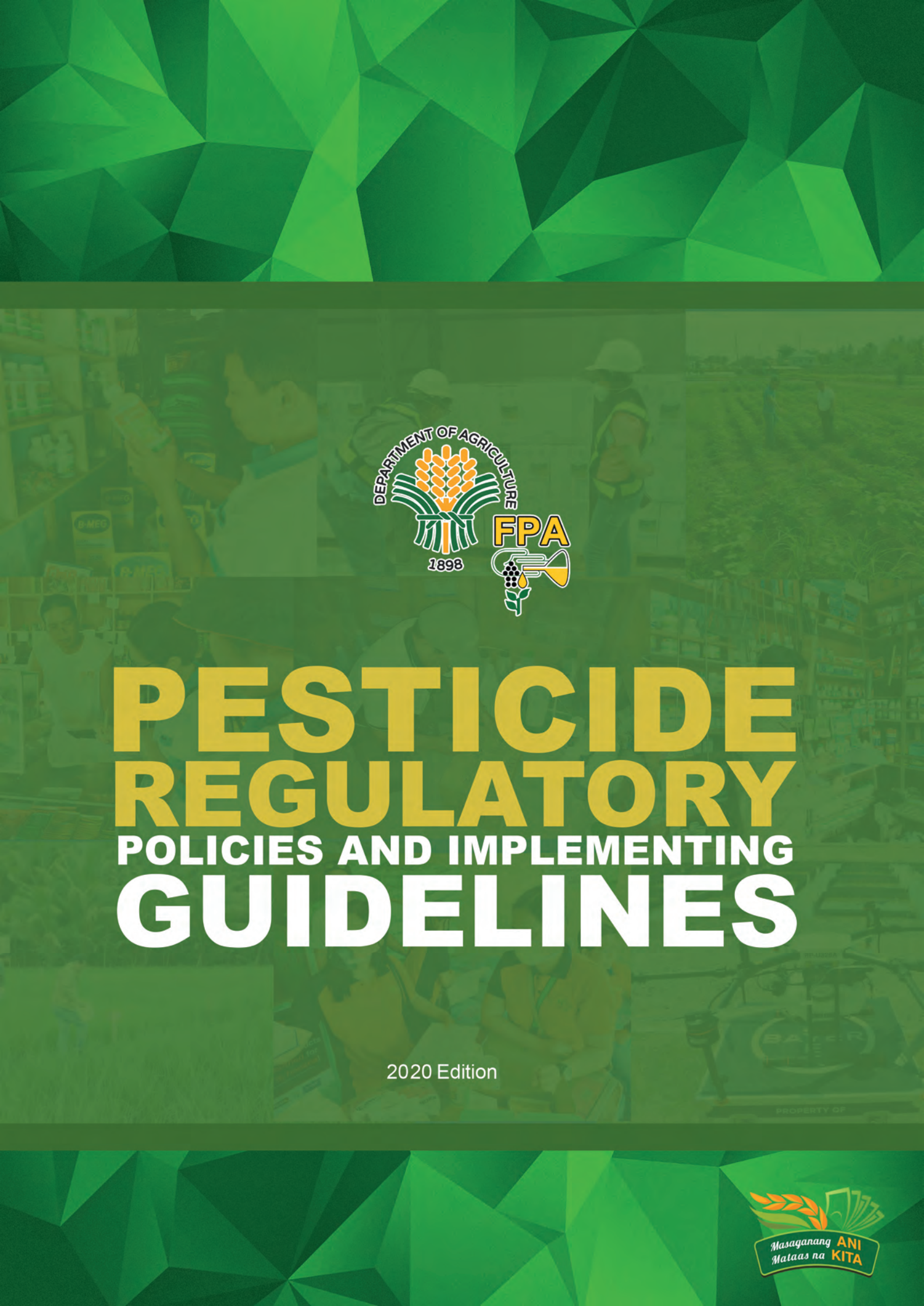



# PESTICIDE REGULATORY POLICIES AND IMPLEMENTING GUIDELINES

2020 Edition

Masaganang ANI
Mataas na KITA

# Pesticide Regulatory Policies and Implementing Guidelines

## PESTICIDE REGULATIONS DIVISION

FERTILIZER AND PESTICIDE AUTHORITY

# Pesticide Regulatory Policies and Implementing Guidelines


**Pesticide Regulations Division**

FERTILIZER AND PESTICIDE AUTHORITY

BAI Compound, Visayas Avenue
Diliman, Quezon City


*Third Edition*

**2020**

## TABLE OF CONTENTS

## LIST OF FIGURES

## LIST OF TABLES

## LIST OF ANNEXES

# MESSAGE FROM THE EXECUTIVE DIRECTOR

Kudos to the Pesticide Regulations Division (PRD) for competently leading the revision of the Pesticide Regulatory Policies and Implementing Guidelines! Your efforts have finally come to fruition after more than a year of meticulous and tireless work.

As a technical regulatory agency, one of our mandates is to eliminate the health and environmental risks inherent in the use of pesticide products. Updating these guidelines is also way of ensuring that we contribute to the food safety campaign by the Department of Agriculture (DA) and the Food and Administration Organization (FAO), through our strengthened monitoring and enforcement activities to ensure that pesticides are efficient and meet the farmer's expectations.

The release of this new edition 2020 makes it possible for us to cover regulatory requirements imposed by innovations in agricultural systems and practices like the use of drones for pesticide spraying, and updates on the inclusion of newly banned or restricted pesticides.

But most of all, the revision would not be possible without the invaluable inputs from the industry stakeholders, academe, technical experts, and pesticide handlers who actively participated in the public consultations. I am proud to say that this is not the work FPA but a product of a FPA-industry-academe partnership in our continuing effort to eliminate the health and environmental risks inherent in the use of pesticide inputs.

I hope that the changes reflected herein address the needs of our pesticide handlers in the country as we gear towards a more sustainable agriculture and food-secure Philippines.

**WILFREDO C. ROLDAN**
**Executive Director**

# ACKNOWLEDGMENTS

We wish to extend our heartfelt gratitude to the Pesticide Policy and Technical Advisory Committee (PPTAC), composed of experts from the government and non-government organizations, which serves as the body the FPA consults in terms of technical inputs and recommendations for the revision of the Pesticide Regulatory Policies and Implementing Guidelines.

Further, the development of these guidelines could not have been possible without the valuable assistance from the officials and members of the Crop Protection Association of the Philippines (CPAP), Croplife Philippines, and Philippine Integrated Crop Management Association, Inc. (PICMA).

We extend our heartfelt gratitude to the members of the FPA Board headed by Agriculture Secretary William Dar who serves as the Chairperson, and the members composed of Undersecretary Rolando Enrique Domingo, Administrator of the Food and Drug Administration; Hon. Ramon M. Lopez, Secretary of the Department of Trade and Industry; Hon. Benjamin E. Diokno, Governor of Banko Sentral ng Pilipinas; Hon. Metodio U. Turbella, Director of the DENR- Environment Management Bureau; Hon. Carlos G. Dominguez III, Secretary of Department of Finance; Hon. Arculfo Z. Veloso, President of the Philippine National Bank; and, Hon. George Y. Culaste, Director of the Bureau of Plant Industry.

We proudly commend FPA employees for their unwavering dedication and commitment to making this Guidebook possible. We give our great thanks to Engr. Jacqueline M. Romualdez, OIC-Chief of the Pesticide Regulations Division (PRD), Executive Director Wilfredo C. Roldan, Deputy Executive Director for Pesticide Mr. Eric C. Divinagracia, Acting Deputy for Fertilizer Mr. Antonio G. Cruz, all staff of PRD, Finance and Administration Chief Ms. Elizabeth T. Ramiro, Planning, Management and Information Division Chief Ms. Digna M. De Leon and her team.

To all those whom we failed to mention, kudos to all of us!

Above all, this will not be complete without the providence of the Divine Being.

PESTICIDE REGULATIONS DIVISION

# PREFACE

This 3rd (2020) edition of the “PESTICIDE REGULATORY POLICIES AND IMPLEMENTING GUIDELINES”, introduces new provisions on the issuance of Experimental Use Permits (EUPs), product labelling requirements, procedures on the disposal of pesticide containers, and FPA acceptance of third-party authorizations (TPA).

The book features eight (8) chapters namely:Mandate and Structure of the Fertilizer and Pesticide Authority Pertaining to Pesticide Regulation (Chapter I); Registration of Chemical Pesticides (Chapter II); Policy Guidelines on Biorational Pesticides (Chapter III); Licensing, Certification and Accreditation of Pesticide Handlers (Chapter IV); Product Stewardship and Responsible Care (Chapter V); Post- Registration Activities (Chapter VI); Penalties for Violations (Chapter VII); and Miscellaneous Provisions and Requirements (Chapter VIII). It basically presents pesticide regulatory requirements, procedures, and processes, and defined technical terminologies for these to be understood.

This document may serve as a guide for all pesticide handlers in their registration requirements and operational activities in the Philippines. The over-riding objective is to streamline and make more practical the regulatory process in line with basic principles and international guidelines contained in relevant documents issued by FAO, WHO and US-EPA. Additional groups likely to be interested in this guidebook are other government agencies, environmentalists, academics, and NGOs.

The revision of the guidelines is the result of the series of meetings, including consultations with the different stakeholders. The lessons learned from the past especially on registration procedures and requirements have been the bases of several changes in these guidelines.

Interestingly, the second edition of these guidelines came out in December 2001. After about eighteen years of implementation, a number of problems had cropped up concerning the practicality and/or ambiguity of some of its provisions, certain difficulties encountered by the Authority in pursuing its mandate, as well as in coping with the rapid changes and development in the pesticide industry.

Regulatory activities are still considered to be the most feasible and practical option for ensuring a balance between the benefits and risks of pesticide use in developing countries like the Philippines. The revised policies aim to do just that. These proposed policies, however, would be meaningful only if the following requisites are in place: a proper structure for effective regulation; a responsible pesticide industry; and an educated populace.

# *Chapter 1*

# *MANDATE AND STRUCTURE OF THE FERTILIZER AND PESTICIDE AUTHORITY PERTAINING TO PESTICIDE REGULATION*

## 1.1 MANDATE AND FUNCTIONS OF THE FERTILIZER AND PESTICIDE AUTHORITY

Created under Presidential Decree No. 1144 on May 30, 1977, the Fertilizer and Pesticide Authority (FPA) is a technically-oriented agency mandated to regulate and ensure safety in the manufacture, formulation, importation, distribution, storage, sale, transport, use and disposal of pesticides and fertilizers to ensure their adequate supply among crop growers and other end-users to support the food security program of the country. It is also mandated to develop both the fertilizer and pesticide industries.

Specifically, to ensure the safe use of pesticides and protect human and animal health and the environment from any detrimental effects of pesticides, FPA is vested with the following powers and functions, as described in Section 6 (I) and (III) of PD 1144;

### I. Common to Fertilizers, Pesticides, and Other Agricultural Chemicals

1. To conduct information campaign regarding the safe and effective use of these products;

2. To promote and coordinate all fertilizer and pesticide research in cooperation with the Philippine Council for Agriculture and Resources Research and other appropriate agencies to ensure scientific pest control in the public interest, safety in the use and handling of pesticides, higher standards and quality of products and better application methods;

3. To call upon any department, bureau, office, agency or instrumentality of the government, including government-owned or controlled corporations, or any officer or employee thereof and on the private sector, for such information or assistance as it may need in the exercise of its powers and in the performance of its functions and duties;

4. To promulgate rules and regulations for the registration and licensing of handlers of these products, collect fees pertaining thereto, as well as the renewal, suspension, revocation, or cancellation of such registration or licenses and such other rules and regulations as may be necessary to implement this Decree;

5. To establish and impose appropriate penalties on handlers of these products for violations of any rules and regulations established by the FPA;

6. To institute proceedings against any person violating any provisions of this Decree and/or such rules and regulations as may be promulgated to implement the provisions of this Decree after due notice and hearing;

7. To delegate such selected privileges, powers or authority as may be allowed by law to corporations, cooperatives, associations or individuals as may presently exist or be organized to assist the FPA in carrying out its functions; and

8. To do any and all acts not contrary to law or existing decrees and regulations as may be necessary to carry out the functions of the FPA.

xxxx xxxx xxxx

**III. Pesticides and Other Agricultural Chemicals**

1. To determine specific use or manners of use for each pesticide or pesticide formulation;

2. To establish and enforce tolerance levels and good agricultural practices for use of pesticides in raw agricultural commodities;

3. To restrict or ban the use of any pesticide or the formulation of certain pesticides in specific areas or during certain periods upon evidence that the pesticide is an imminent hazard, has caused, or is causing widespread serious damage to crops, fish or livestock, or to public health and environment;

4. To prevent the importation of agricultural commodities containing pesticide residues above the accepted tolerance levels and to regulate the exportation of agricultural products containing pesticide residues above accepted tolerance levels;

5. To inspect the establishment and premises of pesticide handlers to insure that industrial health and safety rules and anti-pollution regulations are followed;

6. To enter and inspect farmers' fields to ensure that the recommended pesticides are used in specific crops in accordance with good agricultural practices;

7. To require, if and when necessary, of every handler of these products, the submission to the FPA of a report stating the quantity, value of each kind of product exported, imported, manufactured, produced, formulated, repacked, stored, delivered, distributed, or sold; and

8. Should there be any extraordinary and unreasonable increases in prices, or a severe shortage in supply of pesticides, or imminent dangers or either occurrences, the FPA is empowered to impose such controls as may be necessary in the public interest, including but not limited to, such restrictions and controls as the imposition of price ceilings, controls on inventories, distribution, and transport, and tax-free importations of such pesticides or raw materials thereof as may be in short supply."

## 1.2 ORGANIZATIONAL STRUCTURE

Structurally, the powers and functions of FPA is vested and exercised by a Board of Directors with the Secretary of Agriculture as Chairman of the Board. It has eight members who are mostly members of the Cabinet of the President of the Philippines like the Secretary of Finance, Secretary of Trade and Industry, Governor of Bangko Sentral ng Pilipinas, and others.

Administratively, FPA is run by an Executive Director/Administrator who is assisted by two Deputy Executive Directors/Deputy Administrators and other subordinate officials. The FPA is empowered to determine and create its organizational structure in order to achieve its objectives, including the number, positions and salaries of its officers and employees.

In pursuing its mandates on pesticide regulation, FPA has established a pool of scientists and technical consultants in various aspects of pesticide regulations like pesticide manufacture, registration, licensing, and others. FPA created the Pesticide Policy and Technical Advisory Committee (PPTAC). The Committee is a recommendatory body, which can be assigned to study various issues and problems related to pesticide regulation and other matters. PPTAC Members are recognized scientists/experts in their professional fields. These include Entomologists, Plant Pathologists, Nematologists, Weed Scientists, Mammalian Toxicologists, Occupational Health and Safety Specialists, Environmentalists (Ecologists), Residue Chemists, Food Development Specialists, Economists, and others.

Aside from PPTAC, FPA has also created a group of Pesticide Registration Consultants (PRC) to specifically study and evaluate scientific/technical data on pesticides submitted for registration. To address the growing concern on pesticide residue on food, feeds, and the environment, FPA formed the Committee on Pesticide Product and Residue Assessment Program (CPPRAP) to work on residue monitoring, laboratory networking, and the development of protocol for laboratory accreditation. As the need arises, FPA can also create study committees, ad hoc committees and sub-committees to address specific problem areas in pesticide regulation.

# *Chapter 2*

# *REGISTRATION OF CHEMICAL PESTICIDES*

## 2.1 GENERAL INFORMATION

### 2.1.1 Legal Basis

Pursuant to Section 9 of PD 1144 and Article II, Sec. 1 of FPA Rules and Regulations No. 1, Series of 1977, all pesticides intended for commercial use in the Philippines shall be registered with the Fertilizer and Pesticide Authority.

> "x x x x Separate registrations shall be required for each active ingredient and its possible formulations in the case of pesticides ……x x x x" (Section 9, PD 1144).
>
> "No pesticide shall be imported, manufactured, formulated, repacked, distributed, delivered, sold or offered for sale, transported, delivered for transportation, or used unless it has been duly registered with the Authority or covered by a numbered provisional permit issued by the Authority for use in accordance with the conditions stipulated in the permit. Separate registration shall be required for each brand and formulation of pesticides" (Article II, Sec. 1, FPA Rules and Regulations).

### 2.1.2 Pesticide Definition

Considering the definition stated in PD 1144, the term pesticide means any substance or product, or mixture thereof, including active ingredients, adjuvants and pesticide formulations, intended to control, prevent, destroy, repel or mitigate directly or indirectly, any pest. It shall be understood to include insecticide, fungicide, bactericide, nematicide, herbicide, molluscicide, avicide, rodenticide, plant regulator, defoliant, desiccant and the like.

### 2.1.3 Purpose of Registration

The purpose of the registration system is to ensure that pesticide products meet the prescribed standards before they are imported, manufactured, formulated, distributed and sold in the Philippines.

The standards are set by the FPA and cover the following aspects:

1. Quality and suitability of the active ingredient and of the formulated products
2. Bioefficacy
3. Safety to handlers
4. Safety to consumers or users
5. Safety to the environment
6. Handling, packaging, labelling and disposal

The system is a stringent process of evaluation with the end point that benefits outweigh the risks in the use of the product.

### 2.1.4 Classification of Pesticides for Registration Purposes

For purposes of registration, pesticides are grouped based on their nature and use pattern.

*A. Chemical Pesticides*

1. Agriculture/Home Garden/Turf Use

    a. Insecticide
    b. Fungicide
    c. Herbicide
    d. Rodenticide
    e. Avicide
    f. Nematicide
    g. Bactericide
    h. Molluscicide
    i. Acaricide (miticide)
    j. Piscicide

2. Other Chemical Pesticides
   (used as is or in combination with others in the formulation)

    a. Growth regulator
    b. Defoliant
    c. Desiccant
    d. Systemic activator of resistance
    e. Wood preservative
    f. Surfactant/Adjuvant
    g. Emulsifier, wetting agent, penetrant, synergist
    h. Manufacturing/Intermediate products
    i. Agricultural disinfectant

*B. Biorational Pesticides*

1. Biochemical pest control agents

    a. Semiochemical (pheromone, kairomone, allomone)
    b. Hormone
    c. Natural plant regulator (auxin)
    d. Enzyme

2. Microbial pest control agents

    a. Bacterium
    b. Fungus
    c. Protozoa
    d. Virus

3. Plant-incorporated protectants (PIP)

    a. Single
    b. Combined/ Stacked

### 2.1.5 Types of Products to be Registered

The types of products to be registered include the following:

*A. New End Use Product or Formulation*

This type of application includes the following:

1. New End-Use Product or Formulation Containing new or currently registered active ingredient.

2. New End-Use Product or Formulation Combination products containing:

    a. New active ingredients and currently registered active ingredients
    b. Currently registered active ingredients

*B. Modification in the Registration of a Registered Product*

The following type of modification shall require conduct of local bioefficacy trials and/or SPRT (Supervised Pesticide Residue Trial) to support the proposed changes in the registration.

1. Extension of use or claim
2. Change in rate, timing or frequency of application
3. Amendments to establish Maximum Residue Limit
4. Change in withholding period or pre-harvest interval
5. Change in method of application

A Material Safety Data Sheet (MSDS) shall be submitted if the modification involves the potential occupational health and safety hazards.

*C. Registered Pesticides with Changes in Formulation*

The following changes shall require submission of local bioefficacy data, specifications, and MSDS, upon proof that the change does not bring about any significant difference in toxicology and residue.

1. Change in percentage of active ingredient in formulation
2. Change in inerts (solvents and surfactants) and type of formulation

*D. New Technical Grade Active Ingredient or a New Source*

If there is a change in the manufacturing process resulting in the change of concentration of a registered active ingredient of the technical grade, the concerned company shall notify FPA of the amendment of registration.

If there is a change in the source of a registered technical grade active ingredient, the new source shall be registered.

*E. Permit for an Off-Label Use of Pesticide*

Permit may be sought for use of an unregistered product or use of a registered product other than indicated on the label in emergency cases such as pest outbreaks or disease/epidemic or when important, minor use arises where the cost of registration would exceed economic return to the registrant.

Application for an off-label use permit shall be evaluated on its merit based on the information submitted and may be granted for the duration of the emergency period or a period of one year for minor uses to generate efficacy data for label expansion.

Off-label use permit may be amended or withdrawn by FPA in case the particular minor use has caused adverse health, environmental or efficacy implications.

### 2.1.6 Types of Registration

There are two types of registration granted: full and conditional.

A. Full Registration is granted when the applicant has satisfactorily completed all the requirements regarding bioefficacy, protection of the environment, safety to humans and animals. A certificate of registration is issued to the applicant.

B. Conditional Registration is granted upon satisfaction of the minimum requirements or conditions as described below. A status report of conditional registration with the product registration number is issued to the applicant. Registration is granted but without quantity restrictions. Stipulations to be met and a schedule must be agreed to by the applicant as a condition for registration.

If there are gaps in data such as the long-term studies, but interim progress reports are available, registration shall be granted subject to an agreement to complete the studies and on their acceptability in terms of quality and indication of safety. Other conditions, such as limiting the quantity of importations of the product or areas to be treated, may be imposed as well.

For new proprietary product being registered which merited conditional registration status, health monitoring and exposure study shall be conducted on a case-to-case basis, depending on the use pattern and dermal toxicity of the product.

Foreign data can be submitted, and if not available, assessment of exposure risk based on established calculation model can be submitted to support registration.

*Conversion to Full Registration.* A conditional registration may be converted into a full registration within one year when conditions and requirements have been met satisfactorily. No renewal/extension of conditional registration shall be granted except in cases of force

majeure or fortuitous events and/or where the efficacy trials of other tests require a devotion of more than one year.

Failure to meet requirements agreed upon for a Conditional Registration is a ground for suspending the registration.

### 2.1.7 Miscellaneous Regulations

FPA may register commodity products on another registrant's data or on the basis of international reviews (after data protection period) provided the product is identical or substantially similar to any currently registered pesticide, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects. This determination involves an examination of the registrant's product and a comparison with the composition of currently registered products. Appendix A, Annex 2, of the FAO Manual on Development and Use of FAO Specifications for Plant Protection Products (Annex I) will serve as a guide for comparison.

The registration of pesticides belonging to toxicity Category I is presently suspended pending further review. Toxicity/Hazard Category I has an acute oral $LD_{50}$ (rat) of 50 mg/kg body weight or less for solid and 200 mg/kg b.w. or less for liquid and a dermal $LD_{50}$ (rat) of 100 or less for solid and 400 mg/kg b.w. or less for liquid, based on FPA Memo Circular No. 03, Series of 1988.

Pesticides belonging to this category not covered by the moratorium nor banned but with existing approved registration and uses with FPA cannot be expanded on their usage or increase the number of registration owners. However, further bioefficacy test shall be required if the objective is to reduce the final spray concentration usage and the amount of active ingredient per hectare.

After registration consultants review the data, new application for registration of pesticides belonging to toxicity/ hazard Category II shall be subjected to further evaluation by PPTAC.

Registration of less toxic and environment-friendly chemicals and biorational pesticides is being encouraged.

For purposes of these guidelines all provisional registrations granted to pesticides on or before the promulgation of PD 1144 in May 1977 are revoked and no new provisional registration shall be granted.

FPA reserves the right to suggest a change in the name of the pesticide product before registering it or before renewal of registration. Phase-out period for questionable trade/brand name shall coincide with the three (3) year validity period of a product registration. Use of different trade/brand name for pesticide product with exactly the same formulation for the same usage by the same registrant shall not be allowed also.

***Naming/Branding of Pesticide Products***

Trade name of a pesticide product acceptable for registration shall:

A. not be misleading to the public;

B. not be the same as other toxic products as certified by Bureau of Trade;

C. not be the same as any food item;

D. not be offensive to any cultural group; and

E. not misrepresent something.

***Registration of Mixtures of Two or More Pesticides***

Mixtures of pesticides shall be registered in the same manner as any pesticide product. The evaluation, however, including the number and types of allowable combinations of active ingredients, shall be on a case-to-case basis, with particular emphasis on toxicological and efficacy considerations. In addition, the following specific conditions shall apply:

A. The following mixtures shall not be allowed:

1. Fertilizer and pesticide combinations. While these formulations ostensibly cut down on the labor input for application, it may also encourage the unnecessary use of a pesticide.

2. Mixtures of different types of pesticides e.g. insecticides + fungicides; herbicides + fungicides, etc.

B. Valid comparative field trials must prove significantly increased efficacy of the mixture over each of the individual components.

C. In addition to the toxicity data for each individual active ingredient, acute toxicological data for the mixture as well as potentiation studies may be required.

## 2.2 APPLICATION FOR REGISTRATION

Any person, juridical or individual, may file an application for registration of a pesticide which must be in the prescribed form containing all the data and information prepared under oath. The proprietary nature of the data shall be protected by the FPA.

Only local companies registered by the Securities and Exchange Commission (SEC) to do business in the Philippines and duly licensed by FPA may apply for registration of pesticide products. For purposes of these guidelines, a local company is a juridical person created under the Philippine Law and licensed to do business in the country. Companies operating in the Philippines under PD 218 are excluded in this definition. Foreign suppliers or companies registered under the SEC as regional liaison offices (PD 218) are not allowed to register products. In practice, the applicant or registrant shall be the distributor or the local subsidiary of a foreign-based pesticide company.

### 2.2.1 Procedure

A separate application shall be filed for each formulated product and active ingredient as well as for each source of the active ingredient. When a formulation has two or more active ingredients, registration shall be applied for each active ingredient. Only one source of active ingredient shall be applied/approved at a time.

A complete application, submitted in duplicate consists of:

1. Form for Registration of an Active Ingredient (P-012), Registration of a Pesticide Product (P-022)

2. Complete data required to support registration particularly Table 2. on Data Requirements, with a certification that they comply with good laboratory practices (GLP) and standard test protocols.

3. Summary of data with proper citation and an applicant's assessment of how these data support registration.

4. Proof of registration in other countries where relevant.

5. Proposed product label.

6. A sample of the material to be registered shall be submitted prior to registration. The following must accompany an application: 1 g Analytical Grade of the Active Ingredient(s), 10 g Technical Grade material; and 500 mL or 0.500 Kg of the formulation. The percentage purity of the technical grade and the method used to determine purity should be provided. Information on the shelf life of the analytical and technical grades should be submitted together with the Material Safety Data Sheet and Certification of the origin of samples. Samples submitted to FPA shall be stored and handled properly for future needs of government institutions.

7. Certificate of analysis of active ingredient, both analytical grade or technical material, and the formulated product.

8. Reviews of data done by other countries and international organizations especially US-EPA and European Union if available.

9. Any authorization necessary to cite previously submitted data.

10. Data must be submitted in size 8 1/2 x 11 paper or A4, indexed and bound separately, following the format below:

| Section | Data / Relevant Documents | Format |
|---|---|---|
| N/A | Letter of Intent<br>(addressed to the agency's Executive Director) | Must be found in each folder |
| N/A | Notarized Application Forms<br>(with documentary stamp) | |
| N/A | Proposed Product Label | |
| 1.0 to 8.0 | Summary of Data (with proper citation) | |
| 1.0 | General Information | Merge in Folder 1 |
| 2.0 | Specifications | |
| 3.0 | Bioefficacy | Folder 2 |
| 4.0 | Toxicology | Folder 3 |
| 5.0 | Human Exposure and Safety | Folder 4 |
| 6.0 | Environmental Effects | Merge in Folder 5 |
| 7.0 | Residue<br>(including SPRT protocol, if applicable) | |
| 8.0 | Environmental Fate and Transport | |
| N/A | Copy of approved Experimental Use Permit(s) | Include in Folder 2 |

Any additional data required shall also be submitted as prescribed. Submissions that do not follow these requirements shall not be accepted.

Filing fee for each active ingredient/pesticide product shall be paid upon submission of the application.

### 2.2.2 Steps in Processing an Application

All applications received shall be screened for completeness by the designated Registration Coordinator within one (1) week. If found incomplete, it will not be processed but returned to the applicant. The complete application shall then be entered into the registration tracking system and the applicant shall be notified.

