

### 附属資料(8

Data on Toxicology required for application for registration of pesticide

- 1. Estimate of Acute Oral LD50
- 2. Estimate of Acute Dermal LD50
- 3. Skin irritation
- 4. Dermal sensitization
- 5. Subchronic Toxicity (21 days)
- 6. Subchronic Toxicity (90 days)
- 7. Teratology
- 8. Reproduction
- 9. Chronic toxicity
- 10. Oncogenecity
- 11. Mutagenicity
- 12. Pharmacokinetics

source: FPA PESTICIDE REGURATORY POLICIES AND THE IMPLEMENTING GUIDELINES AND PROCEDURES issued by FPA (October 1989)

## ANNUAL IMPORTS OF MAIN PHILIPPINES' FRUITS IN JAPAN (1993-1995)

### 1. BANABAS

	1995	1994		1993		
· · ·	Quantity(Ton)	% Qu	antity(Ton)	% QI	uantity(Ton)	%
PHILIPPINES	677,518	78	684,588	74	668,837	73
OTHERS	196,247	22	244,791	26	244,498	27
TOTAL	873,765		929,379	:	913,335	

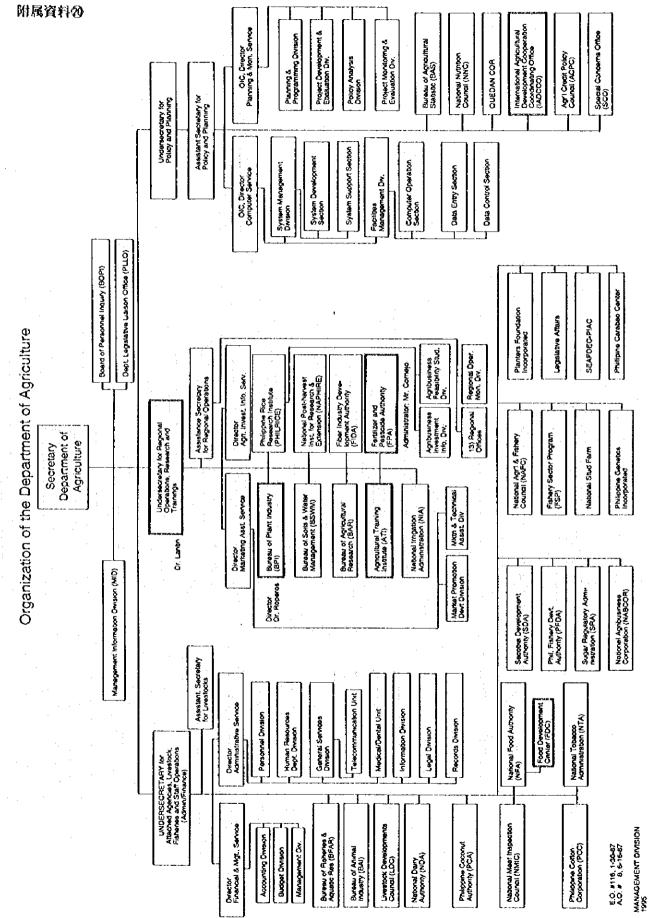
### 2. MANGOES

1995		1994		1993		
	Quantity(Ton)	% Quantity(Ton)		% Quantity(Ton)		%
PHILIPPINES	7,122	71	5,463	72	8,031	87
OTHERS	2,924	29	2,143	28	1,232	13
TOTAL	10,046		7,606		9,263	

