and the Pacific region in the safe development and use of pesticides.
Duties	The consultant, with the help of the National Co-ordinator of the project will: - Advise on the quality control and specification needed for the various pesticides used in the country; - Provide guidance on the good laboratory practice and the international or national standards to be followed in assessing the quality of pesticides and their formulations; - Give lectures on the latest analytical techniques used in pesticide analyses; - Make recommendation to further equip the laboratories of the department of agriculture; - Submit a report on his work, findings and recommendations.
Qualifications	Organic or physical chemist with extensive experience in the area of chemical analysis, with special emphasis on pesticide analysis. He should be familar with the international norms for good laboratory practice, registration requirements of pesticides. Experience in the development of pesticides in developing countries desirable.
Language	English

APPENDIX III

Programme of work

30 June	Lecture on Safety in the laboratory Good Laboratory Practice
1 July	Visit to Chia Tai Co Ltd
2 July	Lecture on Spectroscopy: General, UV/VIS; IR; Mass Spec; Atomic; Raman; NMR; ESR
6 July	Visit to Bayer Thai Co Ltd ICI Asiatic (Agriculture) Co Ltd
7 July	Lecture on Chromatography: General; Paper; TLC; Column; GLC; HPLC.
8 July	Visit to The Shell Co of Thailand Ltd
9 July	Lecture on Pesticides: Formulation; Specification; Registration; Analysis; Use; Residues
14 July	To UNIDO, debriefing with Mr Kei Kimpara
14 July	Lecture on International Organisation: CIPAC; AOAC; FAO/WHO/UNIDO GIFAP: RENPAF: ESCAP Difficulties and Laboratory Troubleshooting.

APPENDIX IV

Organisations and Persons contacted

A. Manufacturers

1. Chia Tai Company Limited
   70 Moo 6, Petkasam Road, Omnoi, Smutsakorn
   Dr Visutr Sucksoong, Manager, Quality Control and Research Division
   Mr Prapoj Wuttigornwipark, Factory Manager

2. Bayer Thai Co Ltd
   Crop Protection Business Group
   130/1 North Sathorn Road, Bangkok 10500
   Mr Charnvit Piyavanichstian, Technical Supervisor
   Factory, 239 Moo 4, Bangpoo Industrial Estate, Samutprakam 10280
   Mrs Arunee Anusaksathien, Assistant Quality Control Manager

3. ICI Asiatic (Agriculture) Co Ltd
   53-55 Oriental Avenue, Bangkok 10500
   Dr Apichai Daorai, Manager, Product Safety and Registration
   Factory, Bangpoo Industrial Estate
   Mr Parkpoom Jarnyaharn, Factory Manager

4. The Shell Co of Thailand Ltd
   10 Soonthornkosa Road, Klongtoey, Bangkok 10110
   Mr Sven E Royall, Agrochemicals Manager
   Mr Prapun Surapong, Area Sales Assistant
   Mrs Thrapsin Punyodyana, HSE Assistant.

B. Staff of the Department of Agriculture

Dr Riksh Syamananda, Deputy Director General

Agricultural Toxic Substances Division

Mr Adul Woravisithumrong, Director
Mrs Chiraporn Sriplakich
Mrs Krisana Chutpong
Mr Vinai Pitiyont
Mrs Nunchana Leutrakool
Mrs Supranee Impithuksa
Mrs Yubon Yingchol
Mrs Nuansri Tayaputch
Mrs Pinya Chamruskul
Mrs Siwaporn Sakulthiangtrong
Mrs Pongsri Biadul

Agricultural Regulatory Division

Mr Boonchob Bhatraruji, Director
Mr Patanan Sangkatawat
Mr Sukhum Wong-Ek
Mrs Suwapee Patarawimol
Mrs Chutima Suthisatabut
Mrs Prapha Wong-Ek

APPENDIX V

WHO Classification of Pesticides

Category	LD50 to rat - mg/kg body weight			
	Oral		Dermal	
	Solids	Liquids	Solids	Liquids
Ia Extremely hazardous	5 or less	20 or less	10 or less	40 or less
Ib Highly hazardous	5 - 50	20 - 200	10 - 100	40 - 400
II Moderately hazardous	50 - 500	200 - 2000	100 - 1000	400 - 4000
III Slightly hazardous	>500	>2000	>1000	>4000

Note: The LD50 figures refer to the product or formulation, not to the active ingredient.

APPENDIX VI

FAO Specification Requirements

The basic data required for the formulated product:

1. Description

   To include physical state of the product and any undesirable features.