The complete data sets shall be sent to the respective consultants for evaluation/assessment. For commodity products, the maximum time for evaluation shall be three (3) months. For proprietary products, simultaneous evaluation of specifications, bioefficacy and residue/fate in the environment shall be three (3) months while that of toxicology will be nine months.

Consultants' evaluation reports shall be consolidated and reviewed by FPA within a period of three (3) weeks. If the evaluation is satisfactory, notice of approval of registration shall be sent to the applicant.

If the evaluators have some questions on the data submitted or require other information on the product, a status report or registration indicating these concerns shall be sent to the applicant. The applicant shall be given reasonable time to resubmit this information. Resubmitted data shall be sent to the original reviewers for evaluation whenever possible.

Products of hazard Category II pesticides or those that have questionable data or issues which the evaluator recommended for further review is referred to PPTAC for resolution.

The steps in processing application for EUP and registration are presented in Figure 1.

### 2.2.3 Estimated Timetable for Review Process

*A. Commodity Products*

Final registration status report shall be made available in three (3) to six (6) months after submission. During this period, an evaluation status report or an interim report shall be given to the applicant after one month from date of submission.

*B. Proprietary Products*

Two sets of procedures shall be followed depending on whether these products are (1) currently registered in the developed countries (USA, Germany, Japan, etc.); or (2) registered and commercialized in the region as per FAO guidelines.

For products in the first case, final registration status report shall be made available within twelve (12) months after submission. During this period, a quarterly evaluation report or an interim report shall be provided to the applicant.

For products in the second case, final registration status report shall be made available within six (6) months after submission. During this period, an evaluation status report or an interim report shall be given to the applicant after three (3) months from date of submission.

In other cases, status shall be available within one (1) month after receipt of application.

Applicant shall be given an opportunity to submit any additional information relevant to the problems at this stage. If FPA believes that the issues may be resolved through a replacement study, the application shall be referred back to the initial reviewer/evaluator.

If the results indicate significant scientific or technical issues, the applicant shall be notified of the problem and of the proposed method of resolution, e.g., PPTAC referral, management policy review, consultation with other registering countries or international review group(s). These issues shall be communicated to the registrant in an evaluation status report after which the registration time for the product is stopped. Registration time is resumed after the applicant has resubmitted data resolving the problems/issues raised by the registration consultant/evaluator.

Problems/issues involving critical decisions may be referred to the PPTAC for review. When this referral is made, the applicant shall be advised of the status within forty five (45) days. A report of the review shall be provided to the applicant whenever appropriate.

FPA shall prepare a status report every three (3) months on the basis of the Registration Tracking System and shall be stated in terms of the following:

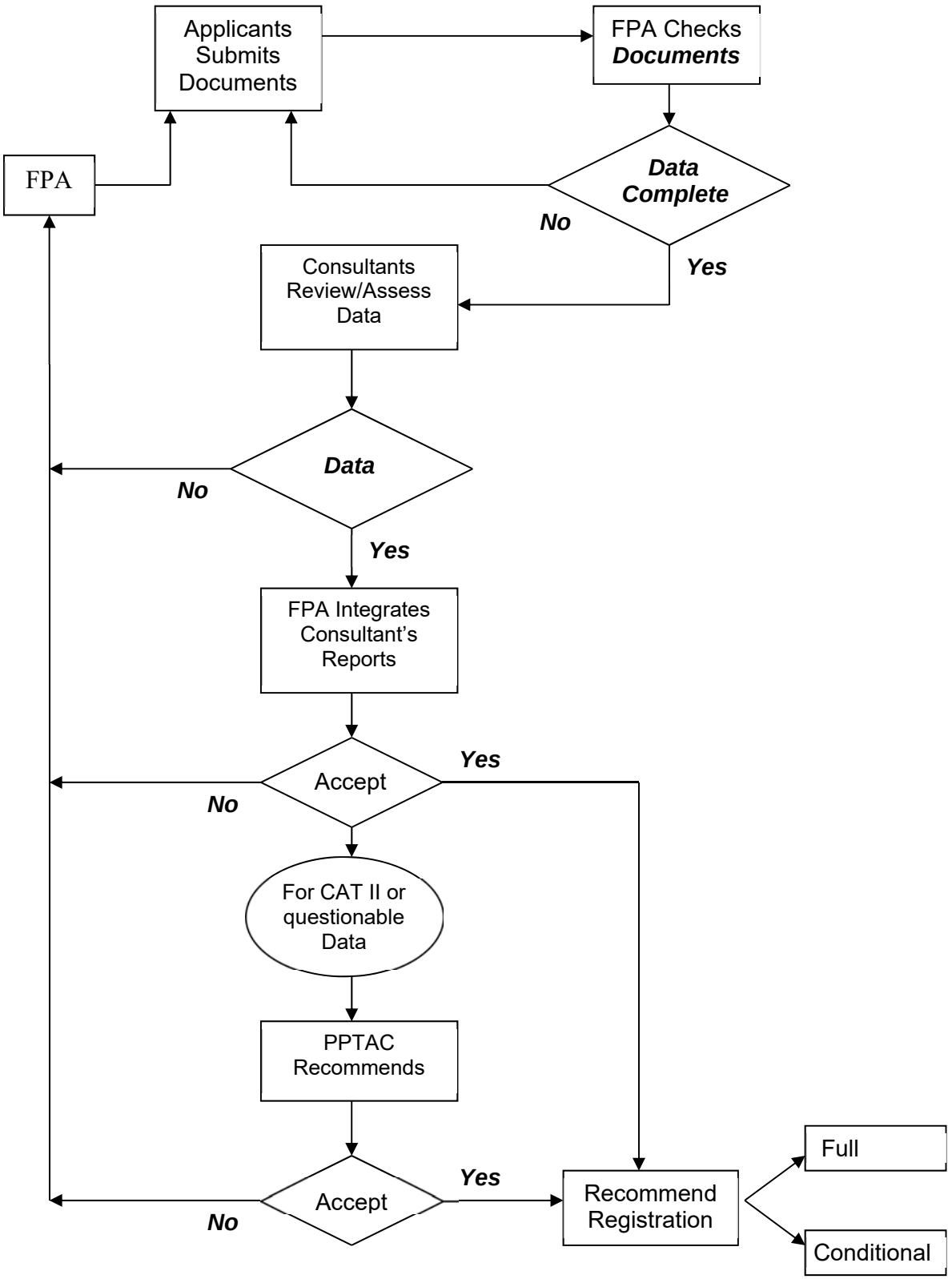
1. In-progress with evaluators/reviewers/PPTAC;

2. Needing replacement/additional data; and

3. Application denied specifying the reasons. Deficiencies or other reasons for denial shall be communicated.

   **Note:** The applicant may apply for reconsideration. Submission of required data shall be within six (6) months after receipt of the official denial. Otherwise it shall be treated as a new application.

**Figure 1. SCHEMATIC DIAGRAM OF THE PESTICIDE PRODUCT REGISTRATION PROCESS**



### 2.2.4 Period of Validity and Renewal of Registration

Pursuant to Art. II, Sec. 6 of the FPA Rules and Regulations, each registration shall be valid for a period of three years, unless earlier revoked or cancelled.

Renewal of registration may be filed three (3) months before its expiry date by paying the appropriate fees and submitting two (2) copies of notarized application form, Material Safety Data Sheet and label.

Application for renewal filed within one (1) month after expiry date of its registration shall be subjected to 50% surcharge while those filed after the said period shall be subjected to a 100% surcharge. Similarly, a separate application for renewal shall be filed for each formulated product and active ingredient.

### 2.2.5 Re-Registration and Renewal Requirements

A. When warranted by occurrence of the development of resistance, unacceptable levels of residues in the field, or other toxicological concerns, a registered product shall be reviewed for purposes of re-registration/renewal. The registrants shall be required to conduct monitoring studies on product performance, supervised residue field trials and/or submit the required toxicological data to FPA.

B. If registration of the product is not renewed, sale shall be stopped immediately and the product shall be recalled within six (6) months at the expense of the registrant.

### 2.2.6 Fees

Fees for filing registration, resubmission, and renewal are indicated in Table 1 and the same shall be subjected to review from time to time.

### 2.2.7 Maintenance of Official FPA Lists of Registered Products and Uses

FPA will maintain a “List of Registered Products” which will be updated and released quarterly for use by field coordinators. FPA will also maintain an updated “List of Registered Use Pattern.” These lists are available at FPA’s official website.

## 2.3 DATA REQUIREMENTS FOR REGISTRATION AND EXPERIMENTAL USE PERMIT

### 2.3.1 General Information

This Section spells out the data that must be submitted with an application for registration or Experimental Use Permit (EUP). The data requirements are specified based on whether the product is a formulation or an active ingredient. The data required for an EUP is a sub-set of the

requirements for registration and these are indicated in Table 2 which summarizes these data requirements.

Special circumstances often arise from the nature of a pesticide or its use or the results of testing which dictate whether more, less, or different data are required. FPA shall make modifications whenever appropriate and necessary.

All data shall be of sufficient scientific quality and reliability to answer questions of safety and efficacy without doubt or uncertainty. Studies done in compliance with good laboratory practices (GLP) such as those of OECD, US FDA or EPA and in consonance with acceptable test protocols shall stand the best chance of meeting the standard. Deficient or invalid studies can be sufficient grounds to deny an application and/or to require a replacement study. A reference list of acceptable test protocols is contained in Section 2.10.

Decision on whether or not registration will be granted shall take into consideration the set of criteria adopted for this purpose.

### *A. General Applicability and Alternative Means for Satisfying Requirements*

The data requirements are generally applicable to all registrants for proprietary interest in the product. For commodity products, data on general information (1.0) and specifications (2.0) are applicable. The nature of information necessary for FPA to perform an adequate evaluation is the same in either case. However, data requirements can be satisfied in a number of ways.

Application for commodity pesticides and some proprietary compounds may be satisfied by citing appropriate reviews of the relevant data in developed countries or providing results of international reviews by organizations such as WHO/IPCS or WHO/FAO JMPR. It can also be done by citing data already submitted to FPA that do not have proprietary protection.

Although the Philippines has not officially adopted national standards for specifications of pesticides, FPA shall utilize the FAO and WHO specifications for pesticides used in agriculture and public health or household purposes, respectively, as the minimum standards for registration purposes, particularly of commodity products. Annex II presents samples of FAO specifications.

Data on specifications especially for commodity products introduced from a new supplier shall be authenticated by an independent laboratory analysis. FPA reserves the right to require confirmatory analyses done by local laboratories which are deemed acceptable through recognition by the FPA.

Data for determining efficacy usually generated in the country may, if cases warrant, be extrapolated from similar crops and pest situations in other countries with similar climatic conditions or from similar formulations. To merit acceptance of efficacy data by FPA, it is important that the prescribed FAO test protocols or other internationally prescribed and accepted protocols be strictly followed. When the use

is in the “List of Pesticide Registered Use Pattern,” these shall suffice for commodity pesticide to meet efficacy requirements for registration of similar subsequent applications.

Acute oral toxicity data on formulations and active ingredients are required. Many of the environmental fate tests maybe done with typical formulations extending the range of applicability to all similar products. Test protocols will generally specify appropriate test materials, i.e. active ingredient, individual formulation or a typical formulation.

### *B. FPA Accepts Third Party Authorizations*

From the data owner for another registrant to cite their data for registration purposes. The following concepts of third party authorizations should be acceptable to both parties:

1. Authorization of this nature is applicable for registration of products still under proprietary data protection, coming from the same supplier.

2. Third party Authorization may also be allowed for commodity products coming from the same supplier.

3. Authorization is only for the use of submitted registration data. Authorized party shall still comply with other requirements: filing of application forms, payment of fees, and submission of technical and analytical grade samples and labels.

4. Third party authorization will be allowed only for pesticide products with full registration.

### *C. Protection of Proprietary Data.*

The proprietary nature of the data is protected by FPA. The patent is not considered by FPA but is an independent consideration to be resolved among the patent holder, the registrant or applicant, and the Intellectual Property Office (IPO). Data submitted to support the first full or conditional registration of a pesticide active ingredient in the Philippines shall be granted proprietary protection[1] for a period of eight (8) years from the date of approval of registration. During this period, no subsequent application for registration, citing the same submitted data, may be entertained.

Pesticides granted provisional registration under PD 1144 shall be considered first registered in 1977, the date of the Decree.

### *D. Protection of New Data Submitted*

New proprietary data (not available in any published literature) which are submitted for registration of a commodity pesticide product shall be granted 3-year data protection upon approval. New proprietary data includes but not limited to the following:

1. New formulation containing generic active ingredient(s);

2. Efficacy data generated through local field testing;

3. Residue data generated through local SPRT;

During this period, subsequent applications for registration of the same product shall not be allowed to cite any previously submitted proprietary data.

---

[1] **The authority of the** FPA was sustained by the Regional Trial Court of Quezon City, Branch 90 in SP Civil Case No. Q-01-42790 entitled, "Pest Management Association of the Philippines (PMAP) vs. FPA." The PMAP appealed the decision of the RTC to the Supreme Court in G.R. No. 156041 and the same is pending decision.

### 2.3.2 Chemical Pesticides

*A. Agriculture/Home Garden/Turf Use*

The guidelines and data requirements for the registration of pesticide products for agriculture are applicable also for products intended for use in home gardens and parks or golf courses.

The data requirements are indicated in Table 2 and discussion or explanatory notes on the required data are presented in Section 2.5.

*B. Registration of Other Chemicals*

Data requirements for registration of insect growth regulator, defoliant, desiccant and wood preservative shall follow that of agricultural pesticides.

The registration requirements for plant growth regulator shall be specifications and biological efficacy only unless the chemical has been shown to be hazardous or has other uses, in which case, the compound shall follow the guidelines for registration of agricultural pesticides.

For the registration of synergist and pheromone, the requirements are bioefficacy, specifications, MSDS, and acute toxicity studies. The same requirements apply to registration of agricultural disinfectants.

For surfactant, emulsifier, penetrant, wetting agent, safener, adjuvant, if used as component of the product formulation, only specifications and MSDS are required. However, if used as a lone material, efficacy data, specifications, MSDS and acute toxicity data are required.

## 2.4 EXPERIMENTAL USE PERMITS

### 2.4.1 General Information

Pesticide products, chemicals and biorationals intended for registration shall be tested for efficacy under local conditions. For field-testing necessary to generate data for registration purposes or other uses, Experimental Use Permit (EUP) shall be applied for and under no circumstance shall the test be conducted without the approved EUP. The experiment shall be conducted by researchers accredited by FPA following the standard protocols for biological efficacy testing. Data submitted without the necessary permit/conditionalities shall not be accepted for registration.

The EUP limits the amount of pesticide necessary to conduct the test so as to safeguard the health of direct and indirect users of the product as well as the environment.

Field trials of tank-mix formulation involving registered products may be conducted without EUP on the same crop(s) and pest(s).

Unless residue data on the crop where the product will be tested and a ninety (90) day oral sub-chronic and an interim or full report on one chronic study are available, crop destruction shall be done in EUPs 1A and 1B and, if deemed necessary, for EUP II.

The FPA Coordinator in the area where the field test will be conducted shall be provided with a copy of the approved EUP for monitoring the manner of use of the products, and the observance of the protection of public health and the environment.

### 2.4.2 Types of Experimental Use Permits (EUP)

There are four (4) types of EUPs and the appropriate type shall be applied for each pesticide to be tested per crop per season per location.

1. **EUP IA** covers coded compounds and formulations in the initial stages of development to be tested only within the FPA-licensed company research station. It includes three (3) different types of test materials:

    a. Coded Technical-Grade – This refers to coded (and still unnamed) technical-grade active ingredient.
    b. Coded Formulation – This refers to coded formulations at early development stage.
    c. Research Formulation – This refers to new formulations of a known active ingredient, a new combination of known registered active ingredients or a combination of known active ingredient with a coded technical.

Research experiment types and objectives are described below.

| Type of Experiment | Objectives |
|---|---|
| Comparative small plot demonstration between current products and local standards | Show performance of commercial products vs. local standards under simulated farmer's field conditions |
| Susceptibility monitoring | Establish and monitor susceptibility level of target pests to commercial products |
| Crop response | Test for effects of test materials on specific crop parts and general plant development |
| Comparative product efficacy test | Test the performance of treatments against target pests as influenced by various conditions |
| Effect on non-targets | Test for effects on Bio-con agents/ natural enemies |
| Other characterization studies needing controlled conditions at the station | Generate additional data to support Product Stewardship and Life Cycle Management activities related to the use of commercial products and compounds being developed for local registration |
| Research Formulation | Evaluate the bioefficacy of new test formulations with known active |

| | |
|---|---|
| | ingredient under small plot conditions inside the company research stations. Formulation toxicity package is usually still not completed at this testing stage. Data generated will not be used for registration. |

.

2. **EUP IB** covers coded compounds and formulations in the initial stages of development to be tested outside the company research station but in a licensed testing site, (not necessarily owned by the company) and conforming to FPA-approved protocol. The researcher will have to use smaller plot sizes to ensure access to basic safety equipment and facilities for the applicator, researcher and other workers available within the area

   EUP IB covers the same research types as specified for EUP IA. It also includes three (3) different types of test material:
   a. Code Technical-Grade
   b. Code Formulation
   c. Research Formulation

   The data generated from experiments covered by EUP IA and IB will not be used for registration purposes.

3. **EUP II** covers those pesticides, coded or branded in the pre-market stage and the bioefficacy data generated may be used for registration purposes. The EUP application requires prior approval before conducting the test because of the larger number of potentially exposed individuals and broader environmental exposure.

4. **EUP III** covers registered pesticides to be tested for additional uses or for label expansion. Advance review and approval shall be required if a registered pesticide is to be tested on a new crop or when hazard is increased wherein higher dose is tested on previously registered crop use.

No EUP is required in situations where the crop and pest uses are registered and the dose to be tested is lower than the registered dose and frequency, thereby, no increase is expected in hazards or crop residue.

All trials requiring EUP should be conducted only by FPA-accredited researchers, following FPA approved protocol.

Same requirements apply to EUP for seed treatment trials involving pesticide compound/formulation.

### 2.4.3 Application

1. EUP IA and IB – The applicant shall accomplish and submit notarized *Notice of Intent to Conduct Experiment* (FPA Form No. P-001) in duplicate, at least one(1) month prior to the start of the experiment..

2. EUP II and EUP III – The applicant shall accomplish and submit notarized *Application Form for Experimental Use Permit* (FPA Form No. P-002) in duplicate. Application for EUP II shall be filed at least six (6)

months prior to the start of the experiment and at least three (3) months for EUP III, to facilitate review of the application.

Fees for filing applications for EUP are indicated in Table 1. Specifically, research formulations under EUP IA and IB follows the schedule of fees for EUP II/III.

### 2.4.4 Data Requirement

1. EUP IA and IB – Applicant must submit FPA-compliant trial protocol and safety data sheet (SDS) only.

2. EUP II and EUP III – The data requirement for EUP II and III applications are described in Table 2 (*Data Requirement for the Registration and Experimental Use Permit of Pesticide Products).*

   Data must be submitted in size 8 1/2 x 11 paper or A4, indexed and bound separately, following the format below:

| Section | Data / Relevant Documents | Format |
|---|---|---|
| N/A | Letter of Intent<br>(addressed to the agency's Executive Director) | Must be found in each folder |
| N/A | Notarized Application Forms<br>(with documentary stamp) | |
| N/A | Proposed Product Label | |
| 1.0 to 8.0 | Summary of Data (with proper citation) | |
| 1.0 | General Information | Merge in Folder 1 |
| 2.0 | Specifications | |
| 3.0 | Bioefficacy (including trial protocol) | Folder 2 |
| 4.0 | Toxicology | Folder 3 |
| 5.0 | Human Exposure and Safety | Folder 4 |
| 6.0 | Environmental Effects | Merge in Folder 5 |
| 7.0 | Residue<br>(including SPRT protocol, if applicable) | |
| 8.0 | Environmental Fate and Transport | |

Any additional data required shall also be submitted as prescribed. Submissions that do not follow these requirements shall not be accepted.

### 2.4.5 Validity and Extension

Each Experimental Use Permit is limited to one (1) pesticide product to be used in one (1) specific crop against the specified target pests with approved trial protocol. The EUP is valid within the indicated trial duration and trial location.

However, the period of coverage of EUP may be extended upon request with proper justification. Filing fee shall be paid upon submission of application for EUP extension (Table 1).

### 2.4.6 Experimental Use Permit for Drones as Method of Application

Registrants must secure Experimental Use Permit (EUP) prior to conduct of any bioefficacy and/or residue trial which utilizes drone as method of application. As per usual applications, EUP is issued upon evaluation and approval of the submitted test protocols and other data requirements (specified in Table 1 below).

All trials requiring EUP should be conducted only by FPA-accredited researchers along with an FPA-accredited drone operators. The bioefficacy and/or residue data generated from these trials may be used to support product registration, except for trials covered by EUP IA & IB.

The following describes the nature of application for EUP for drones and the corresponding requirements.

| | Nature of Application | Type of EUP | Requirements |
|---|---|---|---|
| 1 | If a registered product will be tested on a registered crop/pests/dosage. | III | Duly accomplished and notarized Application Form No. P-002; Bioefficacy trial protocol; Product stewardship program specific for the applied use of drone. |
| 2 | If a registered product will be tested on a different (unregistered) crop/pests. | III | Duly accomplished and notarized Application Form No. P-002; Bioefficacy trial protocol and SPRT trial protocol (if needed); Product stewardship program specific for the applied use of drone. |
| 3 | If a registered product will be tested on a registered crop/pests but using higher dose | III | Duly accomplished and notarized Application Form No. P-002; Bioefficacy trial protocol and SPRT trial protocol (if needed); Data on environmental and human exposure risk assessment; Product stewardship program specific for the applied use of drone. |
| 4 | If a registered product will be tested on a registered crop/pests but using lower dose | III | Duly accomplished and notarized Application Form No. P-002; Bioefficacy trial protocol; Product stewardship program specific for the applied use of drone. |
| 5 | For in-house/profiling trials | IA/IB | Notice of Intent to Conduct Experiment Form No. P-001; Trial Protocol; and MSDS Product stewardship program specific for the applied use of drone. |
| 6 | For local field trials of new product/ new | II | Duly accomplished and notarized Application Form No. P-002; Bioefficacy trial protocol and SPRT trial protocol (if needed); Other data |

| | | | |
|---|---|---|---|
| | formulation to support product registration | | requirements for EUP II as specified in Table 2.2 of FPA Green Book<br>Product stewardship program specific for the applied use of drone. |

## 2.5 EXPLANATORY NOTES ON TYPES AND USES OF REQUIRED DATA

### 2.5.1 Test Substance

The registrant shall be careful to distinguish what are required in Table 2 and what substance is to be tested. The test protocols generally provide information on the test substance.

### 2.5.2 Identification of Registrant, Product and Manufacturing Process

This is basic administrative and background data. A brief description of the manufacturing process supported with a simple flow chart plus a few paragraphs of description shall be submitted. The intent is to understand the basic steps to forecast where impurities or other undesirable constituents may enter into the product and to compare the likelihood that the same product produced by two (2) or more manufacturers will be substantially similar.

### 2.5.3 Specifications

Specifications are necessary to make sure that the registration data were produced using a chemical sufficiently similar to that being proposed for registration; to assure that harmful impurities, etc. are identified and evaluated as well as limited in the final product; and that the product as marketed conforms with what is approved for registration.

Data submitted to meet product chemistry requirements include description of manufacturing process of the active ingredient and the formulation, information on product composition, and chemical and physical characteristics of the pesticide.

*A. Product Composition*

1. Data on product composition are needed to support conclusions expressed in the statement of formula. These data include information on all the ingredients, on the raw materials or unreacted starting materials and manufacturing process, a discussion on formation of impurities, results of preliminary analysis of product samples, a certification of ingredient limits, and an explanation of how the certified limits were determined, the description of, and the validation data for analytical methods

to identify and quantify ingredients especially those above 0.1% which may be toxicologically significant. Any unidentified impurities present shall be considered as part of the total ingredients. If with special toxicological significance, materials even below 0.1% shall be declared.

2. Product composition (as indicated in the confidential statement of formula) is compared with the composition of materials used in toxicity and bioefficacy tests and other studies. This comparison indicates which ingredients in a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning product's composition, impurities and its toxic properties, appropriate use restrictions, labelling requirements, or special packaging requirements may be imposed.

3. Product composition data including the certified limits of the ingredients are used in the review of applications for registration.

*B. Physical and Chemical Characteristics*

1. Data on the physical and chemical properties of active ingredients and formulated products are used to confirm or provide supportive information on their identity.

2. Certain information (e.g. color, odor, physical state) is useful in emergency situations for identification of unlabelled pesticides involved in accidents or spills. Physicians and hospitals can use this information to aid in identification of materials implicated in poisoning episodes.

3. Certain chemical and physical data are used directly in the hazard assessment. These include stability, oxidizing and reducing action, flammability, storage stability, corrosion, etc. For example, the storage stability studies provide data on change in product composition over time. If certain ingredients decompose, other decomposition products may be formed whose toxicity and other characteristics need to be considered.

4. Certain data are needed as basic or supportive evidence in initiating and evaluating other studies. For example, vapor pressure data are needed, among other things, in order to determine suitable re-entry intervals and other label cautions pertaining to worker protection. Data on viscosity and miscibility provide necessary information to support acceptable labelling for tank mix and spray applications.

### 2.5.4 Bioefficacy Data

Bioefficacy data provide a mechanism to ensure that the pesticide product will perform as indicated in the label against the intended pests. It should be generated locally with approved Experimental Use Permit.

FPA-prescribed test protocols for specific crops are attached as Annex III for guidance. In general, for insecticides, fungicides and other pesticides, one-season testing in two (2) locations are acceptable for registration. For herbicides, testing for two (2) seasons on two (2) locations per season are required.

Bioefficacy data generated in other Asian countries with similar climatic conditions and following the FAO Test Protocols or any regionally accepted guidelines developed in the region may be acceptable for the same crops and pest species/strains existing in the Philippines.

### 2.5.5 Toxicology Data

*A. Test Substance*

Under most circumstances, the test substance will be the technical material produced during the normal manufacturing process. Under certain circumstances, it may be required that an analytical pure active ingredient, a contaminant, a metabolite, or any combination of these be tested. In some cases, data for the formulation may be required.

*B. Acute Toxicity Studies*

The data from these studies, as well as the results from skin and eye irritation and dermal sensitization studies, are used to identify the relative acute toxicity of the product for classification and for label precautionary statements. Preliminary information may also be obtained on the specific toxic effects and the mode of action of the test product.

Acute oral toxicity shall be conducted on rodent for the active ingredient and for the formulation product. Acute dermal toxicity shall be conducted on rat, skin and eye irritation on rabbit and dermal sensitization study on guinea pig for both active ingredient and formulation.

*C. Short-term Studies*

These studies delineate the toxic potential of the pesticide through continuous or daily repeated administration for less than one-sixth of the life span of the test species. The data obtained are useful in elucidating such problems as possible cumulative action, variation in species sensitivity and in identifying specific organ effects. These studies shall be conducted on the active ingredient only using rodent for sub-chronic oral and on sub-chronic dermal.

*D. Long-term Studies*

These studies provide information on the maximum dosage level which produces no discernible injury to animals; on the

tumorigenic potential of a pesticide when administered continuously or daily over the major portion of the life span of the test animals; and may reveal effects, which are not predictable from short-term toxicity studies.

Unless other studies indicate otherwise, long-term studies shall be conducted using the technical grade of the active ingredient administered by the oral route on rat.

*E. Special Studies*

In addition to the above studies, the following are also required:

1. *Pharmacokinetic Studies:* A good understanding of the pharmacokinetics of the pesticide shall enable more judicious selection of appropriate routes of administration and dose levels in long-term studies, and actual tests which should be done on the product. Since one of the purposes of such studies is to aid in the extrapolation of animal toxicity data to man, studies in multiple animal models using appropriate species are usually more meaningful.

2. *Mutagenicity Tests* may be used to screen mutagenic potential as well as a pre-screen for carcinogenic potential. Using in *vivo* and *vitro* tests, the limitations of these tests are realized, but they provide useful information which can be used along with the results from the whole animal experiments to give some preliminary indication of the mutagenic and carcinogenic potential of the test product.