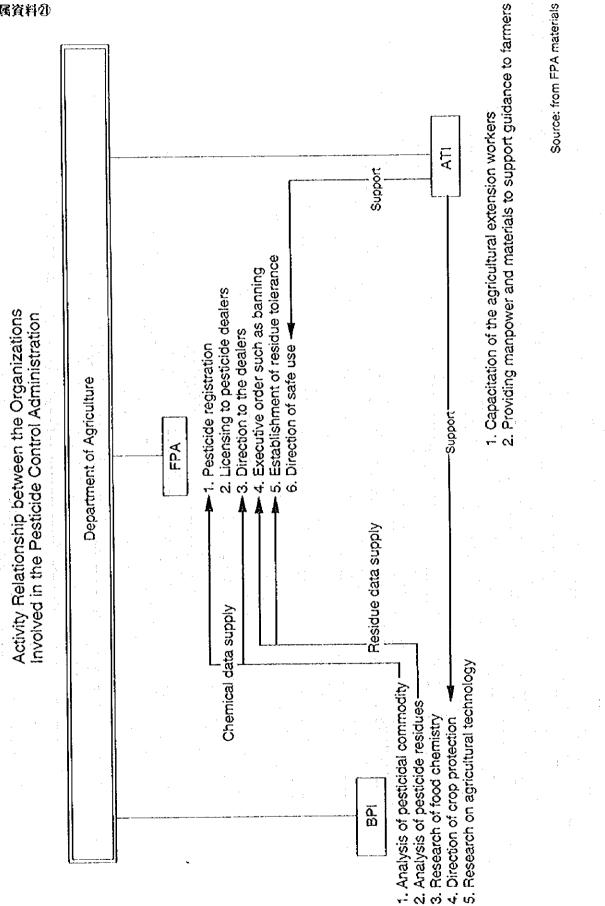
# 3. PINEAPPLES

	1995	1994 % Quantity(Ton)		1993 % Quantity(Ton)		%
	Quantity(Ton)					
PHILIPPINES	107,285	99	112,537	99	119,595	99
OTHERS	655	1	989	- 1	1,367	1
TOTAL	107,940		113,526		120,962	-

(社) 日本青果物輸入安全推進協会、1995年度輸入青果物統計試料



-92--

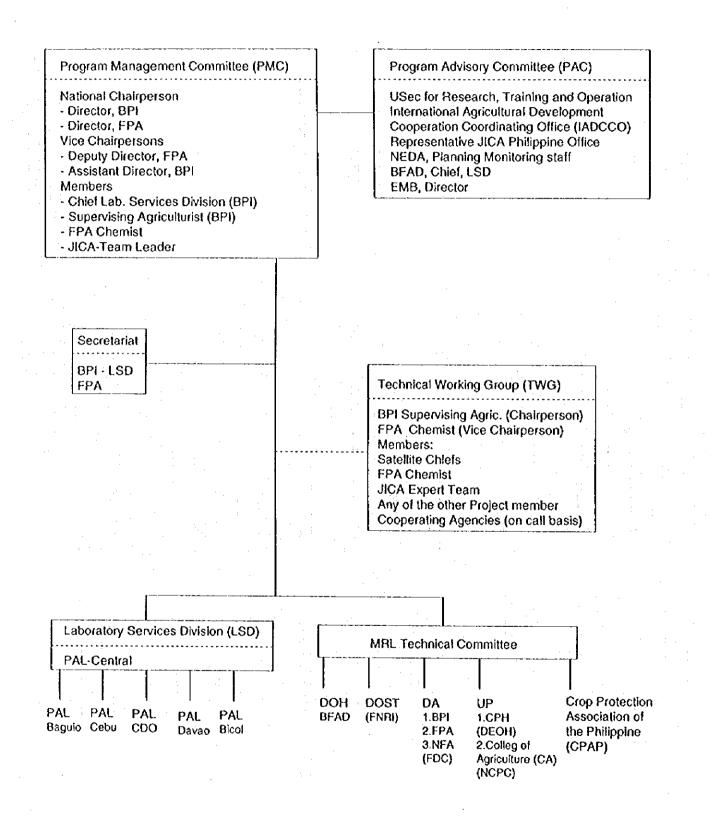


附属資料の

-93-

#### 附属資料の

# Organizations Involved in the Project



#### from the report of the Preliminary Survey Team

#### 附属資料②

#### QUESTIONNAIRE

作物残留試験

1.MRLの設定について

日本及びCACの設定のやり方を記載した上で、

MRLの設定について、具体的な考えを持っているか否か、必要性を感じているか確認する。

どのようにしてー-作物残留試験を実施する意思あるいは予定または計画があるか

どのようにして--作物残留試験データかモニタリングデータか

- だれが ・ 実務はFPAか、BPIか
- いつから ←プロ技との時間的関係

何に対して ←優先的に設定したい組み合わせ

2. GAP (PH1) の設定について

日本のやり方を記載して上で、

現在、どうやって決めているのか把握するとともに、

現在のやり方を変更する意志あるいは予定があるか確認する

現在、ラベルに記載されているPHIなどをどのようにしてきめている BPIが作物残留試験を実施した場合、GAPの設定に利用されるのか 現状のGAPの決め方の問題点はなにか