2. Active Ingredient

   To include identity tests and a declared content of active ingredient.

3. Impurities

   To include limits on any undesirable impurities, e.g. acidity or alkalinity, insoluble material, water etc. Also limits for decomposition products and unwanted manufacturing products.

4. Physical Properties

   Included where relevant to ensure that the product will be able to be applied satisfactorily through the appropriate application equipment

5. Stability

   At both low and high temperature where appropriate.

6. Containers

   Advice on any special precautions necessary

7. Biological Properties

   e.g. Any known phytotoxic effects

For further detailed information see 'The Use of FAO Specifications for Plant Protection Products' FAO, Rome.

Physical Requirements for Specification/Registration

General Requirements

Physical State	)	
Colour/Appearance	)	No test required - visual examination
Odour	)	

Fundamental Properties - required for active ingredient/technical

Melting Point	MT2	
Boiling Point		
Decomposition Point		
Vapour Pressure		
Surface Tension		
Refractive Index	MT136	Abbe Refractometer

Hydrolysis	)	
Stability	)	Information and statement from manufacturer
Solubility	)	
Photolysis	)	No test necessary (except poss. compat.)
Compatibility - for formulation	)	
also	)	

Basic Properties - applicable to AI, TC and formulation

Viscosity	MT22	
Flash point	MT12	
Acidity/Alkalinity/pH	MT31, 75	
S.G./Density	MT3, 33, 58	
Flamability	)	form only - manufacturer's statement
Combustibility	)	

Formulation Properties

Miscibility with oil	MT23
Rate of Solution/Release	MT13, 56, 60
Spontaneity of Dispersion	
Wettability	MT53
Flowability	MT44
Persistent Foam	MT47
Particle Size	MT42, 43
Dry Sieve Test	MT58, 59
Wet Sieve Test	MT59
Pourability	MT148
Emulsion Stability	MT20, 36, 41
Suspensibility	MT15
Re-Dispersibility	
Claying	
Friability	
Adhesion	MT83

APPENDIX VII

Major analytical equipment available to the Pesticide Formulation Analytical Section.

Gas Chromatograph	Tracor 560, two
High Performance Liquid Chromatograph	Tracor 960, fixed wavelength, isocratic Tracor 950 + 970A, variable wavelength, isocratic

pH meter

UV/VIS Spectrophotometer

Shimadzu Integrator CR3A

Takeda Rikan Integrator TR2215A

Sartorius 2462 Analytical balance (not working)

Mettler P1200 Rough balance (not working)

Centrifuge

APPENDIX VIII

Suggested equipment necessary to fully equip the PFAS Laboratory.

IR Spectrophotometer
Capilliary GC facility with Integrator - Shimadzu CR3A
Rotary Evaporator
Melting Point Apparatus
Moisture Determination (Mettler DL40 Automatic Titrator)
Flash Point Apparatus
Deep Freeze
Microwave Oven

Smaller items which can probably be purchased from local budget.

Avometer
Tools
Viscometers
Thermometers
Iodine Flasks
100 ml Centrifuge Tubes
Safety Glasses
Eye Wash Bottles
GC Spares: Liquid Stationary phases, supports etc
HPLC Spares: Columns, Guard columns
Speciality chemicals.

Reference Texts (some already available in PFAS)

1. CIPAC Handbooks I, IA, IB, IC
   Heffers Printers Ltd, Cambridge, England
2. CIPAC Proceedings Volumes, I, II, III
   Heffers Printers Ltd, Cambridge, England
3. Manual of chemical methods for pesticides and devices
   Association of Official Analytical Chemists, Washington,DC, USA
4. Official Methods of Analysis, Editor W Horwitz
   Association of Official Analytical Chemists, Washington,DC, USA
5. The Pesticide Manual, Editor D Worthing. Latest Edition
   British Crop Protection Council, England
6. Analytical Methods for Pesticides, Plant Growth Regulators and Food Additives, Editors G Zweig and J Sherma, Volumes I to date
   Academic Press, New York.
7. Advances in Pesticide Science, Editor H Geissbuhler
   Pergamon Press, Oxford, England
8. Pesticide Analytical Manual
   Food and Drug Administration, Washington DC, USA.
9. Basic Chromatography
   H McNair and E J Bonelli
   Varian Inc. 1969
10. The Packed Column in Gas Chromatography
    W Supina
    Supelco Inc, 1974
11. Gas Chromatographic Detectors
    D J David
    Wiley-Interscience, New York 1974