3. *Studies of Breakdown Products:* Toxicity studies on metabolic and environmental breakdown products may be necessary to evaluate the potential hazards of human exposure to such chemicals in food and in treated areas which must be entered by workers.

4. *Teratogenicity Studies* shall be conducted on rats and rabbits for the active ingredient and shall provide data on the potential of pesticides to produce or alter the incidence of congenital malformation and functional disorder.

5. *Reproduction Studies on Rats* provide information on the potential effects the pesticides might have on the reproductive capacities of the parental generation from the mating through lactation and on the offspring from the conception through lactation and mating. The study shall be conducted on one (“a”) litter from each of two generations unless postnatal adverse effects, doubtful effects on any reproductive parameter, or lack of stabilization of blood and tissue levels (cumulative compound) are observed. Then, (“b”) litters shall be required in at least one generation.

### 2.5.6 Human Safety

Worker exposure study is required for new proprietary products under registration with strong toxicological concern. Worker exposure and safety are generally arrived at by observation or judgement and monitoring or calculation as pointed out in the data requirements table (Table 2). Whenever worker exposure studies are conducted, they shall only be done after there is reasonable assurance that the applicator or farm worker or test subjects will not be placed at undue risk. To reduce the cost of conducting such trials, they should coincide with efficacy field trials.

Worker exposure studies can be very useful in determining the magnitude of the margin of safety under use conditions. Monitoring data generated during exposure studies are used to determine the quantity of pesticide to which people may be exposed after application and to develop re-entry intervals. Studies on toxicity using animal species and residue dissipation can also be used to assess hazard to farm workers and applicators.

### 2.5.7 Environmental Effects

*A. General*

The information required to assess hazard to non-target organisms are derived from tests which determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, reproduction, simulated field, and full field studies arranged in a tier system, which progresses from laboratory tests to the applied field tests. The results of each tier of tests shall be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further tests are required.

*B. Short-term Studies*

These data are used: 1) to establish acute toxicity levels of the active ingredient to the test organisms; 2) to assess potential impacts on fish, wildlife and other non-target organisms; and 3) to indicate whether further laboratory and/or field studies are needed.

*C. Long-term and Field Studies*

Data from these are used to estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment. These are also used to determine whether field or laboratory studies are needed to further evaluate hazards.

### 2.5.8 Environmental Fate and Transport

A. General

The data generated by environmental fate studies are used to assess the following: 1) toxicity to man through exposure to pesticide residues remaining after application, either upon re-entering treated areas or from consuming inadvertently-contaminated food; 2) the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and 3) potential environmental exposure of other non-target organisms, like fish and wildlife, to pesticides.

*B. Degradation Studies*

The data from photolysis and hydrolysis studies are used to determine the rate of pesticide degradation and to identify their adverse effect on non-target organisms.

*C. Metabolism Studies*

Data from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

*D. Mobility Studies*

These data pertain to leaching, adsorption, desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. The data are used to assess potential environmental hazards related to contamination of human and animal food; loss of usable land and water resources; and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

*E. Accumulation Studies*

Accumulation studies indicate pesticide residue levels in food supplies that originate from rotational crops and bodies of water. These data allow FPA to establish label restrictions regarding application of pesticides on sites where residues can be taken up by crops and edible fish or shellfish.

### 2.5.9 Residues in Food

Residue chemistry data are used to estimate the exposure of the general public to pesticide residues in food. Information on the chemical identity and composition of the pesticide product, the amount, frequency and timing of pesticide application, and results of tests on the amount of residues remaining in food, are needed to support findings on the magnitude and identity of the residues which may be found in food as a consequence of a proposed usage.

For registration purposes, FPA may allow applicants to submit residue data generated from other countries with similar agro-climatic conditions and use patterns following FAO guidelines on Supervised Pesticide Residue Field Test.

## 2.6 GROUNDS FOR DENIAL OF REGISTRATION

Registration may be denied on any one of the following grounds:

1. False information in the application and data submitted.

2. Product is very hazardous to health based on the proposed use even if the prescribed precautions are taken to arrest such hazard.

3. Risks are higher over benefits in the use of the product specially when there are less hazardous registered products existing for the same or similar purpose.

4. Product is phytotoxic and when plant recovery is minimal to compensate for crop yield losses.

5. Product is significantly less effective than the reference registered standard product.

6. Persistence of residues in crops and in the environment such as soil and water.

7. Potential or proven carcinogen, fetotoxic, teratogenic, mutagenic, and oncogenic at doses relevant to humans.

## 2.7 OBLIGATIONS OF REGISTRANTS

Registrant shall maintain and submit to FPA a record of all reported adverse chemical reaction or effects associated with the use of the product as directed in the label.

The record shall contain the complainant's name, address, phone number, details of the complaint, investigations performed, quantity of products used, diagnosis and final outcome.

All suspected adverse chemical effects associated with the use of the product or which have serious implications on health and/or environment shall be reported immediately to the FPA and followed up with a report of investigation of the incident.

Any development of resistance to the registered product by a pest or any unforeseen breakdown in stability shall be reported to the FPA together with the corrective action taken.

Failure to meet these obligations could result in a fine and a possible cancellation of registration.

## 2.8 LABELLING REQUIREMENTS

### 2.8.1 General Information

A. *Legal Provisions*

Article V of the FPA Rules and Regulations No. 1, Series of 1977, in particular Sections 1 to 4, 6 and 8, describe the basic requirements for a pesticide label including the prescribed statements, language, FPA control number, precautionary measures, and others. Specifically, Sections 1 and 2 summarize the requirements as follows:

“Section 1. Every container of pesticide offered for sale, distribution, storage and use shall bear a label printed, stenciled, marked, embossed or impressed on or attached to it, which must, among others, include the following:

a. A statement of the composition by percentage, including all ingredients and the chemical identity of the active ingredient(s);
b. The registration or provisional permit number;
c. The name and address of the holder of the registration or provisional permit;
d. The common name;
e. The net contents, in metric unit, of the pesticide in the container;
f. Adequate directions concerning manner in which the pesticide is to be used and time of application;
g. Warning and cautionary statements including the symptoms of poisoning and suitable and adequate safety, health and first aid treatment measures;
h. A suitable indication of hazard, including the appropriate pictorial warnings for highly toxic substances;
i. Instructions concerning the decontamination and safe disposal of used containers;
j. Such label claims, if any, as have been accepted by the Authority;
k. The lot number and year of formulation; and
l. Such further statements as may be prescribed by any other government instrumentality.

Section 2. Each label shall be in English or any of the major dialects, must be legible and distinct in its meaning and attached to, printed or affixed on the side of the container in such a way that the whole content of the label can be read without detaching the same.

Section 3. No label shall be detached, altered, defaced, changed or destroyed, in whole or in part, in a manner that will defeat the purpose of existing rules and regulations.

Section 4. No substance shall be added to or taken away from any pesticide earlier labelled in accordance with the provisions of these rules, unless properly registered.

xxxx xxxx xxxx

Section 6. A pesticide labelled in accordance with these rules, which has so decomposed or deteriorated as to be ineffective or dangerous, or which package containers have deteriorated or have been damaged so as to be

dangerous in storage and use, shall not be offered for sale or distribution.

xxxx xxxx xxxx

Section 8. Any written, printed or graphic material relating to and accompanying a pesticide when held, transported, distributed, stored, sold or offered for sale, used in the country or imported shall include the substance label statements prescribed in Section 1 of this Article."

### 2.8.2 Purpose of the Label

The purpose of the pesticide label is to provide readily-understood information on:

1. The content of the container and the purpose(s) for which it may be used;
2. The direction on how to use the pesticide;
3. The hazard of the pesticide and the appropriate precautions to take in its storage, handling and use; and
4. The symptoms and signs of poisoning and the recommended first aid and medical treatment in the event of poisoning. Specific antidotes and appropriate dosages shall be contained in the labels.

The degree of precautionary labelling shall reflect the assessed hazards of the product. "Overlabelling" of relatively harmless products may promote the development of a general disregard for precautionary texts and may defeat the purpose. The following guidelines are intended to facilitate the implementation of the FPA Rules and Regulations and to assist in determining the appropriate statements for pesticide labels. If followed, they shall expedite the registration process. FPA reserves the right to give additional requirements when necessary.

### 2.8.3 General Considerations on Labelling

Every label on the container of a pesticide shall be:

1. Clearly printed with each statement in a uniform color against a white background; letter prints shall however, be in black.

2. Firmly attached to the container and be of such nature that it will not fade to the extent that it becomes illegible, and will not be detached through the influence of light, temperature, humidity, water or the contents of the container.

3. In such a position that it is not damaged or removed when the container is opened.

All labels shall be in English, unless otherwise specified and approved by the Authority. However, information on safety and precautions shall be in both English and Filipino, or any major dialects such as Cebuano, Ilongo, Ilocano, Bicolano and others. For the smallest packs (100 mL for liquid)

however, only the Filipino version is required. Text prepared in the form of a leaflet is acceptable as a part of the label. This shall however be attached to the container without permanently obscuring the actual label.

With the possible exception of the "***Note to the Physician"***, all label statements shall be in plain, understandable language, readily comprehensible to the layman.

No label of any pesticide shall contain a statement to the effect that the pesticide is harmless or is non-toxic.

The following sections of the label shall appear in the consecutive order as follows:

1. Warning;
2. Precautions;
3. Signs & Symptoms of Poisoning;
4. First Aid; and
5. Note to Physician.

The warning and precaution may be highlighted by enclosing in a rectangular "box" formed by a prominent continuous line.

The label must be legible. A minimum type size of six (6) points for wording on the labels is preferred. FPA has the right to reject illegible type sizes.

### 2.8.4 Specific Considerations

Unless specifically exempted, all pesticide labels shall contain the following:

*A. Product Information*

1. Name and Ingredient Statement

   This includes: a) Trade or commercial name of the product; b) the common names of all active ingredients in the product (approved International Standards Organization names, or when no ISO name has been recommended, one that has been accepted by a local standard association); c) the chemical classification of the pesticides; and d) the minimum guaranteed amount of each active constituent present shall be clearly described as follows:

   a. Solids, Viscous liquids, Aerosols and Volatile liquids: grams per kilogram (g/Kg)

   b. Other liquids: grams per liter (g/L) (e.g. '400 g/L 2,4-D' as sodium salt' not '400 g/L sodium salt 2,4-D').

2. Solvent Statement

   Where a solvent is present, the identity and concentration shall be stated. If the solvent significantly contributes either to user's hazard or flammability of the product, appropriate standard symbols, which indicate flammability and phrases, which indicate user's hazard shall be included on the label.

3. A general statement summarizing the use of the product shall be placed as near as possible to the trade name, (e.g., FOR CONTROL OF POST-EMERGENCE ANNUAL BROADLEAF WEEDS IN RICE).

   The statement shall draw the user's attention to the crops on which the pesticide is registered and can be used.

4. The net weight or volume (in metric units) of the product in the container.

5. Name and address of manufacturer, distributor or agent. (The person or company responsible for registration of the product in the Philippines).

6. The FPA registration number and the phrase REGISTERED WITH THE FERTILIZER AND PESTICIDE AUTHORITY PURSUANT TO P.D. 1144 must be included on the label.

7. Shelf-life of the pesticide product

   a. The following information must be printed on the product labels:
      - Batch/Lot number of the product
      - Date of formulation
      - Expiry date (based on submitted storage stability studies)

   b. Results of stability tests shall be submitted with each application for registration. Storage stability studies shall be conducted in accordance with FAO Accelerated Stability Test Procedures which is usually at 54±2°C for 14 days.

c. When the approved 2-year shelf-life has lapsed, new shelf-life study is required to assess its quality and suitability for continued use and sale in the market. The result of the storage stability tests done on expiring stocks shall be submitted to FPA with a corresponding proposed action plan of the registrant. Samples of the expired product must also be submitted to FPA for analysis of the active ingredient content and its compliance to the product's specification.

d. Upon approval, the company should submit a phase-out and phase-in plan stocks for the depletion of stocks with old labels and the entry of stocks with new labels in the market. The submitted plan must have a corresponding product stewardship plan to support the phase-in, phase-out period.

8. Identification number of manufacturing lot or batch.

9. Product Mode of Action

Print the Mode of Action (MoA) Identification Symbol (available from the WSSA, FRAC, HRAC, and IRAC website) on the end-use product label in a MoA information box following the standard format shown below.

| | | | | |
|---|---|---|---|---|
| Standard Format: | *(Name of Active Ingredient)* | *(Group)* | *(Mode of Action)* | *(Type of Pesticide)* |
| Example 1: | **CYPERMETHRIN** | **GROUP** | **3A** | **INSECTICIDE** |
| Example 2: | **BUTACHLOR** | **GROUP** | **K3** | **HERBICIDE** |
| Example 3: | **DIMETHOMORP + MANCOZEB** | **GROUP** | **40 + M 03** | **FUNGICIDE** |

The MoA information box must be located on the front panel of label, preferably on upper right corner. All text inside the MoA information box should be black, bold face and all caps on a white background, except for the MoA symbol which should be white, bold face and all caps on a black background. All text and columns should be bordered by black solid line.

*B. Directions for Use*

1. The directions for use on the label must clearly indicate how, when and where the product can be legally, effectively and safely used with maximum efficiency and minimum risk. This information may be repeated and expanded in separate technical or promotional literature or label leaflets. However, even if leaflets are used, the LABEL ON EVERY CONTAINER OR OUTER PACKAGE MUST ALWAYS SUPPLY THE ESSENTIAL INSTRUCTIONS NEEDED AT THE TIME OF USE.

2. Information essential to the proper use of the product in all circumstances shall be included, such as: a) Practical advice on preparing, mixing and applying the product, and b) Compatibility of the product with other products.

3. Information about the recommended uses of the product shall be clear and specific, using names, terms or descriptions that will accurately inform the user as to the pests controlled.

4. Directions for use must include information on:

   a. Any warnings intended to prevent incorrect or misuse of the product, example:

      ‘Do not use on sandy soils’
      ‘Apply only at the 2-5 leaf stage’
      ‘Do not apply when rain is imminent/coming’

   b. Crops and pests for which the product has been officially approved and registered.

   c. Application rates and statement critical to the effective use of the product on each crop and pest including timing and method of application. A tabular format is often the clearest method of expressing these. Statements should be short, clear and concise. Common names for pests should be used to completely replace scientific names; simplify labels where possible by using phrases known to users.

   d. Calibration of measuring device. Labels shall show doses in mL. or gram. A suitable measuring device shall be provided.

   e. Pre-harvest Interval. A statement, where required, of the period which shall elapse between last application of the product AND: (a) harvest of plant products; (b) grazing of treated areas;(c) slaughter of treated animals for food; (d) feeding produce to domestic animals; (e) saving, offering for sale or using produce such as milk or eggs for human consumption; (f) seeding or planting of subsequent crops; OR the withdrawal period for treated

feed to avoid unacceptability of residues in animal products. This is known as the 'withholding period' or 'pre-harvest interval'.

f. Re-entry period.

g. Restrictions and limitations, if there are any.

Pre-harvest interval, re-entry period and restrictions and limitations, if required, shall be placed close to the Directions for Use and on the same panel of the label.

Extensive directions for use may be contained in a leaflet or pamphlet that is securely attached to the package or enclosed within the outer packaging.

A separate leaflet in local dialect shall contain information on pesticide threshold, protective clothing needed, direction for use, and re-entry period and pre-harvest interval. The telephone number of responsible person of the company who can give information about the product especially for Categories I and II formulations shall be printed in the leaflet.

h. A resistance management statement shall be indicated on the label to aid in the understanding and use of the MoA number.

*C. Directions for Storage and Disposal*

1. Directions for safe storage including physical and chemical hazards, e.g. flammability, explosivity and others.

2. Directions for disposal of surplus pesticides and containers, and caution on re-use of container.

3. Any special recommendation on storage conditions for the container and product.

*D. Safety Precautions*

1. All information in this regard shall be stated in English, Filipino, or any major local dialect except for small packs of 100 mL where only Filipino language must be used.

2. The appropriate signal words, symbols, pictograms, and color bands shall appear on the label according to the primary and secondary hazards posed by the product.

3. The color band along the base of the label shall have a width equal to at least 11.5% and not more than 30% of the height of the label. Signal words and symbols shall be superimposed on the band in contrasting colors, i.e., black for the red and yellow bands; white for the blue band. The signal words shall be

printed in easily read capital letters of an upright non-serif character and be conspicuous in comparison with any other matter on that panel.

4. The statement, in capital and bold letters: KEEP OUT OF REACH OF CHILDREN shall be displayed permanently on the front page.

5. Hazard/safety information shall be presented with simple concise statements based on toxicity classification including secondary hazards, and should answer the following:

   THE PRODUCT IS (type of hazard…)
   WHEN WORKING WITH OR PREPARING THE PRODUCT (explain appropriate actions)

   WEAR (specify personal protective equipment needed)
   IF CONTAMINATION OCCURS (appropriate steps)
   AFTER USE (proper procedures)

   It is often helpful to capitalize the first few words of such direction as shown above to draw attention to the specific step of possible concern to the user.

6. Sample statements are contained in Section 2.9.

*E. First Aid, Information for Physicians and Treatment*

1. Signs and symptoms of poisoning of the particular pesticide.

2. First aid measures for the particular pesticide.

3. Information for Physician (Toxicity Categories I & II), including antidotes and treatment.

4. Sample statements Section 2.9.

*F. Prohibition/Warranty Statements*

1. The following statement is required:

   ***"It is a violation of FPA rules and regulations to use this product in a manner inconsistent with its label."*** If the above statement is not printed on the label, license shall be cancelled.

2. The following statement shall be allowed:

   "***No warranty of any kind, expressed or implied, is made concerning the use of this product. User assumes all risks and liabilities resulting from handling, use or application."***

### 2.8.5 Classification on the Basis of Toxicity and Hazard

Consistent warnings in the label based on toxicity and other hazards coupled with training, is generally accepted as a way to protect users and others involved in the application of pesticides from accidents and misuse.

**Color Bands, Signal Words, Symbols and Pictograms based on Toxicity and Hazard.** Table 3 shows the appropriate bands of color to be placed on pesticide labels. Superimposed on this band are the appropriate signal words and symbols to signify acute toxicity and degree of hazard to the users and pictograms indicating safety in handling.

Inhalation toxicity shall also be considered for volatile materials such as fumigants. Where data on inhalation toxicity are required because of volatility, use pattern and opportunity for significant exposure shall be considered.

### 2.8.6 Criteria for Classification

1. Where it is shown for a particular compound that the rat is not the most suitable test animal (for example, if another species is conspicuously more sensitive or more closely resembles man in its reactions) then the classification of that compound shall take this into account.

2. In practice, the majority of classification shall be made on the acute oral $LD_{50}$ value. However, dermal toxicity shall always be considered since it has been found that, under most conditions of handling pesticides, a high proportion of the total exposure is dermal. Classification based on dermal data in a class indicating a great risk is necessary when the dermal $LD_{50}$ values indicate greater hazard than oral $LD_{50}$ values.

3. If the active ingredient produces irreversible damage to vital organs, is highly volatile, is markedly cumulative in its effect, or is found after direct observation to be particularly hazardous or significantly allergenic to man, then adjustments to the classification can be made by classifying the compound in a class indicating a higher hazard. Alternatively, if it can be shown that the preparation is less toxic or hazardous than expected from consideration of the $LD_{50}$ values of the ingredient or ingredients, or for any other reason, adjustments should be made in classifying the compound in a class indicating a lower hazard.

4. In certain special cases, the acute oral or dermal $LD_{50}$ values of the compound or formulation shall not be used as the main basis for classification. Provision is made for the classification of a particular compound to be adjusted if, for any reason, the acute hazard to man differs from that indicated by $LD_{50}$ assessments alone. In such cases (for example, aerosol preparations, other special formulations and fumigants), more appropriate criteria shall be used (e.g. inhalation, toxicity for volatile compounds).

5. If the formulation contains more than one active ingredient of significant toxicity-enhancing properties, then the classification shall correspond to the toxicity of the mixed ingredients.

## 2.9 SAMPLE STATEMENTS: WARNING AND PRECAUTIONS, SYMPTOMS, FIRST AID AND TREATMENT, AND INFORMATION FOR PHYSICIANS

### 2.9.1 Warning Statements

The following are generally appropriate warning statements for pesticide formulations falling under FPA Toxicity Categories I and II. However, they may require modification in some cases. For example, reference to inhalation would not be appropriate for granular formulations or baits containing rodenticide.

*A. Category I*

**"DANGER:** ***This product is highly toxic and may cause death if swallowed, inhaled or absorbed through the skin.*****"** Follow directions for use carefully.

*B. Category II*

**"WARNING:** ***This product may be harmful if swallowed, inhaled or absorbed through the skin.*****"** Follow directions for use carefully.

*C. Categories III & IV*

**"Dangerous if not properly used".** No warning statement is necessary unless the substance is a recognized cause of dermatitis or allergy.

### 2.9.2 Precautionary Statements

Sufficient information shall be included under the heading "PRECAUTIONS" to advise the pesticide user on the following aspects: (a) Storage; (b) Avoidance of absorption during mixing and use, (c) Washing after use; (d) Container disposal; (e) Avoidance of contamination of water supplies; and (f) Wearing of protective clothing.

The preferred order of precautionary statements is as above.

The following statements are generally applicable to pesticide formulations in the various categories. However, there will be instances when modified or additional statements will be appropriate. If appropriate, precautions against flammability or explosion shall also be included.

*A. Category II*

"Store in original container, tightly closed, away from food and feeds."
"Do not eat, drink or smoke while using."
"Wear protective clothing including waterproof gloves and overalls or an old long sleeve shirt, particularly when handling the concentrate."

or

"When dusting wear protective clothing including gloves, a respirator and overalls or an old jacket."

or

"When handling granules, wear protective clothing including gloves."
"Do not spray against the wind."
"Avoid skin contamination and inhalation of spray mist or dust."
"Wash splashes of concentrate off skin immediately (liquid concentrate only)."
"Place baits out of reach of children and domestic animals."
"Wash hands and exposed skin before eating and after work."
"Wash separately contaminated clothing and protective equipment after each use."
"Burn or bury empty container."
"Avoid contamination of any water supply with chemical or empty container."
"Remove unused baits and burn any dead pests." (Rodenticides)

*B. Category III*

"Store in original container, tightly closed, away from feeds and foodstuffs."
"While mixing or applying, wear protective clothing, particularly gloves."
"Avoid skin contact and inhalation of spray mist or dust."
"Place baits out of reach of children and domestic animals."
"Wash hands and exposed skin before eating and after work."
"Dispose off empty container safely."
"Avoid contamination of any water supply with chemical or empty container."
"Remove unused baits and burn any dead pests." (Rodenticide)
"Flammable. Contents under pressure. Store in a cool area. Do not spray near sparks or on an open flame. Do not spray directly onto animals or fish tanks. Remove or cover all exposed food. If spraying is heavy, do not enter room for 30 minutes. Do not puncture or burn container, even when empty." (Aerosols)

*C. Category IV*

"Store in original container, tightly closed."
"Avoid skin contact and inhalation of spray mist or dust."
"Place baits out of reach of children and domestic animals."
"Avoid contamination of any water supply with chemical or empty container."
"Remove unused baits and burn any dead pests." (Rodenticides)
"Flammable. Contents under pressure. Store in cool area. Do not spray near sparks or open flame. Do not apply directly to animals or fish tanks. Remove or cover all exposed food before spraying. If spraying is heavy, do not enter room for 30 minutes. Do not puncture or burn container, even when empty." (Aerosols)

### 2.9.3 Mandatory Statements based upon Secondary Hazard

Mandatory precautionary statements relating to skin and eye irritation must be prominently displayed on the label.

Inclusion in the label of other effects noted in the testing may be required along with the secondary hazard warnings. The principal consideration in writing these statements is to clearly convey the type of hazard and then state or suggest how it may be avoided.

A. Skin Irritation

| Test Result | Precautionary Statement |
|---|---|
| Corrosive | Corrosive: - Avoid contact with skin and eyes. |
| Severe Irritation, 72 hours | Severe skin irritant |
| Moderate Irritation, 72 hours | Skin irritant |
| Mild or No Irritation, 72 hours | None |

B. Eye Irritation

| | |
|---|---|
| Effects not reversed after 21 days; or if pH<3 or >11.5 or severe skin irritant | Can cause severe eye damage or blindness. Avoid contact with eyes. |
| Effect reversible, 21 days | May cause severe temporary eye irritation. Avoid contact. |
| Effect reversible, 7 days | May cause eye irritation. Avoid contact. |
| Clear, 24 hours | None |

### 2.9.4 Signs, Symptoms and Treatment of Poisoning

These are only necessary for FPA Toxicity Categories I and II. They shall be expressed in terms readily comprehensible to the layman so that a user may recognize signs or symptoms of poisoning by himself.

Often, it is necessary to make deductions of the likely signs of poisoning from the acute toxicity experiments on laboratory animals, in which case, the predicted signs shall be preceded by a statement to the effect “Signs of poisoning may include…”

In some cases, pesticides belong to well-documented categories such as the organophosphates or the carbamates. To assist those preparing labels of such pesticides, the following list of signs and symptoms may be used, as appropriate:

*A. Organophosphate or Carbamate*

Signs and symptoms of acute poisoning include excessive sweating, tearing of eyes, salivation, headache, giddiness, blurred vision, nausea, vomiting, abdominal cramps, diarrhea, chest tightness and discomfort, and constricted pupils. In severe poisoning, muscle twitching and inability to walk, coma and respiratory arrest may occur.

*B. Organochlorine*

Signs and symptoms of acute poisoning include apprehension, excitability, dizziness, headache, nausea, vomiting, trembling, incoordination and convulsions.

*C. Nitrophenolic and Nitrocresolic Herbicide*

Signs and symptoms of acute, early poisoning include profuse sweating, headache, thirst, malaise and lassitude. Serious poisoning are manifested by warm, flushed skin, rapid heart rate, palpitations, fever, restlessness and convulsions.

*D. Warfarin or Coumarin Type Compounds*

Signs and symptoms of poisoning include bleeding from nose, gums, gastrointestinal tract, easy bruising and anemia.

### 2.9.5 First Aid Statements

These shall consist of simple measures that may be carried out by a layman without the need for special equipment. As appropriate, they shall cover poisoning by the oral, dermal and inhalation routes of poisoning, although generally for most pesticides (except for fumigants) only the first two (2) routes are relevant. Contamination of the eyes may also be covered.

An appropriate selection of the following should be made:

*A. For Ingested Pesticide*

1. If no organic solvent

   "If swallowed and patient is conscious, give 1 glass of water and induce vomiting by tickling back of throat or pressing back of tongue with a finger or blunt instrument. Repeat procedure until vomit fluid is clear in appearance. Get medical attention immediately."

2. If with kerosene, xylene or other organic solvents

   "If swallowed and patient is conscious, give 1-2 glasses of water. Do not induce vomiting. May do careful gastric lavage if feasible. Get medical attention immediately."

*B. Inhaled*

"If inhaled, remove from contaminated area and bring patient to fresh air. If breathing stopped, apply artificial respiration. Get medical attention as soon as possible."

*C. Skin Contact*

"In case of skin contact, remove contaminated clothing and wash affected areas with soap and plain water. Get medical attention as soon as possible if symptoms of poisoning are occurring."

*D. Eye Contamination*

"In case of splashes in the eyes, flush eyes with clean running water for at least 15 minutes and get medical attention immediately."

### 2.9.6 Special Note on Emulsifiable Concentrates and Other Formulations with Hydrocarbon Solvents

Problems may occur if emulsifiable concentrates are vomited and if, during vomiting, some of the vomit fluid containing the solvent is accidentally inhaled into the lungs. Because of their low surface tension, hydrocarbon solvents may spread all over the respiratory surface of the lung, causing a chemical pneumonitis that may be fatal.

The risk of inhaling the solvent must be balanced against the risk of systemic poisoning if the pesticide is allowed to remain in the gastro-intestinal tract.

For substances in Category I, it is suggested that the risk of systemic poisoning might be greater than that of chemical pneumonitis, and the recommendation to cause immediate vomiting may apply. A physician shall be consulted immediately.

For substances in Category II, vomiting should not be induced unless there is a delay (one hour is requested) in obtaining medical treatment.