3.作物残留試験について

日本の作物残留試験のやり方を説明した上で、 現在、作物残留試験を実施しているのか、 今後実施する意志あるいは予定または計画があるのか確認する

現在、だれが国内で作物残留試験を実施しているか、またその規模は →政府か、メーカーか、その他の機関か →今までに得られたデータのとりまとめはあるか 今までにPALは作物残留試験を実施しているか →実施していれば、体制、予算、結果などはどんなものか 現在、作物残留試験を実施していれば問題点はなにか 今後、PALあるいは他の機関が作物残留試験を実施する計画はあるか 残留分析はPAL、資料調整は他機関となるのか 作物残留試験に必要な園場、要員、予算を確保できるか 確保できる圃場箇所数、規模、栽培できる作物、時期はどうか

4.モニタリングについて(特に残留分析)。

モニタリングデータはどのように活用されているのか →モニタリングデータによってGAPが設定されたり、変更されたことはあるか モニタリングデータは安全使用指導(普及活動)に反映されているか サンプリング体制はどのようになっているのか

→だれがサンプリングしているのか。

サンプリング対象はどのようにして決めているのか サンプリングから分析結果を得るまでの時間はどのくらいか 現状の問題点は何か

5. 安全使用指導について

現状の問題点は何か

平均的な農家での農薬使用の姿はどのようなものか →使用する農薬の種類、回数、量、時期 現在、農家に対して農薬の使い方を指導しているのはだれか 今後、体制を整備あるいは変更する予定または計画があるか

6. プロジェクト実施体制

カウンターパートはどこに設置されているのか →BPI/LSD/PAL/FPA/…

運営費等の予算計画の状況はどうなっているか →1997会計年度はどうなるか

要具の採用、配置計画はどうなっているか →1997会計はどうなっているか

必要とする派遣専門家

→活動分野、活動内容、人数、期間についてはどうなっているか、詳細に (例えば、分析そのものか、データ評価か、分析法の開発か、データの利用か、など)

受け入れ研修員

→活動分野、活動内容、人数、期間についてはどうなっているか、詳細に (例えば、分析そのものか、データ評価か、分析法の開発か、データの利用か、など)

供与要請機材があるか →機材名、使用目的、数量

# (作物残留試験の英文)

Pesticide Administration

- 1. Establishment of Maximum Residue Limit (MRL)
  - 1. 1. Do you have a pilot farm for test of pesticide residue in pilot crop?
  - I. 2. Have you planned to make a pilot farm for test of pesticide residue in pilot crop unless you have?
  - 1. 3. Which do you want to chose to establish MRL, from the test data of pesticide residue in pilot crop or of monitoring survey?
  - 1. 4. Which bureau will establish MRL practically?
  - 1. 5. What do you think of that the time of the project should be started?
- 2. Establishment of Good Agricultural Practice (GAP)
  - 2. I. How is PHI on labels of pesticide established?
  - 2. 2. Is the data of crop pesticide residue test used to establish GAP if you take data from crop pesticide residue test?
  - 2. 3. Do you have any problem when you decide GAP?
- 3. Test of Pesticide Residue in Pilot Crop
  - Have you practiced the test of pesticide residue in pilot crop?
  - If your answer is YES, please follow to No. 3. 1., 3. 2., 3. 3, and 3. 4.

If your answer is NO, please follow to No. 3. 5., 3. 6, and 3. 7.

- 3. 1. What organization carry out the test of pesticide residue in pilot crop if the test has taken?
- A. How widely the test is done?
- (e.g. Organization of government, pesticide manufacture, or other organization)
- B. Is there any collection of the test data?
- 3. 2. Has PAL taken test of pesticide residue in pilot crop?
- If the test has been taken under PAL:
- A. How is the system working?
- B. How much is the budget?
- C. What were the results of the test ?
- D. Does PAL have any difficulties on the running of the test?
- 3. 3. Has pesticide residue analysis been tested under PAL?
- 3. 4. The analysis procedure has been separated?
- (e.g. pesticide residue has been analyzed at PAL, sample has been prepared under other organization.)
- 3. 5. Do you have any plan running the pilot farm for the test of pesticide residue in pilot crop?
- 3. 6. Does PAL or other organization have a plan for test of pesticide residue in pilot crop?
- 3. 7. Can the government of Philippine give running cost such as staff to the pilot farm if crop pesticide residue test is needed?
- A. How many pilot farms are available?
- B. How about wildness of a pilot farm?
- C. What kind of crop is able to be cultivated?