12. High Pressure, High Resolution liquid chromatography and its application to pesticide analysis and biochemistry
D A Schooley and G B Quistad
In Progress in Drug Metabolism Vol 3
Editors J W Bridges and L F Chasseau
John Wiley & Sons Ltd 1979, ISBN 0 471 99711 0

13. Introduction to High Performance Liquid Chromatography
R J Hamilton and P A Sewell
Chapman and Hall 1977 ISBN 0 412 13400 4

14. Maintaining and trouble shooting HPLC Systems. A User's Guide
Dennis J Runser
John Wiley & Sons Ltd 1981, ISBN 0 471 06479 3

APPENDIX IX

Photographs

1. Wet Chemical and Physical Testing Laboratory
2. Analytical Instrument Laboratory - Tracor HPLCs
3. Analytical Instrument Laboratory - Tracor GLCs
4. Residue Analysis - Tracor 560 GLC
5. Residue Analysis - Tracor 222 GLC
6. Residue Analysis - Varian Vista 6000 + Tracor 985
7-1 uality Control facilities in manufacturers' laboratories.

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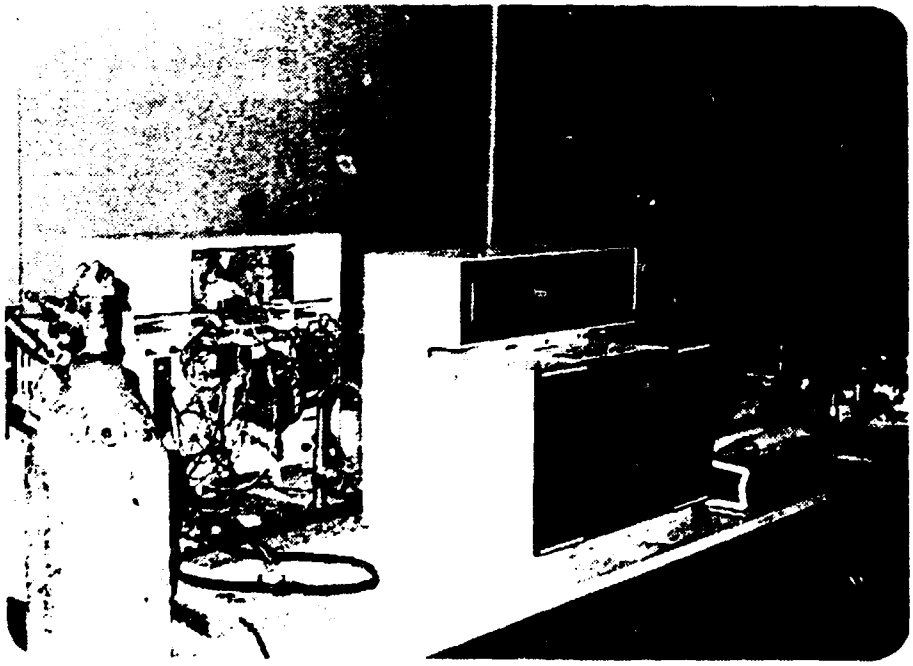