For emulsifiable concentrates in Categories III and IV, the paramount consideration may be the systemic toxicity of the solvent, which may be greater than that of the pesticide itself. In this regard, aromatic solvents are appreciably more toxic than aliphatic solvents. Therefore, it is recommended that labels of Categories III and IV formulations with aromatic solvents contain the statement "not to induce vomiting or to do so only if there is a delay in obtaining medical treatment." Labels of Categories III and IV formulations containing aliphatic solvents should contain a recommendation not to cause vomiting at all.

### 2.9.7 Information for Physicians

This will vary from substance to substance. However, the following phrases may be useful:

*A. Carbamates*

Contains a cholinesterase inhibitor. If swallowed, do careful gastric lavage. Treat with atropine sulfate as antidote. Maintain patent airway and fluid and electrolyte balance. Never give opiates, phenothiazines, xanthines (aminophylline, theophylline, caffeine, etc.) and other respiratory depressants.

*B. Organophosphates*

Contains a long-acting cholinesterase inhibitor. If swallowed, do careful gastric lavage with activated charcoal and follow with sodium sulfate cathartic. Treat with cholinesterase reactivator (pralidoxime or obidoxime, intravenous) if within 24 hours of poisoning. Give atropine sulfate as main antidote. Maintain patent airway, vital signs and fluid and electrolyte balance. Never give opiates, phenothiazines, antipyretics, xanthines (aminophylline, theophylline, caffeine) and other respiratory depressants.

*C. Organochlorines*

Treatment is supportive and symptomatic. Remove poison from body. Maintain patent airway and tissue oxygenation. Control convulsions with pareneral diazepam or short-acting barbiturate. Do not give epinephrine or other adrenergic amines. Oral cholestyramine can promote excretion of swallowed chemical. Phenytoin can control convulsion and hasten metabolism of organochlorines.

*D. Dithiocarbamates (Metallo-dithiocarbamates)*

Can cause irritation to skin and mucous membranes. In cases of systemic poisoning, avoid fats and oils. Alcohol should be avoided since this will result in “disulfiram-like” reaction. Give supportive and symptomatic therapy.

Ethylene bis-dithiocarbamates can cause irritation of skin and mucous membranes. In systemic poisoning, the chemical is converted to a goitrogen. Give supportive and symptomatic therapy.

*E. Nitrophenolic and Nitrocresolic Herbicides*

This is a potent stimulant of cellular metabolism. Treatment is supportive and symptomatic. Never give atropine and antipyretics. Agranulocytosis can occur in large dose poisoning.

*F. Chlorophenoxy Compounds*

Moderately irritating to skin and mucous membranes. In case of systemic poisoning, promote alkaline diuresis with intravenous bicarbonate. Never give atropine, aspirin or other antipyretics to control fever.

*G.* Pyrethroids

Can cause irritation and sensitization on exposure of skin and mucous membranes. In case of systemic poisoning, treat symptomatically with Diazepam for convulsion, maintenance of fluid and electrolyte balance. In oral poisoning, avoid fats, oils and milk. Adrenaline and hydrocortisone may be indicated in anaphylactic reactions.

*H. Bipyridyls (Paraquat and Diquat)*

Can be fatal if swallowed. Contact with the liquid may cause severe damage to eyes or skin. If swallowed, give immediately Fuller's Earth (Bentonite) or Activated charcoal or Kaolin Suspension. Lavage well and administer cathartic. Please refer to MSDS or booklet on paraquat poisoning. If necessary, admit into intensive care unit for proper management of hepatic, renal and pulmonary complication.

### 2.9.8 Position of Information on the Label

The following Table 4 and diagrams show the recommended position of information on labels. While flexibility shall be permitted to accommodate the needs of different products, consistent position of information on all labels makes it easier for the user to find the needed information quickly and easily.

### 2.9.9 Sample Pesticide Labels

Samples of labels are presented in Annex IV to provide a guide to grouping and position of the various types of information. Consistent position of information on the label shall enable a user to locate quickly the needed information and add to the usefulness of the label. Labelling of over-the-counter household pesticide shall follow sample labels as specified in Annex V while those for institutional products shall comply with the guidelines in Section 2.8.

## 2.10 REFERENCES ON ACCEPTABLE PROTOCOL

Bioefficacy Test Protocols, FPA Revised Guidelines, 1985.

FAO Guidelines for the Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Levels in Food and Feed. FAO, Rome, 1997.

FAO Guidelines:
Crop Residue Data

Packaging and Storage of Pesticides
Good Labelling Practice for Pesticides
Disposal of Waste Pesticides and Containers on the Farm

Environmental Criteria for the Registration of Pesticides.

FAO Harmonized Test Protocols, 1994.

Good Analytical Practices, Report of the Fifteenth Session of the Codex Committee on Pesticide Residues, The Hague, 3-10 October 1983. (attached as Annex VI)

Good Laboratory Practice, C (81) 30. Organization for Economic Cooperation and Development, Paris.

Guidelines on Pesticide Residue Trials to Provide Data for Registration of Pesticides and the Establishment of Maximum Residue Limits. FAO of the United Nations; Rome, 1986.

Guidelines for Testing of Chemicals, Organization for Economic Cooperation and Development, Paris, 1981.

Guidelines for Registering Pesticides in the U.S., Environmental Protection Agency

Internationally Accepted Guidelines

Principles for the Toxicological Assessment of Pesticide Residues in Food, Environmental Health Criteria, No. 104. 1990, 117 pages ISBN 9241571047.

Pesticide Residues in Food. FAO-WHO Joint Meeting on Pesticide Residues in Foods Part I: Pesticide Residues Evaluation, Part II: Toxicology Evaluation.

The Use of FAO Specifications for Plant Protection Products, FAO Plant Production and Protection Paper 13, Rome, 1979.

WHO Specifications for Pesticides Used in Public Health, Sixth Ed., Geneva, Rome, 1985.

Codex Recommended National Regulatory Practices to Facilitate Acceptance and Use of Codex Maximum Limits for Pesticide Residues in Foods, ALINORM 85/24A - Add. 2, FAO, 1985.

**Table 1. SCHEDULE OF REVISED FEES AND CHARGES FOR PESTICIDE PRODUCT REGISTRATION***

| ITEM | Fees and Charges (in Pesos) |
|---|---|
| A. New Applications – Filing Fee | |
| Active Ingredient | 4,500.00 |
| Product | 3,000.00 |
| B. Conditional Registration/Renewal (Annually) | |
| Product | |
| Category I and II | 5,000.00 |
| III and IV | 3,000.00 |
| Active Ingredient | |
| Category I and II | 7,000.00 |
| III and IV | 5,000.00 |
| C. Full Registration/Renewal (3 years validity) | |
| Product | |
| Category I and II | 15,000.00 |
| III and IV | 7,000.00 |
| Active Ingredient | |
| Category I and II | 20,000.00 |
| III and IV | 15,000.00 |
| D. Submission of Additional Data/Resubmission | 4,000.00 |
| E. EUP Application/crop/season/protocol | |
| I – A and B | 1,500.00 |
| II and III | 3,000.00 |
| F. Label Expansion/Crop | 3,000.00 |

Pursuant to Administrative Order No. 13, Series of 2000.

* Subject to change

**Table 2. DATA REQUIREMENT FOR THE REGISTRATION AND EXPERIMENTAL USES OF PESTICIDE PRODUCTS**

| NAME OF DATA REQUIREMENT | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|
| | AGR | HSLD[1] | | | | |
| **1.0 GENERAL** | | | | | | |
| 1.1 Name/address of applicant | R | R | R | R | A | Required in all cases |
| 1.2 Product Trade/Brand Name | R | R | R | R | 2, 3 | ditto |
| 1.3 Manufacturer of Technical Pesticide | R | R | R | R | A | ditto |
| 1.4 Description of Production Process[3] | R | R | R | R | X | ditto |
| **2.0 SPECIFICATIONS** | | | | | | |
| 2.1 Common Name of Active Ingredient (Proposed or Accepted ISO name) | R | R | R | R | 2, 3 | Required in all cases |
| 2.2 Chemical Name of Active Ingredient (IUPAC designation) | R | R | R | R | 2, 3 | ditto |
| 2.3 Chemical Abstract Service Number | R | R | R | X | 2, 3 | ditto |
| 2.4 Formula (empirical and structural) | R | R | R | X | 2, 3 | ditto |
| 2.5 Composition of Technical including impurities (all materials present at or over 0.1%)[4] | R | R | R | X | 2 | ditto |
| 2.6 List of ingredients and percent variations of each[5] | R | R | R | R | 2, 3 | ditto |
| 2.7 Appearance, color, state, odor | R | R | R | R | A | ditto |
| 2.8 Melting point | R | R | R | X | A | If solid at room temp |
| 2.9 Boiling point | R | R | R | X | A | If liquid at room temp |
| 2.10 Vapor pressure | R | R | at 20-25°C | X | A | Only if $>10^{-3}$ Pascal |
| 2.11 Density or Specific Gravity | R | R | R | R | A | Required in all cases |
| 2.12 Octanol Partition Coefficient<br>- half-life in soil<br>- $K_{oc}$, organic carbon partition coefficient | R | X | R | X | A | Required if Technical A.I. is organic and non-polar |

**Table 2. continued**

| NAME OF DATA REQUIREMENT | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|
| | AGR | HSLD[1] | | | | |
| 2.13 Formulation Type (GCFP code)[6] | R | X | X | R | 2, 3 | |
| 2.14 Storage stability | R | R | X | R | 2, 3 | |
| 2.15 Solubility in water and solvents | R | R | R | X | 2 | |
| 2.16 Suspensibility/Emulsifying Characteristics | R | X | X | R | 2 | |
| 2.17 Known capability/incompatibility with other pesticide products or Active Ingredients | R | X | X | R | X | |
| 2.18 Flash point and other indicators of flammability | @ | @ | R | R | 2, 3 | If product contains combustible liquid |
| 2.19 pH | R | R | R | R | 2, 3 | |
| 2.20 Methods of destruction or disposal | R | R | R | R | A | For EUP, include treated crop disposition |
| 2.21 Packaging type, sizes and materials | R | R | R | R | A | |
| 2.22 Assessment of Need of Child Resistant Packaging | X | R | X | R | X | For Toxicity Category I and II |
| 2.23 Analytical methods for constituents | R | R | R | R | 2 | |
| 2.24 Submittal of product samples | R | R | 10 g | 500 mL / 0.5 Kg | X | Analytical grade A.I., 1 g required unless reasons provided by applicant |
| **3.0 BIOEFFICACY (Typical Formulation)** | | | | | | |
| 3.1 Description of mode of action or effect on pest for which control is claimed | R | X | X | R | X | |
| 3.2 Pests controlled and names of crops, materials or premises to be protected | R | R | X | R | A | |
| 3.3 Application rate (Kg a.i./Ha or % a.i. spray dilution for each site/pest listed | R | R | X | R | A | |

**Table 2. continued**

| NAME OF DATA REQUIREMENT | | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|---|
| | | AGR | HSLD[1] | | | | |
| 3.4 | Frequency and timing of application for each site/pest listed | R | R | X | R | A | |
| 3.5 | Method of application (ULV, backpack sprayer, fumigation, etc.) | R | R | X | R | A | |
| 3.6 | Phytotoxicity | R | X | X | R | 2, 3 | |
| 3.7 | Results of laboratory studies, if any | R | R | X | R | A | |
| 3.8 | Complete description and data from local field trials or relevant test performed abroad or request for waiver for each site/pest on label | R | R | X | R | X | |
| 3.9 | Effects on beneficial organisms | @ | X | R | Appropriate pest/predator or parasite complex | X | Technical or formulated material may be used; reflect field use conditions. |
| **4.0** | **TOXICOLOGY** | | | | | | |
| 4.1 | Estimation of Acute Oral $LD_{50}$[7] | R | R | Study in rat | Study in rat | A | Calculation permissible in some cases from TGAI |
| 4.2 | Estimation of Acute Dermal $LD_{50}$[7] | R | R | Study in rabbit | Study in rabbit | A | ditto |
| 4.3 | Inhalation $LC_{50}$ | @ | @ | Study in rat | Study in rat | A | Required only if pesticide has high vapor pressure or if used as gas, fog, smoke, fumigant or contains respirable dust |
| 4.4 | Skin Irritation/Corrosivity | R | R | Unabraded rabbit skin | Unabraded rabbit skin | A | |

**Table 2. continued**

| NAME OF DATA REQUIREMENT | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|
| | AGR | HSLD[1] | | | | |
| 4.5 Eye Irritation | @ | @ | X | Study in rabbit | 2, 3 | Not required if pH less than 3 or greater than 11.5; or if corrosive to skin |
| 4.5.1 Dermal Sensitization | R | R | X | Study in guinea pig | 2, 3 | |
| 4.6 Allergic Sensitization | @ | @ | X | R | 2 | If positive in 4.5.1 |
| 4.7 Subchronic toxicity (21 days, dermal) | X | @ | Study in rodent | X | 2, 3 | Required for household products if significant dermal exposure is expected from use |
| 4.7.1 Subchronic toxicity (90 days, oral) | R | @ | Studies in rodent (oral) | X | 2 | Two species for food crop, one for non-food; required for household if significant exposure |
| 4.7.2 Subchronic toxicity (90 days, dermal) | @ | @ | Study in rodent (dermal) | X | 2 | Rarely required. Special exposure cases. |
| 4.8 Teratology | R | R | Studies in rabbit and rat | X | 2, 3 | |
| 4.9 Reproduction | R | @ | Study in rabbit or rat (preferred) | X | 2, 3 | Two generations adequate |
| 4.10 Chronic toxicity | R | @ | Lifetime in rat | X | X | Not required for EUP but submit if available |
| 4.11 Oncogenicity | R | @ | Lifetime in rat and mouse | X | X | ditto<br>May be combined with chronic toxicity test |
| 4.12 Mutagenicity | R | R | Multi-test battery | X | 2, 3 | Battery should include point mutation, chromosomal aberration and in vivo mammalian tests. |

**Table 2. continued**

| NAME OF DATA REQUIREMENT | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|
| | AGR | HSLD[1] | | | | |
| 4.13 Acute delayed neurotoxicity | @ | @ | Study in hen | X | 2, 3 | When cholinesterase depression expected |
| 4.13.1 Subchronic neurotoxicity | @ | @ | Hens or mammals | X | 2, 3 | If effects noted in 4.13 or mammalian acute studies |
| 4.14 Pharmacokinetics (absorption, storage, metabolism and elimination) | R | @ | Appropriate spec. | X | 2, 3 | For EUP only if crop is to be used. |
| 4.15 Observations on Man, if any | R | R | R | R | A | |
| **5.0 HUMAN EXPOSURE AND SAFETY** | | | | | | |
| 5.1 Assessment of applicator exposure | @ | @ | X | Monitoring or calculation | 2, 3 | Required when potential exposure is close to an effect level |
| 5.2 Assessment of farm worker exposure | @ | X | X | Monitoring or calculation | 2, 3 | Required for Toxicity Category 1 when hand labor in dense foliage is concern; and toxic compounds |
| 5.3 Signs and symptoms of acute human poisoning | R | R | Observations or judgments | Observations or judgments | A | |
| 5.4 Recommended first aid procedures | R | R | R | R | A | |
| 5.5 Recommended medical treatment for poisoning, include antidote if any | R | R | R | R | A | |
| 5.6 Proposed Acceptable Daily Intake | R | X | Calculated | X | 2, 3 | Food uses only; For EUP if not crop destruct basis. |
| 5.7 Protective equipment | @ | @ | R | R | A | If needed; Required for Toxicity Category I and II. |
| 5.8 Other precautions | @ | @ | R | R | A | If needed. |

**Table 2. continued**

| NAME OF DATA REQUIREMENT | | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|---|
| | | AGR | HSLD[1] | | | | |
| **6.0** | **ENVIRONMENTAL EFFECTS** | | | | | | |
| 6.1 | Avian acute oral toxicity | R | X | X | Test in one species for each typical formulation | 2, 3 | Suitable species, pigeon, quail, pheasant, duck or a Bengalese finch; hen not suitable |
| 6.2 | Avian dietary acute toxicity | @ | X | X | Test in one species as needed to assess potential effects | X | If indicated by Acute test results and type of formulation and use |
| 6.3 | Fish acute toxicity | R | X | 96 hour test in two species one of which is a local species | X | 2, 3 | Suitable species include rainbow trout, zebra fish, fat head minnow, tilapia fingerlings |
| 6.4 | Subacute fish toxicity | @ | X | Prolonged exposure test, one or more species | X | X | Where prolonged exposure likely; Test period up to 30 days |
| 6.5 | Aquatic acute toxicity | R | X | 48 hour acute test suitable species | X | X | Suitable fish food species, e.g. Daphnia |
| 6.6 | Accumulation in fish | @ | X | Test in one species | X | X | Where indicated by use pattern, formulation type and partition coefficient |
| 6.7 | Avian reproduction | @ | X | Test in one species | X | X | If need is indicated by feeding study results |
| 6.8 | Fish reproduction | @ | X | Test in Daphnia and one fish species | X | X | Test to be performed if persistent exposure indicated by use pattern and chemical persistence |
| 6.9 | Acute toxicity to honey bees | @ | X | R | X | X | Test to be performed if use involves crop where bees are present during or just after treatment |
| 6.10 | Contact toxicity to honey bees | @ | X | X | Typical formulation | X | Test needed for uses involving exposure and acute test shows high bee toxicity |
| 6.11 | Soil non-target microorganisms | @ | X | X | Typical formulation | X | Required if high soil concentrations expected from use; Test maybe conducted with TGAI or formulation |
| 6.12 | Soil non-target macroorganisms | @ | X | X | Earthworms | X | Same as above; also collect residue data if high avian toxicity |

Note: Special pen and field studies may be required depending upon uses, formulation and results of above studies

**Table 2. continued**

| NAME OF DATA REQUIREMENT | | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|---|
| | | AGR | HSLD[1] | | | | |
| **7.0** | **RESIDUE IN FOODS For food use only** | | | | | | |
| 7.1 | Identity of principal residues, metabolites and degradation products in edible crops, foods or feeds | R | X | Each crop | X | 2, 3 | Food/feed uses only |
| 7.2 | Residue decay curves for residues on crops to be treated | R | X | Each crop | X | 2, 3 | Food/feed uses only |
| 7.3 | Residues of active ingredient and principal metabolite in animals fed treated feeds or grazed on treated fields or pastures | R | X | Each crop | X | 2, 3 | Feed or pasture/range – land use only |
| 7.4 | Effects of food processing or home preparation on residues | @ | X | Each crop | X | 2, 3 | For foods which are processed or cooked before eating |
| 7.5 | Analytical method for detection of principal residues, metabolites on treated commodities | @ | X | Each crop | X | 2, 3 | Food/feed uses only when finite residue expected |
| 7.6 | Proposed maximum residue level for each crops, food, feed or animal expected to contain residues | R | X | Each crop | X | 2, 3 | Food/feed uses only Residue definition also required for enforcement |

Note: Residue data may also be required for inerts which are not provided a general exception or generally regarded as safe.
Above residue data not required for EUP on a crop – destruct basis.

**Table 2. continued**

| NAME OF DATA REQUIREMENT | USE PATTERN | | ACTIVE INGREDIENT Tech Grade[2] | FORMULATION[2] | EUP[2] | REMARKS |
|---|---|---|---|---|---|---|
| | AGR | HSLD[1] | | | | |
| **8.0 ENVIRONMENTAL FATE AND TRANSPORT** | | | | | | |
| 8.1 Volatility | R | R | R | X | X | |
| 8.2 Adsorption/desorption | @ | X | Test in two soil types | X | X | If pesticide likely to reach soil or water; radio-labelled test material best. |
| 8.3 Leaching | R | X | Test in several soil types | Sometimes | X | Field leaching tests may also be required. |
| 8.4 Degradation in soil | @ | X | Test in agricultural soil; sandy loam | Sometimes | A | Required for pesticides reaching the soil. Simulate field conditions. Field study may be required. |
| 8.5 Biodegradation | @ | X | Approximate field conditions | X | X | If applied directly to water or likely to enter due to formulation or use. Field tests may be required. |
| 8.6 Hydrolysis | @ | X | R | X | A | Same as above. |
| 8.7 Aqueous photolysis | @ | X | R | X | A | Same as above. |
| 8.8 Analytical method – residues in soil | R | X | R | X | X | |
| 8.9 Analytical method – residues in water | @ | X | R | X | X | When used directly or expected to reach water. |
| **9.0 LABELLING** | | | | | | |
| 9.1 Proposed toxicity category | R | R | R | R | A | |
| 9.2 Draft label (3 copies) | R | R | X | R | A | See note for EUP's. A.I. must meet shipping label requirements. |

Note: EUP labels may be typewritten and need to contain product identification warnings and precautions for storage, use and disposal, symptoms and signs of poisoning, first aid procedures and medical treatment, application directions and a " Experimental Not for Sale" statement and the name and address of the manufacturer.

**Notes to Data Requirement Table:**

1 Symbols used in the table:
- R Test required
- @ Conditionally required; see remarks for conditions
- X Not required

2 These columns indicate whether the data are required to support the registration or EUP for the Technical Active Ingredient, the Formulated Product or one or more types of EUP. An "X" indicates no requirement.

Additionally for EUP's "A" indicates the data are required for all types, or else the type number (1, 2, 3) appears. In no case will a study be required for an EUP if not necessary for ultimate registration.

The symbols do not designate the form of the compound to be used for the test. It may either be the active ingredient, the formulated product or a typical formulation. Most toxicological studies for example are conducted with the technical active ingredient while bioefficacy studies are performed with specific product or representative formulation. Environmental fate and fish and wildlife studies usually require either the technical active ingredient or a representative formulation as the test material. An indication of test material is made in many cases where it would not be obvious, but specific test protocols such as those contained or referenced in the FAO guidelines, in OECD protocols or US EPA testing guidelines should be consulted or the applicant should consult FPA prior to conducting the test.

Where test species are noted, these are the species most generally recommended by international and national guidelines; other species may be acceptable or even preferable in certain circumstances. Any question on species must be resolved by the FPA.

3 For Technical Materials, a description of the manufacturing process is required including an analysis of steps which may cause formation of toxic contaminants. For formulations, describe the process and how the various materials are combined to formulate the end-product from the technical.

4 All ingredients, contaminants, unreacted starting materials must be noted and identified and the nominal concentration of each is reported if it constitutes 0.1% or more of the product. For purposes of this requirement, some isomers may be identified and quantified as a group. Also, the FPA may ask for qualification of materials below 0.1% on a case-by-case basis if there is a special concern with its toxicity. Generally, these data are confidential.

5 The statement of ingredient for each product is the specification by which it will be judged. Upper and lower limits for each ingredient must be specified consistent with the expected variation in the production process. Efficacy determination by FPA may be made with lower limits on A.I. and risk assessments with upper limits. These data are generally considered confidential except for information required on the label although it may be released for safety consideration. The difference between this and the previous requirement is that this is designed to spell out the positive aspect of product formula. This focuses on the intentionally added ingredients and the potential variations in the percentages. It also bears on the variation in the impurities all as a function of manufacturing quality control. This specification is used in comparison with

international specifications. The previous requirement focuses mainly on identification of the impurities for the purpose of assessing risk.

6 Global Crop Protection Federation (GCPF) Formulation Codes: These are examples of the type of code used. The entire list is published in “Catalog of Pesticide Formulation Types Coding System”, Technical Monograph No. 2, GCPF, Avenue Hamoir, 121180 Brussels, Belgium. The entire set should be reproduced in the guidelines if this convention is adopted.

| | |
|---|---|
| EC – Emulsifiable Concentrate | SC – Suspension Concentrate |
| EO – Emulsion, water in oil | WP – Wettable Powder |
| EW – Emulsion, oil in water | GR – Granule |

7 An estimate of the $LD_{50}$ sufficient for labelling purpose can be obtained using significantly fewer animals than the classical $LD_{50}$ studies and will be sufficient in most cases. Occasionally, a more complete study may be needed with the active ingredient to study the mode of chemical toxicity.

**Table 3. CLASSIFICATION OF PESTICIDES BASED ON TOXICITY AND HAZARD[1]**

| Category and Signal Words | Color Band Symbol[2] | Acute Toxicity to Rat[3] | | | |
|---|---|---|---|---|---|
| | | Oral $LD_{50}$ (mg/Kg BW) | | Dermal $LD_{50}$ (mg/Kg BW) | |
| | | Solid[3] | Liquid | Solid | Liquid |
| CATEGORY I<br>DANGER: POISON | RED | 50 or less | 200 or less | 100 or less | 400 or less |
| CATEGORY II<br>WARNING: HARMFUL | YELLOW | 51 to 500 | 201 to 2000 | 101 to 1000 | 401 to 4000 |
| CATEGORY III<br>CAUTION | BLUE | 501 to 2000 | 2001 to 3000 | Over 1000 | Over 4000 |
| CATEGORY IV<br>---------- | GREEN | Over 2000 | Over 3000 | N/A | N/A |

[1] Toxicity classification based on formulation.
The FPA Classification Table is adopted from the World Health Organization (WHO) Classification By Hazards, the only modification being in the Title and combination of Categories 1a and 1b of the WHO Table into Category I for FPA.

[2] The following shades must be used as norms: Pantone red 199-C, Pantone yellow-C, Pantone blue 293-C and Pantone green 347-C.

[3] The terms “solid” and “liquid” refer to the physical state of the product or formulation being classified.

**Table 4. RECOMMENDED POSITIONS AND TYPE SIZE OF INFORMATION ON THE LABEL**

| Key Subject | Position on Label | Type Size Recommendation |
|---|---|---|
| | A = Main Label<br>B = Ancillary Panels<br>C = Label Leaflet<br>D = Pre-measured Pack<br>* = If applicable to packaging | L = Large<br>M = Medium<br>S = Small (minimum)<br>X = Emphasize by using either capitals, bold or heavy type for heading or part/whole or phrase |
| Hazard Symbols | A, *C and *D | LX |
| Product Name | A, *C and *D | LX |
| Active Ingredient Statement | A and *D | M |
| Solvent Statement (if required) | A and *D | L |
| Summary of Uses | A and *C | LX |
| Net Weight | A and *D | M |
| Name and Address | A and *D | M or S |
| Directions for Use | B and *C | M |
| Withholding Period | B and *C | MX or SX |
| General Instructions for Use | B and *C | M or S |
| Warning Phrases and Statements | B and *C | M |
| Safety Precautions | B and *C | MX |
| First-Aid Instructions and Advice to Doctors | B and *C | MX |
| Prohibition and Warranty Statement | B and *D | S |

Note: Where a one-panel label is used, all the above information must be included.
Source: FAO Labelling Guidelines.

# *Chapter 3*

# *POLICY GUIDELINES ON BIORATIONAL PESTICIDES*

## 3.1 DEFINITION AND SCOPE

### 3.1.1 Definition of Biorational Pesticides

Biorational pesticides are a distinct group, inherently different from conventional pesticides. They are comprised of two major categories: the biochemical pest control agents (e.g. pheromones, hormones, natural plant growth regulators and enzymes) and the microbial pest control agents (e.g. microorganisms). The relationships among conventional pesticides, biological control agents, and biorational pesticides are illustrated in Figure 2. Pesticides to be included in these categories must be naturally occurring, or if man synthesizes the chemical, then it must be structurally identical to a naturally occurring chemical. Minor differences between the stereochemical isomer ratios (found in the naturally occurring compound compared to the synthetic compound) will normally not rule out a chemical being classified as a biorational unless an isomer is found to have significantly different toxicological properties from those of another isomer.

### 3.1.2 Biochemical Pest Control Agents

Biochemical pest control agents include four (4) general biologically functional classes, which are described below:

*A. Semiochemicals*

These are chemicals emitted by plants or animals that modify the behaviour of receptor organisms of like or different kinds. They include pheromones, allomones, and kairomones. Pheromones are substances emitted by a member of one species that modify the behaviour of others within the same species. Allomones are chemicals emitted by one species that modify the behaviour of a different species to the benefit of the emitting species. Kairomones are chemicals emitted by one species that modify the behaviour of a different species to the benefit of the receptor species.