D. How about the season of the cultivation of the pilot crop?

4. Monitoring survey

- 4. I. How is the data of monitoring used practically?
- 4. 2. Has GAP been established or changed from the data of monitoring?
- 4. 3. Has the data of monitoring given a guideline of safety pesticide usage?
- 4. 4. What kind of sampling system have you had?
- 4. 5. Who has taken samples?
- 4. 6. How are the samples chosen?
- 4. 7. How many days does it take to reach results from the sampling taken?

4. 8. What kind of difficulty do you have?

- 5. Guideline of safety pesticide usage
  - 5. 1. Do you have any difficulty?
  - 5. 2. Usage of pesticide?
  - A. kinds of pesticide?
  - B. times per a season?
  - C. quantity per season?

D. usage pattern?

5. 3. Who has given a guideline of the safety pesticide usage to the farmers?

5. 4. Do you have any plan to improve or change the system of safety pesticide usage?

6: Project arrangement

6. 1. Please give a detail of 1997 fiscal year budget?

A Running cost

B. Settlement of staff

C. Plan of settlement of staff, etc.

6. 2. Technical Equipment-

What kind of technical equipment do you need?

A. Name of technical equipment/Description

B. Purpose

C. Quantity Experts

Transfer modern techniques on:

team leader coordinator

pesticide monitoring on residue and formulation

establishment of MRL.

networking

e.g. analyst, evaluation of data, improvement of analysis way, usage of data?

- 2. Activities
- 3. How many

4. Term

#### (作物残留試験の質問に対する同答)

ANSWERS TO QUESTIONNAIRES

BUREAU OF PLANT INDUSTRY/FERTILIZER & PESTICIDE AUTHORITY

I. Establishment of MRL

1.1 Yes

1.2 Yes

1.3 from the test data (supervised residue trial)

1.4 BPI/FPA (and other cooperating agencies)

1.5 Immediately as soon as the Grant-Aid Laboratory is operational

2. GAP

2.1 Based on the supervised trial

2.2 Yes

2.3 No

3. Test of Pesticide Residue in Pilot Crop

3.1 Yes

3.1.A BPI, NCPC, Chemical companies with the supervision of the researchers accredited by FPA

3.1 B Yes

3.2 Commodities used (eggplant, cabbage, pechay)

A. test/analysis done by PAL Central

B. P5,000/site

C. to follow

D. at the moment yes, without the new instrument

3.3 Yes

3.4 For quality assurance samples, other organization prepares the sample and PAL just analyzed then report

4. Monitoring Survey

4.1 Monitoring data is used by FPA as basis for policy decisions

4.2 No, it is always from the supervised trial

4.3 Yes

4.4 Market basket sampling and farm level samples

4.5 Researchers/Training Technicians

4.6 by representative fresh samples

4.7 it depends, - sometimes immediately if the location is near but if far - it can be 2 days to 1 week

4.8 Budgetary constraints

5. Guidelines of Safety Pesticide Usage

5.1 No

5.2

A. Organophosphates (OPs), Carbamates

B. Rice - (4-8 times/cropping season)

Vegetables - (7-15 times/cropping season)

C. Label Specifications

D. Label Specifications

5.3 Department of Agriculture, FPA, CPAP, extension workers

- 5.4 Yes, FPA is doing it through its project ARCO collaboration/partnership with CPAP
- 6. Project Arrangement
  - フィリピン農薬モニタリング体制改善計画の調査に関する質問事項

(1996年3月21日)