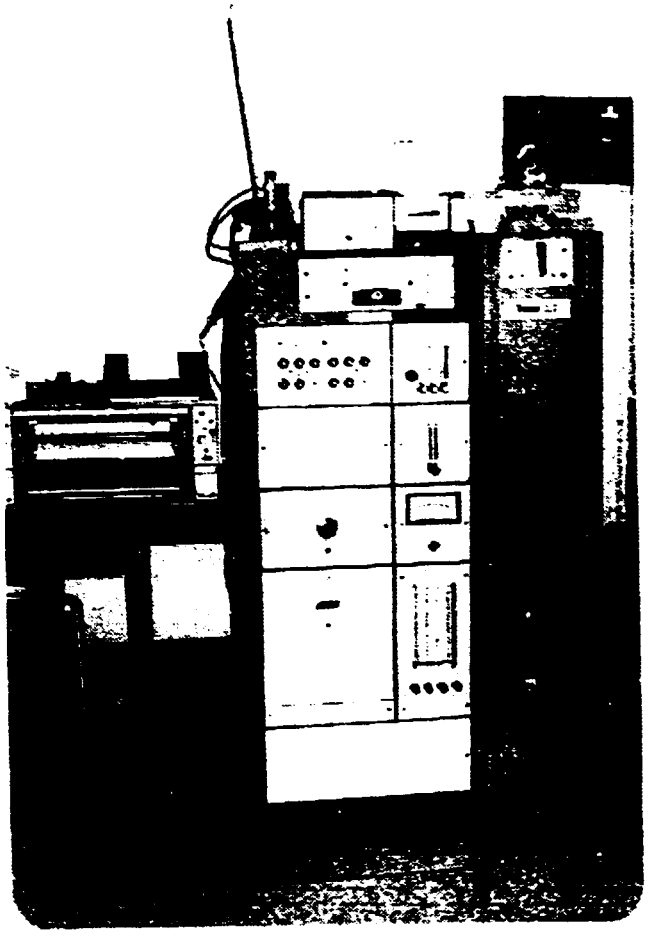

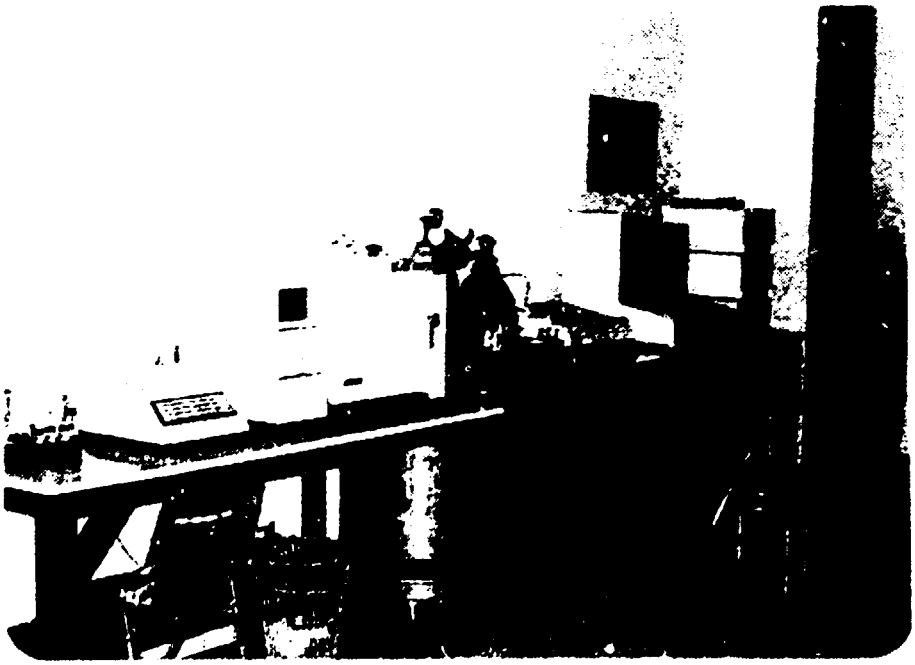

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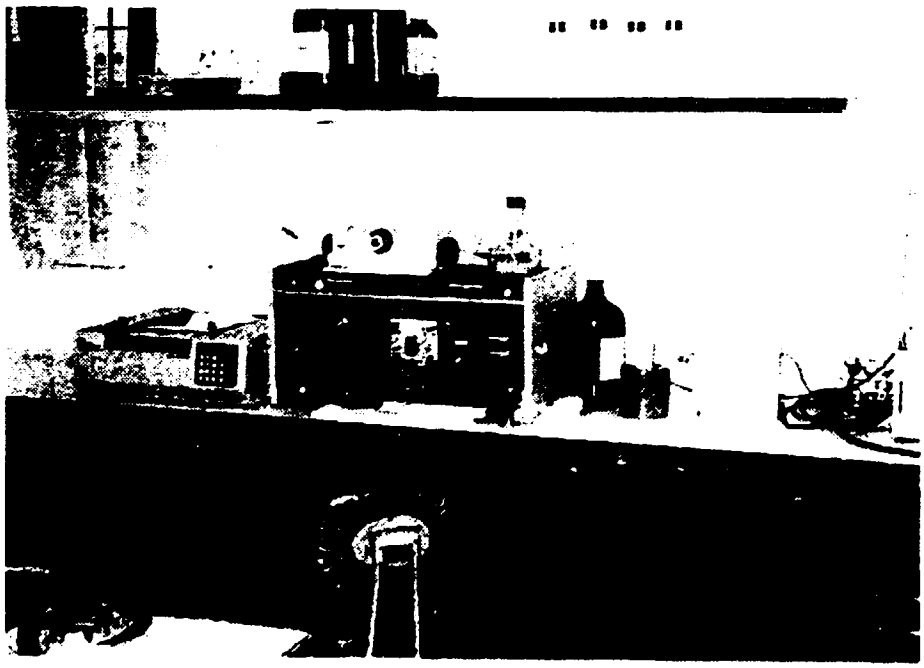

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