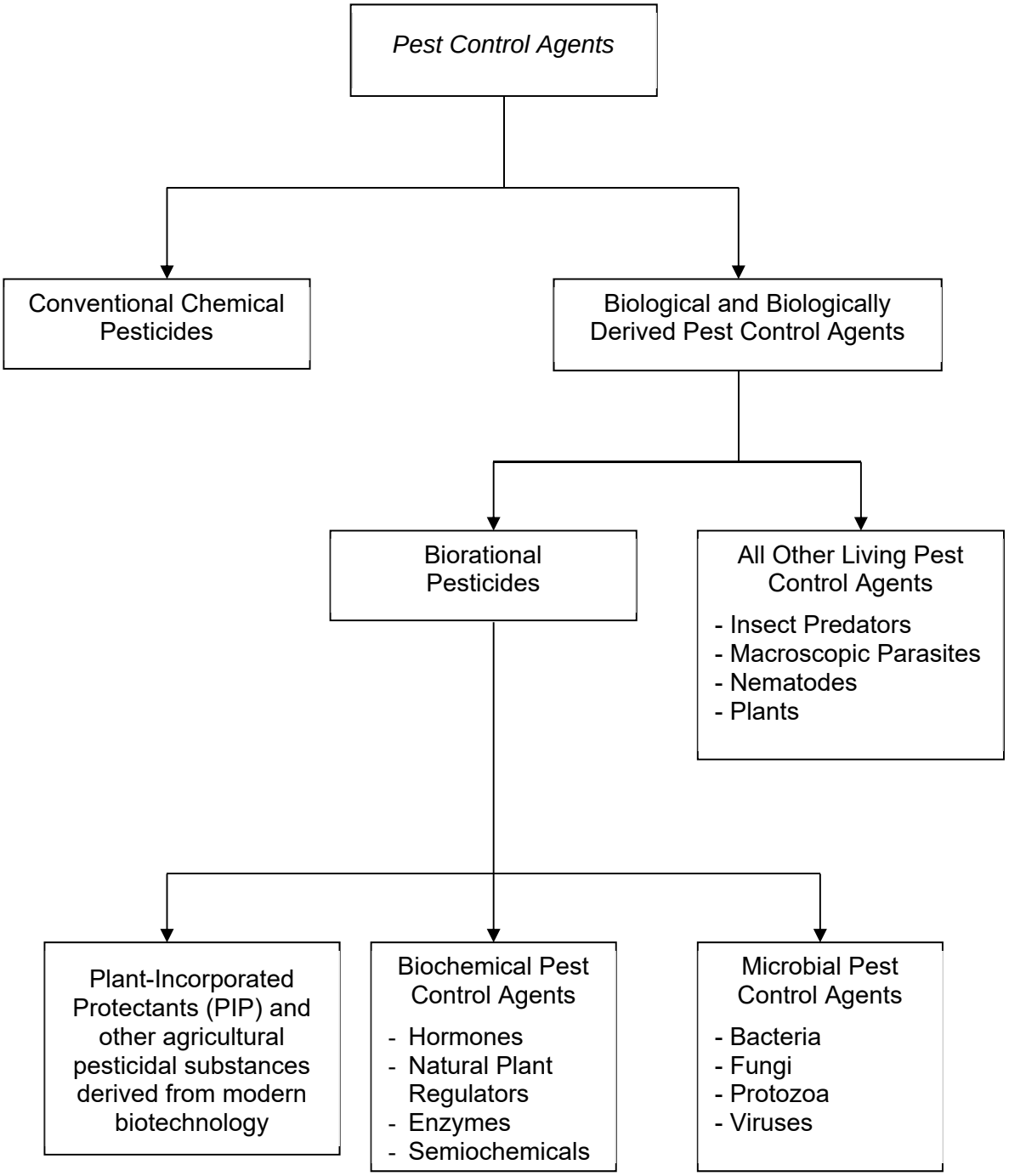
*B. Hormones*

These are biochemical agents synthesized in one part of an organism and translocated to another where they have controlling, behavioral, or regulating effect.

*C. Natural Plant Regulators*

These are chemicals produced by plants that have toxic, inhibitory, stimulatory, or other modifying effects on the same or other species of plants. Some of these are termed “plant hormones” or “phytohormones.”

**Figure 2. RELATIONSHIPS AMONG CONVENTIONAL PESTICIDES, BIOLOGICAL CONTROL AGENTS AND BIORATIONAL PESTICIDES**



*D. Enzymes*

In this regard, enzymes are protein molecules that catalyze biochemical reactions and which are the instruments for expression for gene action.

### 3.1.3 Microbial Pest Control Agents

These biorational pesticides include (but are not limited to) bacteria, fungi, viruses, and protozoans. The guidelines apply to all microbial pest control agents used as pesticides, including not only those that are naturally occurring, but also the improved strains.

### 3.1.4 Pest Control Organisms

Pest control organisms such as insect predators, nematodes, and macroscopic parasites are not considered biorational pesticides, and are exempt from the requirements of these guidelines.

### 3.1.5 Plant-Incorporated Protectants

Plant-incorporated protectant (PIP) refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance. Pest-protected plant (PPP) refers to any plant that is made pest-resistant using any of the techniques of modern biotechnology.

Prior to commercial propagation, the transformation event which serves as the PIP of a pest-protected plant must be duly registered with FPA.

The types of PIP to be registered are as follows:

1. **New Single PIP** – This refers to a PIP resulting from one (1) transformation event.

2. **New Combined/Stacked PIPs**

   a. Registered single PIP + Registered single PIP
   b. Registered single PIP + New single PIP
   c. New single PIP + New single PIP

## 3.2 REGULATION OF BIORATIONAL PESTICIDES

### 3.2.1 Policy Statement

This section describes the philosophy and approach to the regulation of biorational pesticides. In adherence to the rules and regulations of the National Committee on Biosafety of the Philippines (NCBP), FPA shall require registrants to obtain clearance from the said Committee prior to the registration of the product.

In regulating biorational pesticides, FPA shall recognize that these kinds of pesticides are inherently different from conventional pesticides, and will take due consideration that many classes of biorational control agents pose

lower potential risks than conventional pesticides. This does not mean however, that biorational pesticide registrants shall be relieved of the burden of proof of the safety of their products.

The most important inherent difference between biorational pesticides and conventional pesticides are: target species specificity, generally non-toxic mode of action, and natural occurrence of the biorational agents. These factors provide the basis for the FPA's expectation that many classes of biorational pest control agents pose a lower potential hazard than conventional pesticides and support the approach to testing discussed in the following paragraphs.

Nevertheless, the data requirements for registration of those living organisms, which are pesticides, shall be determined on a case-to-case basis after consultation with FPA.

***Formulator's Exemption***. While appropriate data are needed for the registration of manufacturing-use product, a formulator who proposes to purchase a registered pesticide from another producer to formulate such purchased pesticide into an end-use product would not be required to submit or cite data pertaining to the safety of such purchased product. This guideline is based on the expectation that it would be the registrant of the manufacturing-use product who would provide significant amounts of data pertaining to the safety of its product.

### 3.2.2 Approach to Testing

To meet the intent of the above policy, the following elements comprise the approach taken by FPA: exposure criteria (for biochemicals), maximum hazard testing, and a tier testing scheme.

*A. Exposure Criteria*

There are certain factors often associated with biochemical pest control agents or their use that significantly limit the agents' potential for human and other non-target organism exposure and, therefore, hazardous. Any or all of these factors provide the basis for reduced data requirements. These factors are: low exposure from pesticide formulation, low rate of application, non-aquatic use site, and high volatility.

*B. Maximum Hazard Testing*

The concept of maximum hazard testing is used in both the toxicology and non-target organism sections. The concept provides for the most challenging exposure in terms of the treatment dose or concentration, route of administration, and the age of the test animals used in the first tier of testing. Using this approach, negative test results obtained would provide a high degree of confidence that no adverse effects would be likely to occur from the use of the biorational pest control agents.

### *C. Tier Testing Scheme*

The tier testing scheme is used to ensure that only the minimum data necessary to make a scientifically sound regulatory decision are generated. This scheme eliminates the need for submission of extensive data for those pesticides that are determined to be safe on the basis of Tier I data. It is expected that many biorational pesticides would require only Tier I testing. The Tier Testing Scheme is discussed in detail in Section 3.4.

## 3.3 PRODUCT SPECIFICATION DATA

### 3.3.1 Scope of Product Analysis Requirements

The product analysis data for biorational pesticides closely parallel those for conventional chemical pesticides as specified in Table 2. However, important differences exist due to the unique nature and mode of action of biorationals as noted below.

### 3.3.2 Guidelines for Biochemical Pest Control Agents

For this group, the data requirements parallel those required for conventional chemical pesticides in terms of the detailed information on the procedures by which the active ingredient is produced, and the techniques used to ensure a uniform or standardized product. If the standardization techniques include methods of bioassay, then these methods shall be described. Particular interest is given to the ingredients, which may be toxic or sensitizing to humans or other non-target species. The following are the guidelines for product analysis for this group:

*A. Product Identity*

Each application for the registration of a biochemical PCA that is a pesticide product shall contain the product name and the trade name(s) (if different). The company code number(s) may be given.

*B. Confidential Statement of Formula*

An application for registration of a product shall contain a confidential statement of formula. A separate confidential statement of formula is required for each alternate formula of a product. The appropriate FPA form shall be used.

*C. Information on Ingredients*

An application for registration shall contain the following information (if available) on each ingredient, which is listed in the confidential statement of formula required by paragraph (B) of this section:

1. Each biochemical (including microbial toxins) shall be identified by:

   a. The chemical name(s) from the Chemical Abstracts 1972-1976 Index of Nomenclature, or other well-defined name;

   b. The Chemical Abstracts Service (CAS) Registry Number(s);

   c. The structural formula(s), empirical formula(s);

   d. The count of biochemical present in the product in recognized units of potency or other appropriate expression of biological activity or percentage by weight;

e. The genus and species names of the organism(s) from which the biochemical was separated or with which it is commonly associated; and

f. The specificity or host range of the biochemical activity and mode of action. With respect to mode of action of the biochemical, the applicant should discuss any potential hazard to man, the environment, or non-target species.

2. Ingredients, other than biochemicals, shall be identified by;

a. Percentage composition (by weight) of each ingredient;

b. Whether the ingredient is an active ingredient, intentionally added, or an impurity;

c. The chemical name for the Chemical Abstracts or other well-defined name;

d. The CAS registry number;

e. The product name, the trade name, and the common name (if established);

f. The experimental or internal code number;

g. For each active ingredient other than the biochemical, the empirical formula, and the molecular weight or the molecular weight range; and

h. The structural formula, if it can be determined.

3. The composition limits shall be given for each ingredient for which limits are required to be certified. If space permits, this information can be listed in the confidential statement of formula; otherwise, a separate statement on certification of limits must be submitted.

*D. Manufacturing Process*

Each product's registration application shall be supported by an accurate and current description of the process used to manufacture or formulate the product. The description shall contain the following information:

1. Basic manufacturing process for each biochemical derived from biological sources:

    a. The starting material shall be listed;

    b. The steps taken, both chemical and biological, to ensure the integrity of the starting material and to limit the extraneous contamination in the unformulated biochemical shall be given;

    c. The procedures by which the manufacturer established the identity and purity of the seed stock from which the unformulated biochemical is produced shall be described; and

    d. The quality control methods and the techniques used to ensure a uniform or standardized product shall be reported. Unless the quality control methods are well established and recognized, they shall be submitted in detail with information regarding their accuracy, sensitivity, and the interfering substances.

2. Toxic or sensitizing substances. If the presence of ingredients toxic or sensitizing to humans or other non-target mammalian species is suspected at any stage of the manufacturing process, then data shall be submitted to show that the substances do not exist in the final biochemical product or exist only in quantities too small to pose any hazard.

*E. Discussion on the Formation of Unintentional Ingredients*

A registration application shall include a discussion concerning potential formation and presence of unintentional ingredients in the product in quantities that may produce adverse human or environmental effects. Such unintentional ingredients may be introduced during the manufacturing process with the starting material, process solvents, equipment, packaging, and other sources; from side reactions in the manufacturing process; from interactions between ingredients; and from the degradation of ingredients. The applicant shall base his discussion on established chemical theory. For biochemicals, the unintentional ingredients can include but are not limited to extraneous host residues and residues of contaminants that remain following the extraction or purification process.

*F. Analysis of Samples*

A report on the results of preliminary analysis is required to support the registration of each manufacturing-use product and those end-use products produced by an integrated formulation system.

*G. Analytical Methods for Certified Ingredient Limits*

Information concerning analytical methods to verify certified limits is required to support the registration of each manufacturing-use and end-use product.

*H. Physical and Chemical Properties*

Data on physical and chemical properties are required to support the registration of each manufacturing-use product and each end-use product. These data are listed in Table 5..

### 3.3.3 Product Analysis Guidelines for Microbial Pest Control Agents

For this group, due to the unique nature, composition, and mode of action of microbial agents, data requirements differ in some respects. For example, bacteria, fungi, protozoa, and viruses shall be identified to the extent possible by taxonomic position, serotype, composition, and strain, or by any other appropriate specific means. This information would take the place of chemical name and structural formula for conventional pesticides. As a result, certain portions of the data requirements table (Table 6.) do not apply. There must be assurance, however, that the methods used and the data submitted are capable of demonstrating that the biorational pesticide used in the field is the same as that which was tested for safety.

*A. Product Identity*

Each application for registration of a microbial pest control agent shall contain the product name and trade name(s) (if different). The company code number(s) may be given.

*B. Confidential Statement of Formula*

Application for registration of a product shall contain a confidential statement of formula. This statement shall include the nature and quantity of diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such materials.

*C. Information on Ingredients*

Information on ingredients is required to support each application for registration.

1. The identification of bacteria, protozoa, viruses, or fungi in the product shall (to the extent possible) include the following:

a. The taxonomic position, serotype, and strain, or any other appropriate designation. The precise test procedures and criteria used for identification (i.e., the morphological, biochemical, analytical (physical, chemical), serological, or other identification means) and the results of such tests should be provided;

b. The common, alternative, and superseded names;

c. The natural occurrence of the organism, its relationship to other species (particularly those that are pathogenic), and its history; and

d. A description of any unusual morphological, biochemical, or resistance characteristics of the organism if such characteristics are different from the classic description of the organism.

2. An application for registration shall contain the following information on each ingredient, other than the microbial agent, listed in the confidential statement of formula required in item B of this section which is known to be present or which might reasonably be identified in the pesticide products.

a. Percentage composition (by weight) of each ingredient;

b. Whether the ingredient is an active ingredient, an intentionally added ingredient, or any impurity;

c. The chemical name from the Chemical Abstracts 1972-1976 Index of Nomenclature, or other well-defined name;

d. CAS Registry Number;

e. The product name, the trade name, and the common name (if established);

f. The experimental or internal code number;

g. For each active ingredient other than the microbial agents, the empirical formula, and the molecular weight or the molecular weight range;

h. The structural formula (when known);

i. The composition limits for each ingredient for which limits are required to be certified. This may be included in the confidential statement of formula;

j. The amount of microbial agent present in the product in recognized units of potency, percentage of weight, units of viability or replication, or other appropriate expression of biological activity; and

k. The biological properties of the active agent with respect to target species, pest host range, life cycle, and mode of action. With respect to the properties of the microbial agent, any potential hazard (such as ineffectivity) to man, the environment, or non-target species should be discussed.

*D. Manufacturing Process*

Each application for registration of a manufacturing-use or end-use product shall contain a description of the basic manufacturing process. The starting and intermediate materials shall be listed together with the steps taken to ensure the integrity of these materials, and the steps taken to limit the extraneous contamination, both chemical and biological, in the unformulated microbial agent. This description shall include the procedure used by the manufacturer to establish the identity and purity of the culture from which the unformulated microbial agent is produced, the method of manufacture, and the techniques used to ensure a uniform or standardized product. The integrity of the product as determined by the most specific and sensitive chemical or serological test must be demonstrated. If the test is not a recognized standard test, a detailed description of the test together with information regarding specificity, interfering substances, accuracy and sensitivity must be provided.

*E. Certification of Ingredient Limits*

Each registration shall be supported by a certification of ingredient limits. The limits for microbial agents shall also be expressed in terms such as international units of potency per milligram when these are determined in serological or other appropriate tests.

*F. Physical and Chemical Properties*

When required, data on physical and chemical properties must be submitted to support the registration of each manufacturing-use product and each end-use product. Take note of the formulators' exemption from the submission of the required data.

## 3.4 TOXICOLOGY

### 3.4.1 Major Concerns

Biorational pesticides affect pest populations by controlling physiological processes, by altering behavior, by competing for space and nutrients, by parasitizing and lysing the pest, or by replicating in an infective process to cause disease so that the pest is destroyed. The testing for registration of the product and the kinds of data developed must be sufficient to allow scientific experts to assess the potential hazards associated with the use of biorational pesticides.

The major concerns with respect to toxicology are:

1. "infectivity" - the potential for the microorganism to survive and replicate in a human host. Related concerns include persistence, invasiveness, colonization, and other host-parasite interactions.

2. "virulence-toxicity" - the potential for direct injury at the cellular, tissue, or organ level. Included are the long-term effects associated with oncogenicity, carcinogenicity, and teratogenicity.

3. "hypersensitivity" - an immune response leading to an abnormal sensitivity. Serious reactions include allergies and anaphylaxis.

These concerns must be addressed in terms of the potential impact of these agents on the population as a whole particularly on those persons with altered defenses who might encounter these agents, and who represent a sub-population at higher risk. At present, viruses are of particular concern because they generally exhibit a greater incidence of genetic change than other living forms.

Because the field is new, many problems related to toxicology and hazard evaluation would undoubtedly be encountered. It is recognized that for some biorational pesticides, there are no well-recognized and standard test methods for assessing the toxicological hazards to mammals. When problems arise, the registrant is urged to discuss the matter with FPA so that alternative methods and protocols can be considered prior to the actual conduct of the tests.

### 3.4.2 Biochemical Agents

Testing of biochemical agents for possible effects on humans and domestic animals is performed in a tier sequence. The potential for adverse effects can be ascertained by acute toxicity, irritation and hypersensitivity tests, by short-term mutagenicity tests, and by cellular immune response studies. When detrimental effects are found in the first tier of tests, additional studies at the Tier II and III levels shall be required. The Tier sequence and studies involved are outlined in Table 5.

### 3.4.3 Microbial Agents

The testing of microbial agents for possible effects on humans and domestic animals is performed in a tier sequence. These tests consist of acute toxicity/infectivity studies, cellular immune response studies, and irritation, hypersensitivity, virulence enhancement, tissue culture, teratogenicity, mutagenicity, sub-chronic, and chronic studies. Not all studies pertain to each organism at each tier. The general tier sequence and studies involved for microbial agents are outlined in Table 6..

### 3.4.4 Toxicology Data Guidelines for Biochemical Agents

*A. Tier I Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-10 to 152-18, pp. 117-129. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

*B. Tier II Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-19 to 152-24, pp. 129-139. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

*C. Tier III Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-26 to 152-29, pp. 139-141. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

### 3.4.5 Toxicology Data Guidelines for Microbial Agents

*A. Tier I Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-30 to 152-39, pp. 142-173. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

*B. Tier II Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-40 to 152-49, pp. 174-189. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

*C. Tier III Testing*

Guidelines are contained in the following reference documents:

Sub-series 152A, Sections 152-50 to 152-53, pp. 190-192. EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

## 3.5 RESIDUE ANALYSIS

### 3.5.1 Biochemical Pest Control Agents

*A. Approach*

The full set of residue chemistry guidelines for conventional pesticides may not always be applicable to biochemical pest control agents for the following reasons:

1. Biochemical agents occur naturally in the environment or are identical to naturally occurring biochemicals and have properties similar to their natural counterparts;

2. Many biochemical agents are used at very low application rates (i.e., <50 g active ingredient or less per hectare); and

3. Past experience indicates that biochemicals are relatively non-toxic.

Consequently, the resulting residues of biochemicals in food or feed would be very low and the potential for adverse effects would be correspondingly low. Thus, it is expected that significant human dietary exposure will generally not occur from the use of biochemicals.

*B. Tier Progression*

In general, when no potentially adverse effects are observed during the Tier I toxicity testing, a biochemical would be exempted from the need for a tolerance level, provided it is applied at rates of 50 g or less active ingredient per hectare per application. In this situation, FPA would waive the usual metabolism and residue data and would recommend that an exemption from the requirement of a tolerance level be made.

On the other hand, the full range of residue chemistry data required for conventional pesticides would apply to:

1. All biochemical agents proceeding to toxicity testing beyond Tier I (that is, to Tier II or III); and

2. All biochemical agents to be applied on food or feed crops at a rate greater than 50 g active ingredient per hectare per application.

These would include plant metabolism studies, residue data, and analytical methodology. In addition, depending on the level of residue found in animal feed, the Agency may solicit data on animal metabolism and feeding studies to determine the carryover of residues in meat, milk, poultry, and eggs. When appropriate, tolerances for the latter commodities would be necessary.

### 3.5.2 Microbial Pest Control Agents

*A. Approach*

As with a biochemical agent, the use of a microbial agent on food, feed, or raw agricultural commodities requires that a tolerance, or an exemption from the requirement for a tolerance, be established. In considering exemptions from the requirement for tolerances, the FPA recognizes that these agents do not necessarily pose the same potential hazards as conventional chemical pesticides. In fact, certain characteristics of many of these agents suggest that they pose relatively less hazards. These characteristics are described below:

1. The efficacy of the agent often depends upon its ability to replicate in the target pest which is not likely to remain on the crop after harvest;

2. The living form of the agent in most instances will usually not replicate in the absence of the specific target pest (e.g. insect host);

3. Certain environmental conditions such as high sunlight intensity, heavy rainfall, strong wind, low humidity, and high temperature often greatly reduce the viability of the agent and, therefore, the residues of living organisms are apt to be small or relatively insignificant shortly after application;

4. When evaluated by the tier testing scheme, data supporting currently registered microbial agents indicate that microbial pest control agents would not likely pose a hazard to human or other animals;

5. In many instances where and when a microorganism is used as a microbial pest control agent, the microorganism is already normally present in the environment and has demonstrated no adverse effects; and

6. Residues of microorganisms used as microbial pest control agents that are capable of replication on food or feed (a very remote possibility) will possibly be rendered nonviable or be removed by the usual processing of such foods and feeds (i.e., washing, drying, heat sterilization, and addition of sugar, salt, and other preservatives).

*B. Tier Progression*

Residue data for microbial pest control agents used in food, feed, or raw agricultural commodities shall only be required if toxic or other harmful properties were observed in the maximum hazard toxicology tests (Tier I). If Tier I toxicology tests indicate no toxic or other harmful properties, then no residue data would be indicated and thus a recommendation for an exemption from the requirements of a tolerance can be made.

Furthermore, it may be stated in passing that, in many cases, a natural population of microbial agent may be present at some background level at the site where a microbial pest control agent is applied. It may be impossible, therefore, to distinguish between natural and introduced microbial populations and thus, be very difficult to establish and enforce tolerances for naturally occurring microbial agents. This is something that must be considered regarding this section.

## 3.6 NON-TARGET ORGANISM HAZARD

The purpose of non-target organism testing is to generate data necessary to assess potential hazard of biorational pesticides to terrestrial wildlife, aquatic animals, plants, and beneficial insects.

### 3.6.1 Biochemical Agents

*A. Terrestrial Wildlife*

1. Approach. Hazard evaluation of biochemical agents should be similar in approach to that of conventional chemical pesticides. However, the number of Tier I tests should be lower and the test design modified based on the following considerations; Tier I tests should be designed to determine whether $LC_{50}$ or $LD_{50}$ values are above a specified maximum test concentration or dose rather than require that the $LC_{50}$ or $LD_{50}$ be determined.

This modified test design should apply if death was not observed at the maximum concentration or dose.

This approach is deemed appropriate based on the following:

a. Innate toxicity is not inherent to the nature and mode of action of biochemical agents;

b. Experience so far indicates that most of these pesticides will be applied at very low rates compared to conventional chemical pesticides, thereby reducing likelihood or significant exposure to non-target organisms; and

c. Past experience likewise indicates that most biochemical pest control agents are not acutely toxic (e.g. $LC_{50}$ and $LD_{50}$ values in Avian species of most biochemical agents are greater than 5000 ppm or 2000 mg/Kg, respectively).

Both terrestrial wildlife and aquatic animal testing schemes use some or all of the exposure criteria, i.e., low use rate, low exposure formulation, non-aquatic use site, and high volatility, to screen out those pesticides that qualify for reduced testing.

2. Tier Progression. The following criteria are provided for determining the need for testing a biochemical agent beyond the first tier:

a. If signs of abnormal behavior are reported in Tier I tests at levels equal to or less than the maximum expected environmental concentration; or

b. If detrimental growth, developmental, or reproductive effects can be expected, based on: a) Tier I test data; b) available fate data from the product's research and development; c) use pattern information; d) results of mammalian testing required in the Toxicology section; and e) the phylogenetic similarity between target pest and non-target organism; or

c. If the maximum expected environmental concentration is equal to or greater than 1/5 the $LC_{50}$ values established in Tier I terrestrial wildlife studies, or equal to or greater than 1/10 the $LD_{50}$ or $LC_{50}$ values established in Tier I aquatic animal studies.

In addition, both Tier I and Tier II tests should be required if:

- The pesticide is to be applied directly to water; or
- High use rates are proposed; and
- The biochemical agents are not volatile.

3. Major Issues. In the process of developing testing guidelines for terrestrial and aquatic animals, there are at least two (2) areas that need consideration and discussion, namely:

a. Maximum test concentrations and doses. As part of the registration requirements, bioassay tests involving maximum test concentration or dose on one terrestrial animal (e.g. Avian toxicity oral and dietary tests) or aquatic organism should be submitted. Negative results from such tests would provide a high degree of confidence that no adverse effects are likely to occur from the actual use of the biochemical pesticide. If, however, effects are observed at these maximum levels, then further testing at lower levels would be indicated in order to establish precise $LC_{50}$ and $LD_{50}$ values and corresponding 95 % confidence limits.

Regarding the calculation of the maximum test concentrations, the general equations proposed by US EPA are as follows:

$$\text{Maximum Test Dose} = \frac{\text{Maximum application rate in grams AI per ha}^{*}}{454^{**}} \times 2000 \text{ mg/Kg}$$

$$\text{Maximum Test Concentration} = \frac{\text{Maximum application rate in grams AI per ha}^{*}}{454^{**}} \times 5000 \text{ ppm}$$

For example, a 20 gram/acre (49 gram/hectare) rate would give an 88 mg/Kg maximum test dose and a maximum test concentration of 220 ppm.

b. Categorization of semiochemicals by structure /activity relationships. Categorization of chemicals is a method through which scientists can infer which chemicals present risks or harm to humans and to the environment. The study of structure/activity relationships (SAR) seeks to find association between a substance physical and chemical properties and its effect on biological activity. Use of SAR in the assessment of adverse effects of some industrial chemicals to non-target organisms, such as shrimp and clams, had been reported (Mcleese et al, 1979). Since most semiochemicals used as pesticides are applied at very low rates and possess special physicochemical properties (such as high volatility) that lessen their exposure to terrestrial animals, acute toxicity data on terrestrial animals for each new semiochemicals submitted for registration may not be necessary. Rather, a determination of hazard could be based on existing acute toxicity data for structurally similar semiochemicals.

---

* For biochemical pest control agents.

** A typical application rate for conventional pesticides.

These guidelines for biochemical pesticides do not include use of structure/activity relationships. However, the concept when developed for semiochemicals could provide an acceptable database for hazard assessment concerning both terrestrial and aquatic animals. At the same time, it could reduce the data required for registering semiochemicals used as pesticides.

*B. Aquatic Animals*

Regarding risks to aquatic animals, many biochemical agents possess special physicochemical properties, or are applied in a manner such that they are unlikely to enter the aquatic environment in significant quantities. Consequently, they would not be expected to pose hazards to aquatic animals. On this basis, the guidelines are reduced to two ways:

1. The fish acute bioassay test indicated that only one fish species, rather than two, be tested; and

2. One control group and one treatment group per test may be all that are necessary to provide satisfactory data showing no adverse effects.

Moreover, it is expected that each biochemical screened out for reduced testing would have several criteria supporting such a course of action such as: i) non-aquatic use; ii) low potential for significant exposure based on use pattern and formulation; iii) low use rate; and/or iv) high volatility.