1.職員対象の研修に使用されたテキストを人手できないでしょうか

根拠:FPA及びBPI職員へのtrainingは事前調査の質問事項への回答資料中に

「PAL-centralにて年2回40名対象に実施」とあります。

- 2. 1 停電時のバックアップ体制は現状ではどの様なものでしょうか。
- 2.2 また同時に水道も供給がストップしてしまうのでしょうか。
- 3. GC-MSは作物残留分析に必須の機器で将来の供与予定に入っています。このような高度に 作動安定性の求められる分析機器が既に他研究機関あるいは大学に設置済みと思われます が、電気供給不安定な状況下でいかに運用されているかがわかれば非常に参考になります。
- 4. attachment22に記載されている各製剤の分析法はなにに準拠しているのでしょうか。 attachment22:FORMULATION CONTROL UNIT

SUMMARY OF PESTICIDE FORMULATION ANALYSIS

5. attachment 18に記載の作物残留試験に用いられた披験資料は一般の市販作物をモニタリングのために採取したものでしょうか、あるいは作物残留試験専用に栽培されたものでしょうか。

- 6.1 ADIは自国で評価し設定されたものでしょうか。
- 2 また作物残留試験に供試する作物への農薬の散布方法に関するガイドラインはいかなるものでしょうか。

根拠:事前調査の質問事項への回答中1-7.3に「MR L設定のもととなるAD I や 残留データはある」とあります。

(フィリピン農薬モニタリング体制改善計画の調査に関する質問事項の英文) Pesticide Residue Analysis

I Is the texts of FPA and BPI staff training available?

2-1 How is backup system of electricity going on now during power failure?

2-2 Does the water supply also stop during power failure ?

3

How is the GC-MS working under circumstance of power failure at other research

centers and University of the Philippines if the apparatus is put there.

What kind of methods are chosen on the attachment 22 of the answer to the

questionnaire when each pesticide formulation was analyzed?

5 Where did the crop samples on Attachment 18 come from, market or cultivated

as used pesticide residue test?

6-1 ADI has been evaluated and established by Philippine itself?

6-2 What kind of guidelines does BPI have when pesticide is used on the pilot farm

of the crop samples of pesticide residue test?

### 食品衛生制度

1. 農産物の残留農薬基準(MRL)の設定について

(1) MR Lについては、現在国際基準を暫定基準として採用しているとのことであるが、暫定基 準として採用する際に安全性評価を行なっているのか。

(安全性評価を実施している場合)

1)国内における農薬の販売許可とMRL設定は同時に行なっているのか。同時でないとしたら、 農薬の販売許可時には安全性評価はどのような形で行なっているのか。

2) MRL設定に関する安全性評価については、通常専門家から構成される諮問委員会等科学的な 検討の場を設け以下に示す事項等について評価を行なうこととしているが、安全性評価について具 体的に教示願いたい。

・安全性試験(体内動態試験を含む)

・作物残留試験

・物理化学的性質に関する資料

(2) MRL設定に関する安全性評価の今後の具体的取り組みについて教示願いたい。

(3) MRL設定に必要な食品摂取量調査(Food Intake Survey)については科学技術省(DOST)が 実施しているとのことであるが、当該調査の方法、実施状況及びデータの活用状況について教示顔 いたい。

2. 残留農薬基準値を超える農産物に対する監視体制について

(1) MR Lを超える農産物については、当該農産物を喫食することによりただちに衛生上の危害 の発生のおそれのある事例については警察が関与し取締り、ただちに衛生上の危害の発生のない事 例については農家に対する指導を行なうとのことであるが、MR Lを超える農産物に対する監視体 制について今度どのように強化・整備を行ないたいのか具体的に内容を示されたい。(組織・人員 を含む)

(2)輸入農作物の監視制度の有無、ある場合にはその概要及び実績について教示願いたい。また、 今後の取り組みについて教示願いたい。

(3)輸出農産物の残留農薬監視体制について

1) 現在PAしが輸出者等から申請がある場合に分析を実施し検査結果を発行しているとのことで あるが、過去3年間の実績について教示願いたい。

2) 通商行政を所管している省庁等も輸出農産物の検査制度を設けているとのことであるが、その 制度の具体的内容及び実施状況について教示願いたい。

3) 今後輸出農産物の残留農薬の検査体制の整備・強化をはかりたいとのことであるが、今後の具体的な取り組みについて教示願いたい。

3. 農薬摂取量調査の実施の有無、実施している場合にはその方法、実施状況及びデータの活用状 況について教示願いたい。

4. 農産物の残留農薬分析について

(1)現在実施している農産物の残留農業及びその分析方法並びに今後分析対象として導入を予定している農業及びその分析方法について教示願いたい。

(2) MRLを超えた農産物の監視を効率的に実施するためには多種類の農薬を一度に分析する多 成分分析法の策定が必要不可欠である。多成分分析法を実施している場合にはその方法及び実施状 況について教示願いたい。