*C. Non-Target Plants*

1. Approach. The testing procedures for biochemical agents should be similar to those for other chemical pesticides with respect to phytotoxicity studies.

2. Tier Progression. Progression to Tier III and further plant effects testing would depend on whether there are any adverse effects to desirable plants at the Tier I level, and whether there is possible movement by soil, water, or air from the intended site of application to non-target areas as determined by selected tests of Tier II on environmental fate. In the vast majority of biochemical pesticides, such movement might occur, but as levels far below those which would have a detrimental effect as determined in the Tier I tests.

*D. Non-target Insects*

1. *Approach.* Development of baseline (first tier) tests for biochemical pesticides is difficult, for the following two reasons:

a. Effects of these biochemicals will often be long-term (e.g. effects on growth) rather than acute; this type of activity does not lend itself to short term testing; and

b. Effects on development or behavior, unlike mortality, may be difficult to quantify.

In view of the above, no outline for any specific types of Tier I testing for effects of biochemical pesticides on non-target insects will be prescribed. Rather, the registrant should report any adverse effects on non-target insects noted during efficacy testing, including effects such as:

a. Mortality or other adverse effects (e.g. behavioral modification) on insect predators or parasites of the target organism; and

b. Direct adverse or repelling effects on pollinators.

2. *Tier Progression*. As noted above, no Tier I testing shall be required. Rather, Tier I shall consist of data (such as efficacy data) submitted by the registrant or made available from another source. If no such effects are noted during efficacy testing, and in the absence of any other data indicating potential for adverse effects, no non-target insect testing will be indicated. However, if adverse effects are noted and/or auxiliary data indicate a potential for adverse effects, then Tier II (Environmental Fate) testing shall apply. If fate testing do not indicate exposure, no further testing shall be indicated. If fate testing indicates exposure, the registrant shall consult with the FPA regarding further testing at the Tier III level. Testing required at this point would most likely be simulated or actual field-testing.

### 3.6.2 Microbial Pest Control Agents

*A. Terrestrial Wildlife and Aquatic Animals*

3. Approach . Pathogenicity and toxicity are the major effects of concern regarding terrestrial and aquatic organisms. Therefore, guidelines that will allow hazard assessment of possible pathogenicity and toxicity problems are needed.

In addition, it is desirable to have a high level of confidence that no adverse environmental effects will result from actual use of microbial pest control agents. Toward this end, the guidelines in Tier I reflect a maximum hazard approach to testing as described earlier. Prior to registration of naturally occurring and strain-improved microbial agents, applicants would submit only Tier I data on non-target organisms. However, for the registration of genetically engineered microbial pest control agents, both non-target organism data (Tier I) and environmental expression data (Tier II) should be evaluated.

4. Major Issues

a. Maximum hazard dosage levels. The environmental levels of microbial PCAs and any associated toxins are expected to increase at least temporarily when the product is effective. Therefore, the maximum hazard dose for Tier I testing will be based on some safety factor times the maximum amount of active ingredient (microbial agent or its toxin) expected to be available to terrestrial and aquatic plants and animals in the environment. The target hosts (e.g. insects) are likely to contain the highest concentration of the microbial pest control agent that will be available to non-target terrestrial wildlife and aquatic animals following a pesticide application. The maximum amount of microbial pest control agent (active ingredient) that one infected host can contain is called the host equivalent in this guideline. The maximum hazard dose is equal to the host equivalent multiplied by the ratio of the weight of the test animal (e.g., fish or bird) to the weight of the infected host organism (e.g., insect larva). The route(s) of administration (e.g., oral or parenteral) and the size of the test organism(s) will largely determine whether the maximum hazard dose will be a multiple or a fraction of the adjusted host equivalent amount.

In the case of microbial pest control agents applied to the soil to control soil-borne diseases affecting plants, the soil may contain the highest concentration of the agent. The host equivalent concept would not be applicable in this situation since the host, most often, will be a microscopic propagule (a spore, oospore, sclerotium or chlamydospore).

Because test data are not likely to exhibit a log-probit dose-response relationship that is typical of chemical pesticides, it would be very difficult to establish specific $LC_{50}$, $ED_{50}$, or $LD_{50}$ values (e.g., $LD_{50}$ = 1000 mg/Kg) and 95 % confidence limits for most microbial pest control agents. Therefore, the data establishing that the $LD_{50}$, $ED_{50}$, or $LD_{50}$ is greater than the maximum hazard dosage level (e.g., $LD_{50}$>1000 mg/Kg) would often be adequate for purposes of hazard assessment. In most cases, testing at one maximum hazard dosage level is expected to be sufficient to evaluate effects.

b. Maximum hazard routes of administration. The parenteral route (e.g. intravenous (IV), intraperitoneal (IP) is considered an appropriate method for conducting maximum hazard exposure to terrestrial and aquatic animals in Tier I tests. Negative test results obtained using this method and using maximum hazard dosage levels would provide a high level of confidence that no adverse effects would occur from the actual use of the microbial PCA.

c. Age of the test animals. For Tier I tests, the use of immature animals as test organisms is recommended in keeping with the maximum hazard approach to testing.

d. Method for detecting effects. Due to the extremely diverse nature of the active component in microbial PCAs (e.g., natural toxins, acellular agents (viruses), prokaryotic cells (bacteria), eukaryotic cells (fungi, protozoans, most algae), many different methods to detect each agent and assess infections have been developed. To assist applications and registrants, the Agency is providing a scheme which will show some acceptable methods for detecting pathogenic effects for each type of microbial agent (Table 8.).

*B. Aquatic Animals*

1. Approach. The criteria identified to determine the extent of testing for effects on aquatic animals in Tier I are the following:

   a. Site of application and resulting potential for aquatic exposure;

   b. The natural geographic distribution of the microorganism;

   c. The natural population level of the microorganism compared with population levels likely after application;

   d. Ability of the microbial pest control agent to survive and replicate after application; and

   e. The extent to which the microorganism has been manipulated or genetically engineered.

2. Tier Progression. Tier I. For microbial PCA applied in terrestrial use patterns where no direct aquatic exposure is anticipated, one freshwater fish and one freshwater invertebrate shall be tested to assess toxicity and pathogenicity. For microbial PCA applied directly to aquatic bodies, one additional fish species and one additional invertebrate species shall be tested. These tests shall be conducted as 30-day static or static renewal bioassays using one or a combination of methods to administer the pesticide (e.g., aqueous, dietary, or injection).

   No further testing shall be indicated if: (1) results of the aforementioned tests indicate no toxic or pathogenic effects; and (2) host spectrum or beneficial insect tests indicate that the microbial pest control agent has a narrow host spectrum such that the crossover into non-target aquatic invertebrates is not likely. If toxic or pathogenic effects are observed, then environmental expression testing (Tier II) should follow. If crossover into non-target aquatic invertebrates are implied, then additional aquatic invertebrates species in Tier I or Tier II testing should have to be conducted.

All genetically engineered microbial agents should be subjected to Tier II testing. Tier III and Tier IV testings should they become necessary, must be consulted with the FPA.

*C. Non-target Plants*

1. Approach. While phytotoxicity data for conventional chemical and biorational biochemical pesticides will be required only on a case-to-case basis, it seems appropriate that phytotoxicity studies be submitted for all microbial pest control agents. The pesticide science for these agents is relatively new and their adverse effects can be far-reaching. These effects may occur because microbe is capable of extensive regeneration in a favorable environment. If it is transported to other off-target areas and the selectivity is not known, considerable damage to desirable plants can occur.

2. Major Issues. The primary concerns with respect to the use of living organisms on or near desirable or non-target plants in the control of pest plants are the selectivity of the organisms, the purity of the organism or strain produced (quality control), and the persistence or lack thereof of the organism. There are several criteria that must be satisfied in varying degrees in order for the pathogen to be desirable candidate as a biological control agent for pestiferous plant species. These criteria include:

   a. Selectivity for the specific pest organism;

   b. Absence of adverse effect on man; domestic animals, fish, wildlife, and desirable insects;

   c. Absence of adverse effect on non-target or desirable plants;

   d. Absence of any detrimental effects on water quality;

   e. Lack of accumulation in non-target organisms;

   f. Ease of production, dissemination, and self-maintaining capability when established;

   g. Effectiveness under the environmental conditions of the intended use locations; and

   h. Simplicity of assay for its presence in small amounts both quantitatively and qualitatively.

   Similarity of testing procedures to those recommended for the previous groups should be followed, otherwise consult the FPA on this.

*D. Non-target Insects*

1. Approach. Most microbial pest control agents shall be specifically selected and/or designed for their ability to control insect pests. As such, non-target insects represent the organism group most at risk in most cases, relatively closely related to the target insects. Unlike chemical pesticides, most microbials will work through pathogenicity rather than toxicity. Adequate assessment of pathogenicity will demand time to evaluate the microbial agent for infectivity and for its ability to reproduce or develop in the test insect.

2. Tier Testing. The purpose of the Tier I testing is to assess toxicity and pathogenicity of the microbial agent to representatives of a few major orders of beneficial insects. In this case, the honeybee and three species each of predaceous or parasitic insects. Selection of the predator/parasite species to be tested shall take into account such factors as the likelihood of exposure to the microbial agent, phylogenetic proximity of the test species to target pest species and similar relationships. Rationale for selection shall be provided by the registrant. Data derived from Tier I testing shall be in conjunction with available information on use pattern, host range (specificity), fate, and other similar factors, to assess potential for adverse effects. If the results of Tier I testing indicate toxic and/or pathogenic effects, the Tier II testing (environmental expression) would follow, otherwise no further test is required.

   For all genetically-engineered microorganisms, however, testing includes appropriate Tier I tests and Tier II (environmental) testing.

   Tier III. For all microbial pest control agents, Tier III consists of advanced tests specifically responding to adverse effects identified in earlier tier testing. Such tests may be simulated or actual field tests are done. In any case, Tier III testing should be preceded by consultation with FPA.

## 3.7 ENVIRONMENTAL FATE AND EXPRESSION

### 3.7.1 Biochemical Pest Control Agents: Environmental Fate Testing

A. Scope and Approach

The term environmental fate pertains to biochemical pest control agents (whereas, the term environmental expression pertains to microbial pest control agents). The purpose of environmental fate testing is to generate the data necessary to estimate the concentration of a biochemical pesticide and its degradates occurring in or on various media (i.e., soil, water, air) at intervals after pesticide application. Generally, these data should be submitted if adverse effects are observed in Tier I environmental effect tests or if the biochemical is applied directly to water. Figure 3 outlines the Environmental Fate Testing Scheme.

**Figure 3. ENVIRONMENTAL FATE TESTING SCHEME**

Potential adverse effects are seen in Tier I Testing. (If not, no testing is indicated in Tier II unless product is in aquatic use pattern or if biochemical is not applied in a controlled release device, in which case the process should proceed directly to Persistence Testing.

TRANSPORT TESTING
Volatility (# 155-4)*
Dispenser Water Leaching (#155-5)
Vapor Pressure (#151-17)*
Water Solubility (#151-17)

Estimated Environmental Concentration (EEC) determination from mass-balance analysis

EEC indicates potential hazard. (If none, no further testing is indicated.)

PERSISTENCE TESTING

Adsorption/desorption (#155-6)*
Octanol/water partition coefficient (#155-7)
Hydrolysis (#155-9)
Aerobic soil metabolism (#155-11)
Soil photolysis (#155-12)
Aquatic photolysis (#155-13)

Potential for adverse effects to non-target organisms.
(If not, no further testing is indicated.)

Additional non-target organism testing is indicated (Tier III)

* Number in parenthesis indicate the section series and sub-series number in US EPA Pesticide Assessment Guidelines, Subdivision M Biorational Pesticides.

*B. Tier Testing*

The Tier II environmental fate testing scheme consists of twelve (12) separate tests. Seven of these tests are identical to those described for conventional chemical pesticides. The remaining five tests are new. These tests (volatility of dispensed product, dispenser-water leaching, UV (ultraviolet) absorption spectra, bio-monitoring for degradation products, and bio-monitoring for disappearance of biochemicals) address some of the unique properties of biochemical pesticides. Each of these tests is described in the respective section series/sub-series numbers as shown in Figure 3.

### 3.7.2 Microbial Pest Control Agents: Environmental Expression Testing

*A. Scope and Definition*

The term environmental expression as applied to microbial pest control agents is defined as the ability of the physiologically active component of the microbial pest control agent to propagate and become established in a new niche or host after it has been introduced (applied). "Expression" is the counterpart of "fate" which applies to chemical or biochemical pesticides and is defined as the transport and transformation of a chemical by natural means after it is released to the environment.

*B. Tier Testing*

The Tier testing scheme in section series 154 and 155 of Subdivision M is designed to present the maximum hazard to non-target organisms in the initial (Tier I) testing of microbial PCA. Negative results in Tier I mean no further testing is indicated. However, positive results (toxic or pathogenic effects) observed shall mandate further testing in Tier II, environmental expression testing.

Likewise, whenever the agent is a genetically engineered organism, Tier II is also required.

Tier II consists of screening tests that will eliminate the need for Tier III testing whenever the results show that the agent will not become permanently established once applied or inadvertently inserted into a new niche or host, or cannot survive except under special conditions (e.g., specific host, obligatory heterotoph).

In Tier II, the agent is tested for ability to persist in a terrestrial freshwater, marine, or estuarine environment so that potential exposure of non-target organism can be determined. Depending on the use pattern, the tests could be a greenhouse test for determining expression in a terrestrial environment and two aquaria tests for determining expression in a terrestrial environment and two aquaria tests for determining expression in freshwater and in estuarine /marine environments.

## 3.8 PRODUCT PERFORMANCE DATA REQUIREMENTS

### 3.8.1 General Provisions

*A. Waiver of Data Requirements: Policy*

In considering an application for registration of a pesticide, the Administrator may waive the data requirements pertaining to efficacy under certain conditions. The FPA is limiting its direct concern to, and requiring efficacy data for products having health related use patterns and products proposing new and added uses of chemicals which have been identified as posing a risk of unreasonable adverse effects. In keeping with this concern, the Administrator has deemed it proper that all applications for products not having a direct impact on public health may have their efficacy data requirements waived.

*B. Efficacy data generally will be required only for products of the following types:*

1. Uses of agents intended to control microorganisms infectious to man in any area (inanimate surface) where these microorganisms may present a health hazard; and

2. Uses of agents intended for control of fungal organisms that produce aflatoxins.

C. Data on phytotoxicity to the target site, i.e., crops or other desirable plants are considered part of an efficacy evaluation and are thus waived. On the other hand, data on phytotoxicity to crops or other plants that are non-target sites are considered to be data for hazard evaluation and must be submitted on a case to case basis as prescribed in Section series 154-10 and 14. Data on the effects of microbial pest control agents on non-target plants must be submitted for all such products as described in Section series 154-22 and -31.

### 3.8.2 Specific Provisions

The following provisions apply to all biorational pesticides regardless of whether product performance data are or are not waived in accordance with the foregoing policy statement.

1. The available information on host spectrum shall be reported;

2. The time required to achieve the desirable level of pest control or other product performance standard shall be reported; and

3. The minimum effective dosage (MED) necessary to achieve the desirable level of pest control or other product performance standard shall be reported.

## 3.9 EXPERIMENTAL USE PERMIT GUIDELINES

### 3.9.1 Scope and Intent

This section deals with the data necessary to support the application for an experimental use permit for a biorational pesticide. These data generally include those that would ordinarily be developed first in preparation for product development and registration. For example, most product analysis information would be developed early in the product development stages, and the Tier I toxicology and non-target organism toxicity tests would usually be conducted first in preparation for registration. Unless these test results indicate toxic, pathogenic, or other harmful properties, no data on residues or environmental fate would be necessary. Efficacy data follow the pattern already established in guidelines for conventional pesticides which waive the requirements for most products not dealing with public health areas, but the submittal of data on host spectrum, and time and minimum effective dosage required to achieve the product performance standard is required.

### 3.9.2 General and Specific Provisions

*A. General Provision*

In developing plans and information for experimental use permit application, the applicant should carefully review the guidelines for the registration of conventional pesticides which generally apply to biorational pesticides unless otherwise waived or noted.

*B. Specific Data Requirements*

1. Product analysis data - See Section 3.3

2. Toxicology Data

The following data are required to support EUP application:

a. Biochemical Pest Control Agent (PCA) not used on food crops:

- Acute oral toxicity;
- Acute dermal toxicity;
- Primary eye irritation;
- Primary dermal irritation; and
- Studies to detect gene mutation.

b. Biochemical PCA used on food crops:

- All studies listed above in B.2.a of this section; and
- Cellular immune response studies.

c. Microbial PCA not used on food crops:

- Acute dermal infectivity;
- Intravenous, intrecerebral, intraperitoneal infectivity;
- Primary dermal irritation; and
- Primary eye irritation.

d. Microbial PCA used on food crops:

- All studies listed in B.2.c of this section;
- Cellular immune response; and
- Tissue culture with viral agents.

*C. Residue Data*

For biochemical PCA, residue data are required to support an application for EUP when the product will be used on food or feed crops or when its use is expected to result in residues in or on food or feed and for any of the following situations:

1. The rate of application of biochemical PCA exceeds 50 grams active ingredient per acre (120 g/Ha) per application; or

2. Tier I toxicology studies conducted under paragraph B.2.b indicate a potential for human hazard. Residue data requirements shall be determined on individual basis for bio-chemicals applied directly to food or feed, and for biochemicals whose application rate can not be expressed in grams per hectare per application.

For microbial PCA used on food or feed crop or whose use is expected to result in residues in or on food or feed, no data are required unless Tier I toxicology studies conducted under B.2.d of this section indicates a potential for human hazard.

*D. Non-target Organism Toxicology Tests*

To support an application for an experimental use permit, non-target organism data developed in Tier I studies of biochemical and microbial pest control agents as described in Section 3.6 are required.

*E. Environmental Fate and Expression Data*

To support an application for an EUP, data from environmental fate and expression studies are required according to Section 3.7. For those biochemical and microbial PCAs whose Tier I non-target organism test results indicate that Tier II studies for environmental fate and expression shall be conducted. For those PCAs where Tier I non-target organism test results indicate that no Tier II studies are necessary, no environmental fate and expression data are required for EUP application. In those instances where field data from Tier II studies are required for a permit, any comparable or limited field data would suffice in lieu of extensive field data; this policy is needed to preclude generation of extensive field data without a permit in order to obtain information necessary to get a permit.

*F. Product Performance or Efficiency Data*

In general, efficacy data shall not be required to support the issuance of an experimental use permit, except under the following situations:

1. Initial permits. Efficacy data may be required on a case-to-case basis for the following use patterns:

    - Public health uses dealing with microscopic pest organisms; and
    - Use of cancelled or suspended pesticides.

2. Extensions, renewals, and amendments. Summaries of product performance data collected under an experimental use permit may be requested on a case-to-case basis for the purpose of:

    - Determining the need for additional quantities of product requested by the applicant;
    - Evaluating requests for permit extensions; and
    - Assessing requests for permit renewals.

## 3.10 PLANT-INCORPORATED PROTECTANT AND OTHER AGRICULTURAL PESTICIDAL SUBSTANCES DERIVED THROUGH MODERN BIOTECHNOLOGY

In compliance with JDC No. 1, Series of 2016, entitled *Rules and Regulations for the Research and Development, Handling and Use of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology* and pursuant to the provisions of Section 9 of P.D. No. 1144 and its Implementing Rules and Regulations, the FPA promulgated these guidelines for the registration of PIPs in PPPs and other pesticidal substances derived through modern biotechnology.

### 3.10.1 Requirements for the Licensing of Handlers

All technology developers, dealers, importers and all other handlers of PIP and other agricultural pesticidal substances shall obtain the specific dealer license with assigned license number by the Authority before such a person or company can commercialize PIP and other pesticidal substances. The application requirements, validity renewal and fee shall be based on Sections 4.2 and 4.3.

### 3.10.2 Requirements for Registration

PIPs and other agricultural pesticidal substances shall be registered by FPA based on the general principles of biorational pesticides, but with the following modifications specified below, due to their distinct and contained nature.

A. *Approach to Testing* – The approach to testing of PIPs and other agricultural pesticidal substances shall be conducted in accordance with Section 3.2.2

B. *Data on Product Specification for PIPs and other agricultural pesticidal substances* – Based on Section 3.3.2, the following are the data required for product analysis of PIPs and other agricultural pesticidal substances:

1. Product Identity – Each application for the registration of a PIP and other agricultural pesticidal substances shall contain the product name (gene, protein/s, or substance) and the trade name{s) (if different), the company code numbers.

2. Confidential Statement of Formula – An application for registration of a PIP and other agricultural pesticidal substances shall contain a confidential statement of formula. This shall include the gene construct sequences incorporated in the genome, proteins, etc. A separate confidential statement of formula is required for each alternate formula of a product. The appropriate FPA form shall be used.

3. Information on Ingredients – Refer to Section 3.3.2.C.

4. Transformation Process – The data should include the gene/s and DNA elements integrated, sources of genes and DNA elements, the process of transformation, genetic stability, the biochemical pathways involved, and the localization and levels of the PIP and other agricultural pesticidal substances.

5. Purification Process – Each product's registration application shall be supported by an accurate and current description of the process used to manufacture, extract and purify the PIP. The description shall contain the following information:

   a. Basic manufacturing process for each biochemical derived from biological sources:

      i. The starting material shall be listed;

      ii. The steps taken, both chemical and biological, to ensure the integrity of the starting material and to limit the extraneous contamination in the unformulated biochemical shall be given;

      iii. The procedures by which the manufacturer established the identity and purity of the seed stock from which the unformulated biochemical is produced shall be described;

      iv. These quality control methods and the techniques used to ensure a uniform or standardized product shall be reported. Unless the quality control methods are well established and recognized, they shall be submitted in detail with information regarding their accuracy, sensitivity, and the interfering substances; and

b. In the event that the PIP is produced in an organism other than the host plant, tests must be conducted and reported to indicate that the purified PIP thus produced is the same as that made in the host plant.

c. Toxic or sensitizing substances. If the presence of ingredients that are toxic or sensitizing to humans or other non-target mammalian species is suspected at any stage of the manufacturing process, then data shall be submitted to show that the substances do not exist in the final biochemical product or exist only in quantities too small to pose any hazard.

6. Discussion on the Formation of Unintentional Ingredients – It is recognized that unlike agricultural pesticidal substances there will likely be no extraction of the PIP product. However, a registration application shall include a discussion concerning potential formation and presence of unintentional ingredients in the product in quantities that may produce adverse human or environmental effects. Such unintentional ingredients may be introduced during the manufacturing process with the starting material, process solvents, equipment, packaging, and other sources; from interactions between ingredients; and from degradation of ingredients. The applicant shall base his discussion on established chemical theory. For biochemicals, the unintentional ingredients may include, but not limited to, extraneous host residues and residues of contaminants that remain following the extraction or purification process.

7. Physical and Chemical Properties – Data on physical and chemical properties are required to support the registration of each manufacturing-use product and each end-use product.

*C. Toxicology Data Guidelines for PIPs and Other Pesticidal Substances*

Toxicology data guidelines for PIPs and other agricultural pesticidal substances shall be conducted in accordance with Section 3.4.4

However, toxicological testing is not generally required for nucleic acid- based pest control agents, unless the protein product demonstrates enhanced stability/resistance to biodegradation.

*D. Protein Expression Levels of the PIP in the Edible Portion of the Pest-Protected Plant*

1. Approach – Analysis of the protein expression levels of the PIP in the edible portion of the PPP shall be conducted in accordance with internationally accepted methodologies, such as those of, but not limited to, the Association of Official Analytical Chemists (AOAC).

2. Tier Progression – shall be followed in accordance with Section 3.5.I.B

*E. Non-Target Effect Testing for PIPs and Other Agricultural Pesticidal Substances*

The purpose of testing for non-target effects of PIP and other agricultural pesticidal substances is to analyze data, which may be generated locally or abroad, to assess potential risks of PIPs and other substances with pesticidal action to terrestrial wildlife, aquatic animals, non-target plants, and non-target insects.

Non-target effect testing for PIPs and other agricultural pesticidal substances shall be conducted in accordance with Section 3. 6.1

*F. Environmental Fate for PIPs and Other Agricultural Pesticidal Substances*

1. Scope and Approach – Environmental fate data confirm what is the expected fate of PIP and other agricultural pesticidal substances. It validates the anticipated persistence of the PIP and other agricultural pesticidal substances and the Expected Environmental Exposure. Its purpose is to generate data necessary to estimate the concentration of the regulated substance expelled into the surrounding environment during the growth of the crop. The data required in this section should include whether the regulated substance is expressed in the pollen and other parts of the plant that can be borne by wind, insects, etc., and whether the regulated substance is easily dispersed or transferred in such a manner. Data should also be presented as to whether the regulated substance is extruded from the roots into the rhizosphere, and the stability of the extruded substance in the soil. Also, data on the fate of the crop residue should be discussed, whether any of the regulated substance would remain in the soil, and how long it is expected to stay in its active form. These data should be derived from or aligned with the environmental risk assessment that would be conducted during field testing of the pest-protected plant for biosafety purposes. Most PIPs will not need higher tier testing
than Tier I. Refer to Figure 3 for the diagram that outlines the Environmental Fate Testing Scheme.

2. Tier Testing – shall be followed in accordance with Section 3.7.1.B

*G. Product Performance Data Requirements for PIPs and Other Agricultural Pesticidal Substances*

1. General Provisions
   a. Policy on the Waiver of Data Requirements – shall be followed in accordance with Section 3.8.1.A
   b. Efficacy Data – shall be required in accordance with Section 3.8. l.B
   c. Data on phytotoxicity is waived in PIPs since it is incorporated in the pest-protected plant itself. Other plants within and surrounding areas will not be unduly exposed to the regulated substance. Data on phytotoxicity for other pesticidal substances will be provided as deemed necessary.
2. Specific Provisions – shall be followed in accordance with Section 3.8.2 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

*H. Experimental Use Permit and Field Testing Guidelines*

1. General Provisions:
   a. Registration of PIPs in PPPs and other agricultural pesticidal substances is a condition for securing a biosafety permit for commercial propagation under JDC No. l, s. 2016.
   b. The experimental use permit {EUP) for the registration of PIPs and other agricultural pesticidal substances shall be harmonized with the requirements for, and the conduct of field trial of pest- protected plants, pursuant to Article V of JDC No. l, s. 2016. There shall be one common field trial that will take into consideration the requirements for the EUP of FPA and the biosafety permit conditions for field trial of the Bureau of Plant Industry {BPI).

2. Specific Provisions:

   a. The harmonized field trials and EUP for the registration of PIPs and other agricultural pesticidal substances shall cover the generation of local bioefficacy data.
   b. The field trial shall be conducted by the registrant (technology developer) in the country in field trial sites that comply with the EUP requirements of FPA and biosafety permit conditions for field trial of BPI. FPA and BPI shall closely coordinate

in the approval of the planning and design and in the conduct of field trials.

c. Field trial management shall strictly follow the approved experimental protocol, employ best practices, and comply with biosafety guidelines.

*I*. *Decision by FPA* – Within sixty (60) days from submission by the registrant of all technical requirements for the registration of PIP and other agricultural pesticidal substances, FPA shall evaluate the application for registration and the Executive Director of FPA shall decide whether to approve or deny the applied registration based on the technical evaluation. If approved, the registration of PIP and other agricultural pesticidal substances shall be valid for a period of one (1) year for conditional registration or three (3) years for full registration.

Conditional registration is granted for application that complied minimum data requirements while Full registration is granted for application that satisfactorily complied all of the requirements regarding bioefficacy, protection of the environment, safety to humans and animals.

*J. Penalties/Sanctions*

1. Non-compliance to any provision on data requirements stated in this guideline shall serve as ground for denial of registration of PIP and other agricultural pesticidal substances.

Whenever necessary to prevent or control serious injury to plant or animal life, public health and the environment, any PIP containing product and/or other agricultural pesticidal substances that are whether or not registered with FPA but there is either a scientific evidence that the product is unsafe to animal life, public health and environment or there is a reasonable ground to believe that there is a violation of any provision of PD No. 1144 and/or JDC No. I, s. 2016 has been committed, the FPA shall hold the person or the registrant liable to penalties under the law; suspend registration of PIP products and/or other agricultural pesticidal substances; and may be summarily impounded, removed or stopped from being sold or used and seized while waiting for final proceedings and disposition.

2. Public Awareness on PIPs and Other Agricultural Pesticidal Substances -The conduct of public awareness on PIPs and other agricultural pesticidal substances shall be in accordance with Section 3.11. The FPA requires the technology developer/registrant to publish one (1) time the application form in three (3) newspapers of general circulation within 60 days, and to be uploaded in the FPA website.

### 3.10.3. Payment of Fees

Fees and charges for the registration of PIP and other agricultural pesticidal substances shall be collected based on Administrative Order No. 13, s. 2000, entitled "Revised *Fees and Charges for Services Rendered by FPA* ".

### 3.10.4. Revocation

FPA reserves the right to amend, alter, add or delete any part of these guidelines, if in the assessment , such alterations, amendments, and additions are reasonable and necessary.

In the event of such alterations, amendments, and additions, reasonable time shall be given to all clients to fully adopt and comply with the altered terms and conditions of this guideline.

## 3.11. PROMOTING BIORATIONAL PESTICIDES

### 3.11.1 Approach

Consistent with the agency's mandate to protect public health and the environment, the FPA is currently pursuing and promoting the development and use of biological and biologically derived control agents. The FPA has recognized that biorational pesticides are inherently different from conventional pesticides and that the fundamentally different modes of action of biorationals and the consequent lower risks of adverse effects from their use must be taken into account. Embracing this policy, the guidelines sought to reduce the burden of extensive data generation by the introduction of the tier testing concept. This departure from standard procedures is intended to function as a catalyst for development of additional innovative control agents consistent with the promotion of Integrated Pest Management (IPM) and "the safe and effective use of chemical, biological and alternative methods to combat and control pests."

### 3.11.2 Product Label Guidelines

Public awareness of the unique qualities inherent in biorational pesticides is an integral element to the successful promotion of these agents for practical use. One of the more obvious vehicles available for reaching the public is pesticide labelling. While biochemical agents are viewed essentially the same as conventional chemical pesticides with respect to label requirements, labelling for microbial agents differs principally with respect to the ingredient statement. Also, current labelling guidelines prohibit "claims as to the safety of a pesticide or its ingredients, including statements such as 'safe', 'non-poisonous', 'non-injurious', 'harmless, or 'non-toxic to humans or pets'..." This could be amended for biorational pesticides to allow claims as to lack of adverse effect on beneficial agents critical to IPM and crop production systems when supported by appropriate data. The lower degree risk inherent in biorational pesticides shall be discernible through the label signal words and the relative reduction of precautionary statements. Any amendment however, must be subject to the guidelines prescribed herein, particularly Section 3.6, on Non-Target Organism Hazards.

**Table 5. SUMMARY OF DATA REQUIREMENTS FOR THE REGISTRATION OF BIORATIONALS (BIOCHEMICAL CONTROL AGENTS)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| **1.0 GENERAL INFORMATION** | | | |
| 1.1 Name/Address of Applicant | R | R | R |
| 1.2 Product Trade/Brand Name | R | R | R |
| 1.3 Manufacturer Source of Technical Material | R | R | R |
| 1.4 Description of Manufacturing Process includes starting material, steps taken, both chemical and biological, procedures in establishing identity and purity of feedstock quality control methods and presence of toxic or sentisizing substances. | R | R | R |
| 1.5 Method of Analysis | R | R | R |
| **2.0 SPECIFICATIONS** | | | |
| 2.1 Common Name | R | R | R |
| 2.2 Chemical Name | R | R | R |
| Chemical Abstract Registry Number | R | R | R |
| 2.3 Formula (Empirical and Structural) | R | R | R |
| 2.4 Scientific Name of Associated Organism | R | R | R |
| 2.5 List of Ingredients, Percent Composition and Molecular Wt. of each Ingredient, include impurities (Certification of Composition Limits for each Ingredient must be submitted) | R | R | R |
| 2.6 Physical State, Colour, Odor | R | R | R |
| 2.7 Melting Point | R (solid) | X | X |
| 2.8 Boiling Point | R (liquid) | X | X |
| 2.9 Vapor Pressure | R (pure form) | X | X |
| 2.10 Density or Specific Gravity | R | R | R |
| 2.11 Octanol/Water Partition Coefficient | R (non-polar, pure organic) | X | X |
| 2.12 Solubility | R | X | X |
| 2.13 Stability / Storage Stability | R | X | X |
| 2.14 Flash Point / Flammability | X | R | R |
| 2.15 Flame Extension | X | X | R |
| 2.16 Viscosity | X | R | R |
| 2.17 Miscibility | X | R (only emulsifiable liquids) | R (only emulsifiable liquids) |
| 2.18 pH | R | R | R |
| 2.19 Corrosion Characteristics | X | R (when packed in metal, plastic or paper) | R (when packed in metal, plastic or paper) |

**Table 5. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| **3.0 BIOEFFICACY** | | | |
| 3.1 Description of mode of action of active agent on pest for which control is claimed | X | X | R |
| 3.2 Pest controlled and names of crops, materials or premises to be protected | X | X | R |
| 3.3 Application rate (Kg ai/Ha or % ai spray dilution for each site/pest tested) | X | X | R |
| 3.4 Frequency and timing of application for each site/pest tested | X | X | R |
| 3.5 Method of application | X | X | R |
| 3.6 Phytotoxicity | X | X | R |
| 3.7 Results of laboratory study if any | X | X | R |
| 3.8 Effects on beneficial organisms or non-target organisms | X | X | R |
| 3.9 Complete description and data from local field trials or relevant test performed abroad or request for waiver for each site/pest on label | X | X | R |
| **4.0 TOXICOLOGY (Biochemical Pesticides)** | | | |
| **TIER I** | | | |
| 4.1 $LD_{50}$ Determination | | | |
| Oral (rat) | R | R | R |
| Dermal (rat, mouse or rabbit) | R | R | R |
| Inhalation (rat, mouse, rabbit or guinea pig) | R | R | R |
| 4.2 Irritation | | | |
| Occular, primary (albino rabbit) | X | R | R |
| Dermal, primary (albino rabbit or guinea pig) | X | R | R |
| 4.3 Hypersensitivity | | | |
| Immediate (human experience during product development) | X | R | R |
| Non-immediate (honesty or albino guinea pig) | R | R | R |
| 4.4 Mutagenicity (microbial organisms, see text) | R | R | R |
| 4.5 Cellular Immune Response (mouse) | X | X | X |
| **TIER II** | | | |
| 4.6 Mutagenecity (mamalian cell, see text) | R | R | R |
| 4.7 Subchronic Oral (rat, mouse or dog) | R | X | X |
| 4.8 Subchronic Dermal (rabbit or guinea pig, species not tested in TIER I) | R | X | X |

**Table 5. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| 4.9 Subchronic Inhalation (rat) | R | X | X |
| 4.10 Cellular Immune Response (mouse) | R | X | X |
| 4.11 Teratogenecity (two species from rat, mouse, hamster, rabbit) | R | X | X |
| 4.12 Chronic Exposure (rat) | R | X | X |
| 4.13 Oncogenic (newly weaned rat or mouse) | X | X | X |
| **5.0 ENVIRONMENTAL EFFECTS** | | | |
| 5.1 Avian Acute Oral Toxicity | R | X | R |
| 5.2 Avian Dietary Acute Toxicity<br>If need is indicated by Acute Oral | R | X | R |
| 5.3 Fish Acute Toxicity (one species) | R | X | R |
| 5.4 Sub Acute Fish Toxicity<br>When prolonged exposure is likely; test period up to 30 days | R | X | R |
| 5.5 Aquatic Acute Toxicity | R | X | R |
| 5.6 Fish Accumulation<br>If need is indicated by use pattern | R | X | R |
| 5.7 Avian reproduction<br>If need is indicated by feeding study results | R | X | R |
| 5.8 Fish Reproduction<br>If there is persistent exposure indicated by use pattern and persistence | R | X | R |
| 5.9 Acute Toxicity to Honeybees<br>If use involves crops where bees are present during and just after spraying | R | X | R |
| 5.10 Contact Toxicity to Honeybees<br>If exposure and acute test shows high bee toxicity | R | X | R |
| 5.11 Soil non-target microorganisms<br>If high soil concentration is expected from use | R | X | R |
| 5.12 Soil non-target macroorganisms<br>If high soil concentration is expected from use | R | X | R |

**Table 5. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| **6.0 ENVIRONMENTAL FATE AND EXPRESSION*** | | | |
| 6.1 Volatility | R | R | R |
| 6.2 Adsorption/Desorption | R | R | R |
| If pesticide is likely to reach soil or water | | | |
| 6.3 Leaching | R | R | R |
| 6.4 Degradation in soil | R | R | R |
| If pesticide is likely to reach soil | | | |
| 6.5 Biodegradation | R | R | R |
| 6.6 Hydrolyses | R | R | R |
| 6.7 Aqueous photolysis | R | R | R |
| 6.8 Ultra Violet Absorption Spectra | R | R | R |
| 6.9 Biomonitoring for Degradation Products | R | R | R |
| 6.10 Biomonitoring for Disappearance of Biochemicals | R | R | R |
| 6.11 Analytical Method for Residues in Soil | R | R | R |
| 6.12 Analytical Method for Residues in Water | R | R | R |
| **7.0 LABELLING** | | | |
| 7.1 Proposed Toxicity Category | R | R | R |
| 7.2 Draft Label | | R | R |

* Require only if TIER I Environmental effects showed adverse effects or if organism is genetically engineered.

**Table 6. SUMMARY OF DATA REQUIREMENTS FOR THE REGISTRATION OF BIORATIONALS (MICROBIAL PEST CONTROL AGENTS)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| **1.0 GENERAL INFORMATION** | | | |
| 1.1 Name/Address of Applicant | R | R | R |
| 1.2 Product Trade/Brand Name | R | R | R |
| 1.3 Company Code Number | R | R | R |
| 1.4 Manufacturer Source of Microbial Material | R | R | R |
| 1.5 Confidential Statement of Formula (includes nature and quantity of diluents and other ingredients) | R | R | R |
| 1.6 Description of manufacturing process includes starting and intermediate materials, steps taken both chemical and biological, in unformulated microbial agent, procedures used in establishing identity and purity of product, quality control methods and presence of toxic sensitizing substances | R | R | R |
| 1.7 Methods of Analysis If not standard, provide detailed description | R | R | R |
| **2.0 SPECIFICATIONS** | | | |
| 2.1 Identification of Organism (bacteria, protozoa, viruses or fungi in the product) | | | |
| • Taxonomic position, stereotype and strain | R | R | R |
| • Test procedure used for identification | R | R | R |
| • Common alternative or superseded names | R | R | R |
| • Natural occurrence and history of organism | R | R | R |
| • Description of any unusual morphological and biochemical characteristics | R | R | R |
| 2.2 List of Ingredients – Percent composition, whatever active, intentionally added or impurity | R | R | R |
| • Chemical name and CAS number | R | R | R |
| • Empirical and/or structural formula and Molecular Wt. or Mol. Wt. Range | R | R | R |
| • Composition limits for each ingredient | R | R | R |
| • Amount of microbial agent in the product in recognized units of potency, weight percent, etc. | R | X | R |

**Table 6. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| 2.3 Physical State, Color, Odor | R | R | R |
| 2.4 Density or Specific Gravity | R | R | X |
| 2.5 Stability | R | X | X |
| 2.6 Storage Stability | R | R | R |
| 2.7 Viscosity | X | R (for liquids) | R |
| 2.8 Corrosion Characteristics | X | R (when packed in metal, paper or plastic) | R |
| **3.0 BIOEFFICACY** | | | |
| 3.1 Description of mode of action of active agent on pest for which control is claimed | X | X | R |
| 3.2 Pest controlled and names of crops, materials or premises to be protected, and life cycle | X | X | R |
| 3.3 Application rate (Kg ai/Ha or % ai spray dilution for each site/pest tested) | X | X | R |
| 3.4 Frequency and timing of application | X | X | R |
| 3.5 Method of application | X | X | R |
| 3.6 Phytotoxicity | X | X | R |
| 3.7 Results of laboratory study, if any | X | X | R |
| 3.8 Effects on beneficial organisms or non-target organisms | X | X | R |
| 3.9 Complete description and data from local field trials or relevant tests performed abroad on request | X | X | R |
| **4.0 TOXICOLOGY (Tier Tests on Microbial Pest Control Agents)*** | | | |
| **TIER I** | | | |
| 4.1 $LD_{50}$ Determination | | | |
| Oral (rat) | BFVP | BFVP | BFVP |
| Dermal (rat or mouse) | BFVP | BFVP | BFVP |
| Inhalation (mouse, rabbit or guinea pig) | BFVP | BFVP | BFVP |
| 4.2 Infectivity | | | |
| Intravenous (newly weaned mouse and hamster) | B, V | | |
| Intracerebral (newborn mouse and hamster) | V | | |
| Intracerebral (mouse and rabbit) | P | | |
| Intraperitoneal (mouse and rabbit) | P | | |
| Intraperitoneal (mouse and one other species) | F | B | B |

* B – Bacteria, F – Fungi, V – Virus, P – Protozoa

**Table 6. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| 4.3 Irritation | | | |
| Ocular, primary (rabbit) | B | BFVP | BFVP |
| Dermal, primary (rabbit or guinea pig) | | BFVP | BFVP |
| 4.4 Hypersensitivity | | | |
| Immediate (human experience during product development) | FVP | BFVP | BFVP |
| Non-immediate (honesty or albino guinea pig) | B | BFVP | BFVP |
| 4.5 Cellular Immune Response (mouse) | FVP | | |
| 4.6 Tissue Culture (various cell lines, see section on viral agents) | V | | |
| **TIER II*** | | | |
| 4.7 Acute oral (puppies administered large doses) | | P | P |
| 4.8 Acute oral (newly weaned mouse and/or hamster) | | V | V |
| 4.9 Acute inhalation (a different species than used in Tier I) | | P | P |
| 4.10 Acute inhalation (newly weaned mouse and/or hamster) | | V | V |
| 4.11 Acute interperitoneal or intracerebral (two species other than those used in Tier I; half the group are immunodepressed) | BF | | |
| 4.12 Subchronic oral (mice, rat or dog; 90 day test) | P | | |
| 4.13 Primary dermal (guinea pig, use dilution doses) | P | | |
| 4.14 Primary ocular (rabbit, use dilution doses) | | | BFVP |
| 4.15 Cellular Immune Response (antibody formation cell mediated response) | | | BFVP |
| 4.16 Teratogenicity tests (two species from rat, mouse, hamster, rabbit) | BFVP | | |
| 4.17 Mutagenicity tests (mammalian cell, see text) | BFV | | |
| 4.18 Virulence enhancement (mice or hamster, serial passage) | BFVP | | |
| **TIER III*** | | | |
| 4.19 Chronic oral (rat) | BFVP | | |
| 4.20 Oncogenicity test (newly weaned mouse and or rat) | BFVP | | |
| 4.21 Mutagenicity test (mammals using the expected route of exposure) | BFVP | | |
| 4.22 Teratogenicity test (two species from rat, mouse, hamster or rabbit) | BFVP | | |

* Not all tests may be indicated for each microbial pest control agent, the appropriate tests will depend on the results of Tier I and/or Tier II tests.

**Table 6. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| **5.0 ENVIRONMENTAL EFFECTS** | | | |
| 5.1 Avian Acute Oral Toxicity | R | X | R |
| 5.2 Avian Dietary Acute Toxicity<br>If need is indicated by Acute Oral | R | X | R |
| 5.3 Fish Acute Toxicity (one species) | R | X | R |
| 5.4 Sub Acute Fish Toxicity<br>When prolonged exposure is likely; test period up to 30 days | R | X | R |
| 5.5 Aquatic Acute Toxicity | R | X | R |
| 5.6 Fish Accumulation<br>When need is indicated by use pattern | R | X | R |
| 5.7 Avian reproduction<br>If need is indicated by feeding study results | R | X | R |
| 5.8 Fish Reproduction<br>If there is persistent exposure indicated by use pattern and persistence | R | X | R |
| 5.9 Acute Toxicity to Honeybees<br>If use involves crops where bees are present during and just after spraying | R | X | R |
| 5.10 Contact Toxicity to Honeybees<br>If exposure and acute test show high bee toxicity | R | X | R |
| 5.11 Soil non-target microorganisms<br>If high soil concentration is expected from use | R | X | R |
| **6.0 ENVIRONMENTAL FATE AND EXPRESSION*** | | | |
| 6.1 Volatility | R | R | R |
| 6.2 Adsorption/Desorption<br>If pesticide is likely to reach soil or water | R | R | R |
| 6.3 Leaching | R | R | R |
| 6.4 Degradation in soil<br>If pesticide is likely to reach soil | R | R | R |
| 6.5 Biodegradation | R | R | R |
| 6.6 Hydrolyses | R | R | R |

* Require only if TIER I Environmental effects showed adverse effects or if organism is genetically engineered.

**Table 6. (continued)**

| DATA REQUIRED | Technical/ Purer Grade of Active Ingredient | Manufacturing-Use Product | End-Use Product |
|---|---|---|---|
| 6.7 Aqueous photolysis | R | R | R |
| 6.8 Ultra Violet Absorption Spectra | R | R | R |
| 6.9 Biomonitoring for Degradation Products | R | R | R |
| 6.10 Biomonitoring for Disappearance of Biochemicals | R | R | R |
| 6.11 Analytical Method for Residues in Soil | R | R | R |
| 6.12 Analytical Method for Residues in Water | R | R | R |
| **7.0 LABELLING** | | | |
| 7.1 Proposed Toxicity Category | R | R | R |
| 7.2 Draft/Final Label | | R | R |

**Table 7. SUMMARY OF DATA REQUIREMENTS FOR EUP BIORATIONALS**

| Types of Data | | Food Crop Use | | Non-Food Crop Use | |
|---|---|---|---|---|---|
| | | Biochemical | Microbial | Biochemical | Microbial |
| **1.0** | **GENERAL** | | | | |
| 1.1 | Name/Address of Applicant | R | R | R | R |
| 1.2 | Product Trade Name | X | X | R | R |
| 1.3 | Source of Technical Grade Material | R | R | R | R |
| 1.4 | Material Safety Data Sheet | X | X | R | R |
| **2.0** | **SPECIFICATIONS** | | | | |
| | Full Specifications required as in the Registration of Biorationals (see Table 5) | R | R | R | R |
| **3.0** | **BIOEFFICACY** | | | | |
| 3.1 | Pests Controlled and Names of Crops Materials as Premises to be Protected | R | R | R | R |
| 3.2 | Application Rate (Kg ai/Ha or % ai dilution rate) | R | R | R | R |
| 3.3 | Frequency and Timing of Application for each site/pest listed | R | R | R | R |
| 3.4 | Method of Application | R | R | R | R |
| 3.5 | Phytotoxicity | R | R | X | X |
| 3.6 | Laboratory Studies if any | X | R | X | R |
| 3.7 | Effects on Beneficial Organisms | X | R | X | X |
| **4.0** | **TOXICOLOGY** | | | | |
| 4.1 | Acute Oral Toxicity | R | X | R | X |
| 4.2 | Acute Dermal Toxicity | R | R | R | R |
| 4.3 | Primary Eye Irritation | R | R | R | R |
| 4.4 | Primary Dermal Irritation | R | R | R | R |
| 4.5 | Studies to Detect Gene Mutation | R | X | R | X |
| 4.6 | Cellular Immune Response Studies | R | R | X | X |
| 4.7 | Intravenous, Intracerebral, Interperitoneal Infectivity | X | R | X | R |
| 4.8 | Tissue Culture with Viral Agents | X | R | X | X |
| **5.0** | **RESIDUE DATA** | | | | |
| | If rate of application exceeds 120 g ai/Ha and if Tier I toxicological studies indicate potential human hazard | R | X<br>R | X<br>X | X<br>X |

**Table 7. (continued)**

| Types of Data | Food Crop Use | | Non-Food Crop Use | |
|---|---|---|---|---|
| | Biochemical | Microbial | Biochemical | Microbial |
| **6.0 NON-TARGET ORGANISM TOXICOLOGY** | | | | |
| Test developed in Tier I studies | R | R | R | R |
| **7.0 ENVIRONMENTAL FATE AND EXPRESSION DATA** | | | | |
| Tier I studies only | R | R | X | X |
| **8.0 LABELLING** | | | | |
| 8.1 Proposed Toxicity Category | R | R | R | R |
| 8.2 Draft Label (3 copies) | R | R | R | R |

**Table 8. METHODS OF DETECTING EFFECTS OF MICROBIAL PEST CONTROL AGENTS IN SAFETY TESTS[1]**

| Method of Assessment | Cellular Agents Microbial Toxins | Acellular Agent (Bacteria, Fungi, Protozoa) | Virus |
|---|---|---|---|
| Histopathology | D | X | X |
| Serology[2] | NA | D | X |
| Nucleic Acid Hybridization[3] | NA | NA | D |

Key to Table Symbols:

D : All members of this group detectable by this method.
X : Not all infections by this group are detectable by this method.
NA : Not applicable

[1] Source: C.Y. Kawanisi, 1979
[2] Radioimmunoassay, Enzyme-Linked Immunosorbent Assay
[3] DNA: DNA and RNA: DNA Hybridization Techniques

# *Chapter 4*

# *LICENSING, CERTIFICATION AND ACCREDITATION OF PESTICIDE HANDLERS*

## 4.1 LEGAL BASIS

Pursuant to Section 9 of PD 1144 and Sections 1 and 2 of Article III of the FPA Rules and Regulations No. 1, Series 1977, all pesticide handlers must obtain a license from the Fertilizer and Pesticide Authority.

> "No person shall engage in the business of importing, manufacturing, formulating, exporting, repacking, distributing, storing or selling any pesticide, except under a license issued by the Authority. A separate license shall be required for each establishment or place of business subject to these rules, to be conspicuously displayed therein.
>
> All commercial applicators of pesticides shall apply for a license, in a form to be supplied by the Authority and shall obtain a commercial applicator's license and be assigned a license number by the Authority before such person shall perform services as a commercial applicator. Each commercial applicator shall obtain a license for each place of business maintained in the Philippines."

## 4.2 APPLICATION AND REQUIREMENTS

### 4.2.1 Licensing of Pesticide Companies and Other Handlers

The licensing requirements and application forms for pesticide companies and other handlers are as follows:

1. Application for Pesticide Manufacturer/Formulator/Extruder License (Form No. P-110).

2. Application for Pesticide Repacker License (Form No. P-120). The applicator shall submit a written authority to repack from the supplier.

3. Application for Pesticide Importer/Indentor License (Form No. P-150). The license to import/indent is a pre-requisite to opening a letter of credit. End-users are also required to obtain a license to import.

4. Application for Pesticide Distributor License (Form No. P-160 for National Distributor) and (Form No. P-160A for Area Distributor). The distributor must submit a distributorship agreement with the Pesticide Company and "Good Housekeeping Compliance Certificate" issued by CRAN (CPAP Regional Action Network) and FPA representative(s).

5. Application for Pesticide Supplier's Local Representative/Local Subsidiaries (Form No. P-170).

6. Application for Pesticide Dealership License (Form No. P-130).

7. Application for Pest Control Operator's License (Form No. P-180) (Drone Spraying Operator or Fumigator).

   In addition, the applicant must submit a photocopy of FPA identification card of the Drone Controller, Spray Operation Crew and/or Certified Pesticide Applicator.

8. Application for Warehouse Registration (Form No. P-140); The registrant must submit recommendation and inspection report from FPA Regional/Provincial Officer.

The prescribed application forms are attached as Annex VII.

### 4.2.2 Licensing of Dealers

Any person/partnership/corporation or cooperative desiring to sell pesticides and other agricultural chemicals has to apply and secure a license from the Fertilizer and Pesticide Authority (FPA), through the FPA Provincial Officer.

In addition to the requirements stated under Section 4.2.1 for pesticide companies, applications for dealership license must include:

1. Recommendation from the FPA Regional and Provincial Officer;

2. Copy of registration of business name with:

    - Department of Trade and Industry for Single Proprietorship;
    - Securities and Exchange Commission (SEC) for Corporation/Partnership; or
    - Cooperative Development Authority (CDA) for Cooperative;

3. List of registered agricultural pesticide products to be sold;

4. For members of Agro Dealers' Association – Certificate of Membership from the association and copy of FPA ID of Accredited Safety Dispenser

For renewal, only requirement numbers 1, 3 and 6 above are needed in addition to the requirements stated under Section 4.2.1.

A separate application form and corresponding fee shall be paid for each branch and outlet.

## 4.3 VALIDITY, RENEWAL AND FEE

Licenses issued to (a) all handlers other than dealers and (b) dealers shall be renewed every year and every three (3) years, respectively; from the date of its issuance.

Renewal of licenses shall be filed at least three (3) months before its expiry date. Failure of a handler to renew his license one (1) month after its expiration shall be subject to a 50% surcharge while those who renewed after the said period shall be subject to a 100% surcharge for every year that such handler remains unlicensed.

Fees and charges are computed on per activity basis. Fees and charges for application and renewal of license of pesticide handlers are indicated in Table 9.

## 4.4 "GOOD HOUSEKEEPING" REQUIREMENT FOR LICENSING OF PESTICIDE DEALERS AND DISTRIBUTORS

All licensed Pesticide dealers and distributors, including new applicants, are required to meet the minimum standards of "Good Housekeeping" in the storage and handling of pesticides both in the store and warehouse. The audit team composed of CRAN member(s) and FPA representative(s) will issue a proof of compliance in the form of a "Good Housekeeping Compliance Certificate". The establishment shall be inspected at least once a year and be issued with the certificate if the minimum standards of "Good Housekeeping" were met. A risk appraisal checklist for warehouse/store, Annex VIII, shall be used during inspection. Those who fail to meet the minimum standards shall be notified, and given a period of time within which improvements shall be made.

Integral to good housekeeping is the presence of appropriate tools/gadgets to contain spillage of toxic materials and maintain cleanliness and orderliness.

## 4.5 CERTIFICATION AND ACCREDITATION

The certification and accreditation program for pesticide handlers is designed to update and upgrade the technical knowledge of commercial users, distributors, dealers and researchers in the application of pesticides.

### 4.5.1 Agricultural Certified Pesticide Applicator (CPA)

#### *A. Scope and Application*

This covers individuals who are obtaining accreditation as agricultural certified pesticide applicator. The pesticide applicator may be Exterminator, Fumigator, Drone Controller or Drone Spray Crew Supervisor. Once accredited, the person shall be called "Agricultural Certified Pesticide Applicator (CPA)".

#### *B. Area of Activity Coverage*

1. Crops
2. Grains
3. Ornamentals
4. Raw Wood Materials
5. Seed Crops
6. Trees
7. Turfs
8. Wood Packaging Materials

#### *C. Definition of Terms*

1. *Accreditation* – authorization, manifested in accreditation card, accorded to individuals who attended the training course, passed the written examination and complied with all the requirements. It allows

the CPA to apply restricted pesticides but not to purchase and enter into commercial contracts for pest control work.

2. *Agricultural Certified Pesticide Applicator (CPA)* – a person who has attended the required training, passed the FPA licensure examination and accredited as an individual with the capacity to safely manage the handling of pesticides.

3. *Agricultural Products* – refers to products of plant origin such as wood, rattan, among others.

4. *Company/Institution* -whose business includes any item under the areas of activity coverage (section 4.5.1.B) and the same is being treated for agricultural pests either by its in-house CPA or by a service provider.

5. *Drone Controller* – an accredited CPA who has a license from the Civil Aviation Authority of the Phils. (CAAP) to operate/fly drone and uses it in the application of pesticides. He should be competent and knowledgeable in the use and application of pesticides such as: (1) appropriateness of pesticide formulation to be applied; (2) correct dose/rate and manner of application; (3) awareness of hazards in the use of product; and (4) first aid procedure.

6. *Drone Spray Crew Supervisor* – an assistant of a Drone Controller, an accredited CPA or ARCO who is knowledgeable and fully conversant with drone operation as well as with procedures in case of pesticide exposure.

7. *Exterminator*– a CPA who uses liquid and powder forms of pesticides, including restricted pesticides and coded compounds in the control/treatment of agricultural pests. The exterminator must be employed in company/institution as its in-house agricultural exterminator and he/she is not allowed to do extermination work outside his/her company/institution. This is not, however, refers to urban pest application.