(3)現在使用し、今後も調達可能な標準物質、有機溶媒等の試薬について救示願いたい。

## (食品衛生制度の英文) SYSTEM OF FOOD SANITATION

1. With respect to Establishment of Maximum residues limits for pesticides in agriculture product (MRL)

(1) Concerning Maximum residues limits for pesticides in agriculture products (MRL) Philippines has introduced CODEX MRL as tentative standards. Do you have scientific evaluation procedures for establishment of tentative. MRL?

(In cases where scientific evaluation conducted)

1) Do you give permission to sell pesticide and establish MRL coincidentally? If not, how do you conduct scientific evaluation of pesticide when permitted.

2) Scientific evaluation is usually performed at expert committee consist of toxicologists, chemists etc. through examination of the data on the following items. Please tell me the methods of scientific evaluation.

\* Safety studies (including a metabolism and kinetic study)

\* Pesticide residues survey

\* Physicochemical characteristics

(2) Please tell me how to cope with safety evaluation on MRL establishment in future.(3) DOST conduct the food intake survey which is necessary to set up MRL. Please tell me the way of survey, actual result and practical use.

2. With respect to inspection system for pesticides residues in agriculture products. (1) Concerning the cases of agricultural products contain pesticides residues exceed MRL, in case of those which were found to cause the health hazard through eating them are treated or controlled by police power, on the other hand in case of those which were found to be no possibility of health hazard are treated to give a safe use guidance to farmers. What kind of planning do you consider to improve or reinforce the inspection system?

(2) Do you have regulatory system on inspection for imported agriculture products? If you do please tell me the outline, actual records and the future program to be considered.

(3) Inspection system for exported agricultural products

1) If a exporter apply for pesticide analysis for agricultural products for export, PAL analyze and issue a result. Please tell me the actual records of analysis carried out for past 3 years?

2) It is said that other departments or agencies such as Department of Trade Industry have the inspection regime for exported agricultural products. Please tell me these regulatory system and actual inspection results.

3) DOA intend to introduce or establish inspection system for export agriculture products. What kind of planning will DOA take into consideration?

With respect to pesticide dairy intake survey (market basket method)
(1) Have you carried out "pesticides intake survey based on market basket method?"
If you have, please tell me the method, recent actual records and how to practical use of the data obtained.

4. With respect to analysis for pesticide residues in agricultural products

(1) What kind of pesticides and analytical methods have you introduced and will you introduce to detect pesticide residues in agricultural products?

(2) It is necessary to set up multi-analytical method for pesticide residues in agricultural products in order to conduct inspection effectively and efficiently. Have you introduce multi-analytical method? Please tell me the method and recent analysis records if you have.

(3) What kind of materials such as reagents and organic solvents can you and will you be able to obtain?

#### **SYSTEMS OF FOOD SANITATION**

1. Yes, based on FAO Guidelines on Supervised Residue Trials and ADI of CODEX.

(In cases where scientific evaluation is conducted)

1.1 Before any pesticide is registered and sold, it should have local residue data or data conducted within the same tropical climate.

1.2 Usually, toxicological data conducted abroad are accepted - only bioefficacy data are required locally. For new pesticide/new usage, local residue data is required. Data for specific disciplines are evaluated by the following, experts:

a) Toxicology data - Pharmacologist/Toxicologist/Medial Doctor

b) Environmental Fate & Residues - Pesticide Toxicologist & Environment Chemist

c) Bioefficacy - Entomologist/Weed Scientist/Plant Pathologist

d) Product and Technical Specifications - Analytical Chemist

2. A regular sustainable budget and laboratory and manpower upgrading

3. Survey - per capita consumption/food group/region

2. INSPECTION SYSTEM

2.1 In case MRL is exceeded, FPA will prevent the entrance of such. On local produce exceeding MRL, such will be advised to delay harvest. Also, to show that washing, cooking and other procedures will reduce residues.

## 附属資料砂

## 語 集

略

Abbreviation	Word
ADB	Asian Development Bank
ADI	Acceptable Daily Intake
AOAC	Association of Official Analytical Chemists
APC	Agricultural Promotion Center
AT	Agricultural Technologist
ATI	Agricultural Training Institute
BANGON	Bohol Alliance of Non-Government Organizations
BAS	Bureau of Agricultural Statistics
8FAD	Bureau of Food and Drug
BHIP	Bohol Irrigation Project
8PI	Bureau of Plant Industry
BSWM	Bureau of Soils and Water Management
CA	College of Agriculture
CAIP	Certificate Authorizing Importation of Pesticide
CDA	Cooperatives Development Authority
CENVIARC	Central Visayas Integrated Agricultural Research Center
CEOH	Center for Environment and Occupational Health
CIP	Capayas Irrigation Project
СРАР	Crop Protection Association of the Philippines
СРН	Collage of Public Health
DA	Department of Agriculture
DAS	Days after sowing
DAT	Days after Transplanting
DENR	Department of Environment and Natural Resources
DOH	Department of Health
DOLE	Department of Labor and Employment
DOST	Department of Science and Technology
DS	Dry Season
ECD	Electron Capture Detector
EMB	Environment Management Bureau
ETL	the Economic Threshold Level
FAO	Food and Agriculture Organization
FDC	Food Development Center
FNRI	Food and Nutrition Research Institute
FPA	Fertilizer and Pesticide Authority
FPD	Flame Photometric Detector
FTC	Farmers Training Center
GAP	Gintong Ani Program
GC	Gas Chromatograph
GDP	Gross Domestic Products
GLH	Green Leafhopper

 $\{ \cdot, \cdot \}_i$ 

\$

Abbreviation	Word
GO	Government Organization
GPEP	Grains Production Enhancement Program
HPLC	High-Performance Liquid Chromatograph
HYV	High Yielding Variety
tA	Irrigator Association
IADCCO	the International Agricultural Development Cooperation Coordinating Office
ICC	Investment Coordinating Committee
IDO	Institutional Development Officer
IPB	Institute of Plant Breeding
IPM	Integrated Pest Management
IBRI	International Rice Research Institute
KCCDP	Key Commercial Crop Development Project
KGA	Key Grains Area
LGU	Local Government Unit
LSA	Laboratory Service Division
MAO	Municipal Agricultural Offier
MPDP	Multipurpose Drying Pavement
MRL	Maximum Residue Limit
NAPHIRE	National Post Harvest Institute for Research and Extension
NCPC	National Crop Protection Center
NCRDC	National Crop Research Development Center
NEDA	National Economic and Development Authority
NFA	National Food Authority
NIA	National Irrigation Administration
NPD	Nitrogen Phosphorus Detector
NSRI	Natural Sciences Research Institute
NTC	National Training Center
OPA	Office of the Provincial Agriculturist
OSHC	Occupational Safety and Health Center
PAC	the Program Advisory Council
PAFCO	Provincial Agricultural and Fisheries Council
PAL	Pesticide Analysis Laboratory
PAO	Provincial Agricultural Officer
PCC	Philippine Carabao Center
PD	Presidential Decree
PHI	Pre Harvest Interval
PhilRice	Philippine Rice Research Institute
PMC	the Program Management Coouncil
PO	People's Organization
PSB	Philippine Seed Board
PTAC	Pesticide Technical Advisory Committee

Abbreviation	Word	
PTAC	Provincial Training Advisory Council	]
ΡΤΙΑ	Provincial Technical Institute of Agriculture	
RFU	Regional Field Unit	
RIARC	Regional Integrated Agricultural Research Center	
RIC	Rural Improvement Clubs	
ROS	Research Outreach Station	
RTC	Regional Training Center	
RTV	Rice Tungro Virus	
SFR	Small Farm Reservoir	
SOP	Standard Operation Procedure	
STW	Shallow Tube Well	
UMMB	Urea Molasses Mineral Block	
UP	University of the Philippines	<u> </u>
UPCM	UP College of Medicine	
UPCPH	UP College of Public Health	
UPLB	University of the Philippines Los Banos College	[
UPLBCA	University of the Philippine Los Banos, College of Agriculture	
USF	Ubay Stock Farm	
WHO	World Health Organization	
WS	Wet Season	

. . .