8. *Fumigator* – a CPA who uses restricted gaseous pesticides or fumigants/coded compounds in the control/treatment of agricultural pests. A fumigator maybe an employee of an FPA-licensed PCO or of company/institution doing in-house work.

9. *Pest Control Operator (PCO)* – refers to the establishment engaged in commercial application of pesticides and other pest control services.

10. *Raw Wood Materials* – refers to the wood (e.g. lumber, plywood, rattan, etc.) to be used in making furniture for export, which shall

undergo treatment prior to its production/manufacture as furniture or handicrafts as required by the importing country.

11. *Wood Packaging Materials* – refers to pallets, crates and lead frames used in the exportation of goods which shall be treated as required by the importing country.

### *D. Responsibilities of CPA*

1. The CPA shall demonstrate competence and practical knowledge in the following areas:

    1.1 Safe use, handling, storage and disposal of restricted pesticides;
    1.2 Life cycle of a wide variety of agricultural pests;
    1.3 Types of formulations appropriate for agricultural pest extermination and fumigation;
    1.4 Safe and effective pest control management; and
    1.5 Appropriate personal protective equipment (PPE).

2. The CPA shall have direct supervision of service technicians and shall always be present during application of the restricted pesticides.

3. The CPA shall ensure that only FPA-registered pesticides shall be used/applied.

4. The CPA shall keep a record of the name and address of clients, pesticide formulation and volume used, and the target pests most especially when restricted pesticides were used. All these records shall be made available to FPA every six (6) months.

5. The CPA shall inform FPA of the termination of his services with the FPA's licensed Pest Control Operator (PCO) and his movement to another pest control company.

6. In case of in-house CPA, his service is limited only to his own company/institution specified in his accreditation card.

7. The CPA shall regularly attend symposium or seminar sponsored by FATA to update and upgrade his technical knowledge.

## *E. Guidelines in the accreditation of CPA*

### E.1 Qualification, Training and Examination

1. There will be a standard module for each type of CPA trainings;

2. The duration of the training is three (3) days;

3. The administration of CPA exam shall follow one (1) day after the training;

4. The concerned FATA shall ensure that the training participants possess the following qualifications:

   a. A Filipino citizen;
   b. Of legal age; and
   c. Have a college level of education; and

5. Only applicants who have attended the training course shall be allowed to take the FPA examination;

6. The passing mark is set at 70%. However, those who obtained a rating of 66% to 69.4% may take one (1) removal examination within one (1) year from the date of issuance of test result without undergoing another training;

7. The names of passers shall be published at the FPA website within seven (7) working days from examination date; and

8. At the end of the course, the concerned FPA Accredited Training Association (FATA) and its resource speakers shall be assessed by the training participants and FPA's Regional Officer. The results of the assessments and the percentage of passers are the factors in the evaluation of the FATA for the renewal of its accreditation with FPA.

### E.2 Accreditation

Accreditation for agricultural exterminator shall only be given to an individual who is employed to company/institution as its in-house CPA.

In case of agricultural fumigator, accreditation shall be given to employees of FPA- licensed PCO and of company/institution as its in-house CPA.

**1.** Requirements for NEW applicant

| REQUIREMENT | Agricultural Fumigator | Agricultural Exterminator | Drone Controller | Drone Spray Crew Supervisor |
|---|---|---|---|---|
| 1. Accomplished application with 1x1 latest picture (white background) | ✓ | ✓ | ✓ | ✓ |
| 2. Certificate of attendance to applicable training | ✓ | ✓ | ✓ | ✓ |
| 3. Passed the written examination administered by FPA | ✓ | ✓ | | |
| 4. Certificate of employment | ✓ | ✓ | ✓ | ✓ |
| 5. Copy of Civil Aviation Authority of the Philippines (CAAP) license | | | ✓ | |
| 6. Valid CPA accreditation | | | ✓ | |
| 7. Valid CPA or ARCO accreditation | | | | ✓ |
| 8. Details on the agricultural produce and the other pending pests to be treated | | ✓ | | |

**2.** Requirements for RENEWAL

| REQUIREMENT | Agricultural Fumigator | Agricultural Exterminator | Drone Controller | Drone Spray Crew Supervisor |
|---|---|---|---|---|
| 1. Accomplished application with 1 x 1 latest picture (white background) | ✓ | ✓ | ✓ | ✓ |
| 2. Certificate of attendance to symposium | ✓ | ✓ | ✓ | ✓ |
| 3. Certificate of employment | ✓ | ✓ | ✓ | ✓ |
| 4. CAAP license | | | ✓ | ✓ |
| 5. Valid CPA accreditation | | | ✓ | |
| 6. Valid CPA or ARCO accreditation | | | | ✓ |
| 7. Details on the agricultural produce, pest treated, pesticide formulation and volume used | | ✓ | | |

***F. Validity and Fee***

The applicable Accreditation Card shall be issued by the FPA after evaluation and compliance with the requirements.

The accreditation fee is ₱600 with a validity of one (1) year from the date of its issuance. No surcharges shall be imposed on late renewal.

### 4.5.2 Accredited Responsible Care Officer (ARCO)

***A. Scope and Application***

This covers persons obtaining accreditation from the FPA as responsible care officers. They may be proprietors or employees of licensed handlers (except for dealers and pest control operators). Once accredited, the person shall be called “Accredited Responsible Care Officer (ARCO)”.

***B. Responsibilities of ARCO***

1. They shall be expected to initiate promotion of responsible care program in their respective companies; and

2. They shall provide active leadership in the education and training of farmers, contracted applicators and relevant clients.

## *C. Guidelines in the accreditation of ARCO*

### C.1 Training and Examination

1. There will be a standard module for ARCO training;

2. The duration of the training is three (3) days;

3. The administration of ARCO examination shall follow one (1) day after the training;

4. The schedule of trainings, examinations and symposia shall be published at the FPA website;

5. Only applicants who have attended the training course shall be allowed to take the FPA examination;

6. The passing mark is set at 70%. However, those who obtained a rating of 60% to 69% may take one (1) removal examination within one (1) year from the date of issuance of test result without undergoing another training;

7. The names of passers shall be published at the FPA website within seven (7) working days from examination date; and

8. At the end of the course, the concerned FPA Accredited Training Association (FATA) and its resource speakers shall be assessed by the training participants and FPA's Regional Officer. The results of the assessments and the percentage of passers are the factors in the evaluation of the FATA for the renewal of its accreditation with FPA.

### C.2 Accreditation

**C.2.1** Requirements for NEW applicant

1. Accomplished application with 1 x 1 latest picture (white background);
2. Certificate of attendance to ARCO training conducted by the FPA Accredited Training Associations (FATA); and
3. Passed the written examination administered by FPA.

**C.2.2** Requirements for RENEWAL

1. Accomplished application with 1 x 1 latest picture (white background); and
2. Certificate of attendance to at least two (2) symposia conducted by FATA.
3.

### *D. Validity and Fee*

An ARCO card shall be issued by the FPA after evaluation and compliance with the requirements.

The accreditation card is valid for three (3) years from the date of its issuance with an accreditation fee of ₱900. No surcharges shall be imposed on late renewal.

## 4.5.3 Accredited Pesticide Researcher

### *A. Scope and Application*

This covers pesticide researchers who obtain accreditation from FPA to conduct experiments to generate data to support pesticide product registration. The research disciplines include:

1. Entomology
2. Plant Pathology
3. Weed Science
4. Nematology
5. Statistics
6. Pesticide Toxicology and Analytical Chemistry
7. Rodent Control,
8. Plant Physiology
9. Supervised Pesticide Residue Trial (SPRT)
10. Other Allied Research Disciplines

### *B. Responsibilities of Researchers*

1. Researchers should conduct only experiments on pesticides covered by Experimental Use Permits if the data will be used for registration of the product;

2. Researchers should carry out only experiments within the limit of their accreditation;

3. Researchers are required to self-regulate the total number of experiments conducted. In cases where more than five (5) product/trial crops are to be handled at one (1) time, prior approval from the FPA is required;

4. In cases where government facilities will be used and the researchers are employed by the government, prior approval from the head of concerned agency is required before starting the research;

5. Researchers employed by chemical companies are not allowed to conduct product efficacy trials intended for registration. Their role is

limited to the supervision of the trials conducted by other contracted accredited researchers; and

6. A certificate signed by the researchers indicating that the study was conducted following good agricultural practices and standard protocols shall be submitted to FPA.

### *C. Guidelines in the accreditation of Pesticide Researchers*

#### C.1. Training and submission of approved protocol

1. There will be a standard module for fertilizer and pesticide researcher's training workshop. The module shall conform with the Food and Agriculture Organization research protocols on testing pesticides including review of statistical design for experimentation and writing the research terminal report.
2. The duration of the training workshop is 2 days.
3. The workshop output includes presentation of test protocols for representative disciplines and crops written by the participants, as well as critiquing of the protocols.
4. The protocols shall be reviewed and approved by the pesticide technical evaluators specified in the Special Order issued by the FPA. The approved protocol shall be submitted to the FPA.
5. At the end of the course, the concerned FPA Accredited Training Association (FATA) and its resource speakers shall be assessed by the training participants and FPA's Regional Officer. The results of the assessments and the percentage of passers are the factors in the evaluation of the FATA for the renewal of its accreditation with FPA.

#### C.2. Accreditation

The applicants must apply for accreditation on the discipline well supported by their academic specialization, training, published research or current research undertakings, and years of research experience to indicate competence.

In the case of in-house researchers where publication of researches are not allowed due to confidentiality, a certification stating the same shall be part of the requirements.

Expansion of accreditation for additional research discipline may be granted upon request provided that it is supported with authorship of one (1) publication in a refereed journal or two (2) publications in non-refereed journals or at least 5 years' research experience on the additional discipline

being applied for. Presentation of research paper may be requested by the FPA.

### C.3. Basic Requirements

**C.3.1.** NEW applicant

a. Accomplished application with 1 x 1 latest picture (white background);
b. Certificate of attendance to fertilizer and pesticide researchers' training conducted by the FPA Accredited Training Associations (FATA);
c. Latest resume with details on research undertakings;
d. Approved protocol; and
e. With at least 3 years' research experience on the discipline being applied for.

**C.3.2.** RENEWAL

a. Accomplished application with 1 x 1 latest picture (white background);
b. Certificate of attendance to at least one (1) symposium conducted by FATA; and
c. Latest resume with details on research undertakings.

**C.3.3.** ADDITIONAL research discipline (New)

a. Accomplished application with 1 x 1 latest picture (white background);
b. Certificate of attendance to fertilizer and pesticide researchers' training conducted by the FPA Accredited Training Associations (FATA);
c. Latest resume with details on research undertakings; and
d. Approved protocol.

## *D. Status of Accredited Researchers*

The status of FPA accredited researchers could either be active or inactive. *Active* researchers are those who have attended the symposium and renewed their accreditation while *inactive* researchers are those who failed to renew their accreditation and therefore could not conduct research on efficacy trials for agrochemicals.

## *E. Validity and Fees*

The applicable Certificate and Accreditation Card shall be issued after evaluation and compliance with the requirements.

The following are the accreditation fees:

| | |
|---|---|
| First discipline | ₱1,200 |
| Additional discipline (with separate ID) | 1,200 |
| Additional discipline (without separate ID) | 400 |

The accreditation card is valid for two (2) years from the date of its issuance. Failure to renew the accreditation shall automatically classify researcher to inactive status. No surcharges shall be imposed on late renewal.

### 4.5.4. Accredited Safety Dispenser (ASD)

#### *A. Scope and Application*

This covers persons obtaining accreditation from the FPA as safety dispensers of fertilizer and/or pesticide products which are composed of:

1. Proprietors or employees of licensed dealers; and

2. Individual business operator (IBO) who does not have a permanent store/structure licensed by the FPA and is authorized to dispense registered fertilizer and/or pesticide products which are carried/owned by a licensed handler.

Once accredited, the person shall be called “Accredited Safety Dispenser (ASD)”.

#### *B. Definition of Terms*

1. *Accreditation* - authorization, manifested in accreditation card, accorded to individuals who have attended a training course and complied with all the requirements.

2. *Handler* – FPA licensed exporter, importer, indentor, processor, manufacturer, formulator, distributor, dealer or repacker of fertilizer products.

3. *Individual Business Operator (IBO)* – a person in the networking or multi-level marketing scheme.

#### *C. Responsibilities of ASD*

1. The ASD shall advise buyers/end-users on the safe use, handling and storage of fertilizer and pesticide products at the store or during business operation, in the case of IBO;

2. The ASD is required to be personally present at the store during business hours;

3. The ASD shall keep records of sale and disposition of fertilizer/pesticide products and the same shall be available for inspection by FPA; and

4. The ASD shall ensure that only FPA-registered fertilizer and pesticide products are to be dispensed.

## *D. Guidelines in the accreditation of ASD*

### D.1. Training

1. The attendees should have the following qualifications:
   - At least 18 years of age.
   - At least high school graduate.

2. The duration of the training is two (2) days; 1 day for IBO;

3. A 50-item pretest and posttest shall be administered to determine the progress of learning and the effectiveness of the training; and

4. Certificate of Attendance shall be issued to those individuals who completed the ASD Training Course.

### D.2. Accreditation

**D.2.1.** Holders of Accredited Pesticide Dispenser (APD) and Accredited Professional Pesticide Adviser (APPA) cards are required to attend the ASD training course before an ASD card can be issued.

**D.2.2.** Requirements:

**A.** NEW applicant

1. Accomplished application with 1 x 1 latest picture (white background)
2. Certificate of attendance to ASD training

**B.** RENEWAL

1. Accomplished application with 1 x 1 latest picture (white background)

### *E. Validity and Fee*

An ASD accreditation card shall be issued by the FPA after evaluation and compliance with the requirements.

The accreditation fee is ₱600 with a validity of three (3) years from the date of its issuance. No surcharges shall be imposed on the late renewal.

## 4.5.5. Accredited Training Associations

### A. *Scope and Application*

Anchored on FPA's mandate to educate the agricultural sector in the proper use and handling of fertilizer, pesticide and other agricultural chemicals, training associations/organizations are accredited to manage the conduct of technical trainings and symposia on the following training programs:

1. Fertilizer and pesticide researchers
2. Accredited responsible care officers (ARCO)
3. Agricultural certified pesticide applicators (CPA)

    a) Fumigator
    b) Exterminator

Once accredited, the association/organization shall be called "FPA Accredited Training Association (FATA)".

### *B. Responsibilities of FATA*

1. To submit the training manual for the chosen training program for approval of the FPA;

2. To update the module and manual, as applicable;

3. To manage the conduct of the training program and symposium;

4. To provide competent resource persons as required in the program;

5. To evaluate applicants to the training program based on the criteria set forth by the FPA;

6. To provide the needed training materials, manuals, certificates, and other paraphernalia;

7. To collect reasonable fees to defray the cost of food, materials, resource speakers, among others;

8. To evaluate the participants' training performance and submit the same to FPA within one (1) month after the training; and

9. To submit to FPA the training, symposium and financial reports within one (1) month after the conduct of the training; and

10. To attend the annual meeting every January.

## *C. Guidelines*

### C.1. Training & Symposium

**1.** The FATA shall manage the conduct of trainings and symposia based on the agreed schedules, otherwise, an approval from the FPA is required.

**2.** The FATA shall submit the topics of the symposium within two (2) months prior to its conduct for FPA's comments/approval.

**3.** The FATA shall ensure that the symposium to be conducted is aligned with the chosen training program (i.e., if the chosen training program is CPA-Fumigator, then the symposium's topics shall be related to fumigation and the participants shall solely be CPA-Fumigators). However, if multiple training programs are to be conducted in a scheduled date, the FATA may combine the topics and participants.

### C.2. Accreditation

**C.2.1.** NEW

1. The association/organization shall submit the following documents for evaluation of the FPA:
   a. Accomplished Application for Accreditation
   b. SEC Registration
   c. General Information Sheet (contains the roster of membership)
   d. Association Profile
   e. List of Trainors and their Qualifications
   f. Training Module

2. The FPA shall inform the association/organization of the approval/disapproval of its application within 1 month from receipt of complete accreditation documents.

3. The training manual shall be submitted within two (2) months after the approval of accreditation from the FPA.

4. The training manual shall be approved by the FPA within one (1) month after its submission.

5. The Memorandum of Understanding (MOU) shall be signed by both parties within one (1) month after approval of the training manual.

6. The newly accredited training association shall attend the annual meeting to discuss and finalize the schedule of the trainings and symposia to be managed during the year. In line with this, the conduct of the trainings and symposia shall commence the year after the approval of accreditation.

**C.2.2.** RENEWAL

**A. Requirements**

1. Overall training evaluation rating of at least Satisfactory; and
2. Updated General Information Sheet of the association/organization.

**B. Bases of Evaluation**

1. All examinees shall be requested to evaluate the training program, resource speakers, food and venue, and the FATA concerned prior to exam administration.

2. The Regional Office which has jurisdiction over the venue where the training was conducted shall likewise submit their respective evaluations of the FATA concerned.

3. The percentage of those who passed vis-à-vis the total number of takers shall also be considered as one of the bases of evaluation. The removal shall be included in the “passed” category once the examinee passed the removal exam. The ratings shall be as follows:

**ARCO**

| *Passing Rate Range* | *Numerical Rating* | *Adjectival Rating* |
|---|---|---|
| *91% - 100%* | *5* | *Excellent* |
| *81% - 90%* | *4* | *Very Satisfactory* |
| *71% - 80%* | *3* | *Satisfactory* |
| *61% - 70%* | *2* | *Unsatisfactory* |
| *≥ 60%* | *1* | *Poor* |

**CPA**

| *Passing Rate Range* | *Numerical Rating* | *Adjectival Rating* |
|---|---|---|
| *85.01.% - 100%* | *5* | *Excellent* |
| *70.01% - 85%* | *4* | *Very Satisfactory* |
| *55.01% - 70%.* | *3* | *Satisfactory* |
| *40.01% - 55%* | *2* | *Unsatisfactory* |
| *≥ 40%* | *1* | *Poor* |

4. The Planning, Management and Information Division (PMID) shall summarize the evaluation of every training conducted.

5. At the end of the year, an overall rating of each FATA shall also be summarized by PMID including the comments and suggestions from the participants and FPA Regional Officers. The FATA shall have at least an overall rating of Satisfactory to be eligible for the renewal of accreditation. If not, their accreditation shall be suspended for the ensuing year.

   The overall rating shall be the average of all trainings conducted within the year except for 2019 which covers the second semester only. The standard overall rating scale shall be as follows:

| Range | Adjectival Rating |
|---|---|
| *5.00* | *Excellent* |
| *4.00 - 4.99* | *Very Satisfactory* |
| *3.00 - 3.99* | *Satisfactory* |
| *2.00 - 2.99* | *Unsatisfactory* |
| *1.00 - 1.99* | *Poor* |

6. The overall rating/result of evaluation shall be presented and discussed during the annual meeting every January. A complete set shall be provided to the concerned FATA.

7. The MOU shall be signed by both parties within one (1) month after the annual meeting.

**C. Validity and Renewal**

The validity of accreditation is one (1) year, renewable every January.

## 4.5.6. LABORATORY RECOGNITION PROGRAM

The FPA Laboratory Recognition Program is being established to support the agency's monitoring and regulatory activities on testing of fertilizer and pesticide formulations and residues both in agriculture and the environment mainly in remote areas and locations where shipment of samples to be submitted for analysis to LSD is not possible, thereby, enhancing the quality and safety of local and imported agricultural inputs and products while ensuring the protection of the environment.

This recognition program will also cover laboratories that can provide analytical services to stakeholders that cannot be accommodated by FPA laboratory but necessary for agency's regulatory decision making.

**A. DEFINITION/ SCOPE OF QUALITY**

***1) FPA Laboratory Recognition***

FPA Laboratory Recognition is an official issuance acknowledging the technical competency of a laboratory to perform analytical testing of fertilizer and pesticide formulations and residues.

***2) FPA Recognized Laboratories***

FPA Recognized Laboratories refer to all competent laboratories in the Philippines that are approved by FPA to conduct fertilizer and pesticide analysis in support of the implementation of FPA Rules and Regulations. An FPA Laboratory Recognition Certificate shall be issued to the laboratories only if they comply with the FPA Laboratory Recognition requirements.

***3) Scope of Laboratory Recognition***

The Laboratory Recognition Program shall cover all participating laboratories that have the technical competence or capability to carry out specific

analytical tests on fertilizers, pesticides and/or other agricultural chemicals. Moreover, LSD shall be the principal authorized laboratory to conduct analyses on all fertilizer, pesticides and other agricultural chemicals. All requests for laboratory analysis of fertilizers, pesticides and other agricultural chemicals from FRD, PRD and RFUs shall be submitted to and coordinated with LSD. FPA shall tap the services of FPA recognized laboratories only when:

a. there are transportation issues; or
b. if LSD, for some valid technical reason, has determined that it cannot perform the analysis or can no longer accommodate the request for analysis.

Only specific tests on fertilizers, pesticides and other agricultural chemicals within the scope of the Laboratory Recognition for which the participating laboratory has been approved and recognized by FPA shall be considered as valid.

***4) Types of Recognition***

a. Full recognition will be granted to the applicant laboratory that has satisfactorily completed all the requirements specified in this Guidelines. An FPA Laboratory Recognition Certificate will be issued to the qualified laboratory.
b. In case of emergency, as will be determined by FPA, a special recognition will be granted to a laboratory that can perform the required analysis.

***5) Duration***

The FPA Laboratory Recognition Certificate shall be effective for three (3) years from the date of issuance unless earlier revoked/ cancelled.

**B. REQUIREMENTS FOR LABORATORY RECOGNITION**

***1) Documentary requirements***

Applicant laboratory shall provide to the FPA the following documents:

a. Application Documents

   i. Letter of Intent
   ii. Duly accomplished and notarized FPA prescribed application form

b. Legal Documents

   i. Registration certificate from SEC for corporations or Department of Trade and Industry (DTI) for sole proprietorship

ii. Mayor's/Business permit issued by the city or municipality where the laboratory is located, or the equivalent document for Exclusive Economic Zones or Areas
iii. Tax clearance per E.O. 398, s. 2005, as finally reviewed and approved by the Bureau of Internal Revenue (BIR)

c. Technical Documents

i. Organizational and functional chart of the laboratory including its position in its parent organization, if any, and job descriptions of its technical and support personnel
ii. Accreditation/Recognition record of the laboratory (if any)
iii. Laboratory test report forms
iv. List of reference literatures available in the laboratory
v. Equipment calibration and maintenance program of the laboratory
vi. Quality assurance program of the laboratory
vii. Track record of the laboratory
viii. Validation report of test methods
ix. Results of proficiency testing participated or intra-laboratory exercise(s) conducted
x. Floor plan of the laboratory and related facilities (scale=1:100)

***2) Track Record of the Applicant Laboratory***

Applicant laboratory shall be in operation for at least two (2) years and shall have analyzed a minimum of three hundred (300) fertilizer and/or pesticide samples.

***3) Manpower Requirement***

a. The Laboratory Head of the fertilizer and/or pesticide laboratory shall be a registered chemist holding a valid Professional Identification Card (PIC) issued by the Professional Regulatory Commission (PRC) and has at least five (5) years experience in laboratory analysis and management;

b. The laboratory shall have a minimum of one (1) registered chemist, having the necessary education, training, technical knowledge and experience to carry out the assigned function in the generation of test results. The said chemist shall have at least one (1) year experience in performing various fertilizer and/ or pesticide analyses;

c. The number of laboratory personnel shall be proportionate to the number of analysis and samples performed by the laboratory. In case the laboratory has a chemical technician, the same shall have a valid PIC and must be supervised by a registered chemist.

### *4) Physical Layout*

a. The laboratory shall be housed in a permanent building constructed of strong materials.
b. The laboratory shall have adequate running water supply and regular electric power supply and provisions for emergency power source.
c. Workrooms shall be well ventilated with adequate provisions for either natural or artificial lightning.
d. The working space shall correlate with the volume and type of analysis to be undertaken, including provisions for periods of peak workload.
e. The laboratory shall include sufficient bench top area for processing samples, storage space for chemicals, glassware, portable and fixed equipment, and an adequate appropriate area for cleaning glassware and sterilizing materials
f. The laboratory shall ensure separation of incompatible laboratory activities (e.g. pesticide formulation area should be separated from pesticide residue area)
g. The laboratory shall have provisions for safety in the laboratory work area and its personnel by having emergency exits and egress, emergency eye wash, shower, medical kit, fire extinguishers, fume hoods and personal protective equipment (PPE).

### *5) Equipment and Apparatus*

a. The laboratory shall be equipped with laboratory instruments, apparatus and other equipment required for the conduct of testing which include sampling, physical testing, sample preparation, extraction, clean-up, assay determination, processing and analysis of test data and storage as specified in their documented sampling and test procedure(s).

b. The laboratory shall ensure that all analytical instruments, equipment and apparatus used in the analysis of fertilizer and pesticide samples are calibrated and maintained. Maintenance and calibration records of these equipment shall be kept and updated and must be available upon request of the FPA.

### *6) Test Methods*

a. The laboratory shall use only the test methods authorized by FPA which include but not limited to:

    i. The test methods prescribed and authorized by Codex Committee on Pesticide Residues (CCPR);
    ii. Standard procedures and methods (e.g. AOAC, US EPA and FDA, ASTM, CIPAC or FAO); and
    iii. In-house developed test methods or modified from standard methods for analysis of proprietary products provided these are properly

documented and validated. Validation shall be done using analytical standards, through inter-laboratory calibration, or parallel runs with standard methods.

b. All test methods shall be properly documented.

***7) Quality Control***

a. The laboratory shall perform the adequate quality control for each batch of analysis which shall include:

i. replicate test samples;
ii. replicate spike control samples;
iii. method blanks; and
iv. use of quality control chart for the analysis to evaluate the validity of the test results.

b. The laboratory shall satisfy the quality objectives for each test method set by FPA to suit the purpose for which the analysis is done.

c. The laboratory shall have a program to periodically validate the performance of the test methods.

***8) Laboratory Procedures***

a. The laboratory shall have documented standard operational procedures (SOP) and work instructions for the receipt of the samples, turnover of results, assignment of analysis, analyst reporting, checking of results, preparation of the laboratory test report, storage and filing of requests for analysis test reports, disposal of test solutions and samples. The SOPs shall include the pertinent forms used in the different processes involved. The SOPs shall also insure traceability of samples.

b. The laboratory shall have documented procedure in addressing clients' complaints on test reports.

## C. PROCEDURE IN THE RECOGNITION PROCESS

***1) Submission of Documentary Requirements***

The applicant laboratory must submit all the documentary requirements listed in Section 4.1 and payment of FPA Laboratory Recognition fee.

***2) Preliminary Assessment of the Laboratory***

The FPA Laboratory Recognition Committee (FLRC) shall make preliminary assessment of the completeness of the documentary

requirements. If complete, FLRC shall advise the applicant laboratory to submit one (1) hard copy and an electronic copy of the complete documentary requirements and pay the FPA approved laboratory recognition fee.

***3) Laboratory Assessment***

Upon the receipt of complete documentary requirements, FLRC Secretariat shall schedule the visits of FLRC to the laboratory for assessment. Each member of FLRC present as assessor shall be provided with the documentary requirements at least 1 week before the scheduled visit.

During the assessment visit, the FLRC assessors shall validate the data and information contained in the documentary requirements and evaluate the laboratory's compliance with FPA laboratory recognition guidelines.

***4) Consolidation and Review of Data and Information***

The FLRC Secretariat shall consolidate and make a summary of the Laboratory Assessment Reports by the FLRC assessors. Based on the reports and data or information available, the FLRC shall recommend to the FPA Executive Director the issuance/non-issuance of the FPA Laboratory Recognition Certificate to the applicant laboratory.

***5) Re-assessment of Laboratory***

a. If FLRC found the applicant laboratory not complying with the requirement(s) for recognition, the FLRC shall:

   i. Immediately inform the management of the applicant laboratory of its non-compliance(s) and make recommendations on how to correct the laboratory's non-compliance(s).

   ii. Provide the Executive Director and the applicant laboratory with the Non-compliance Report that they prepared in accordance with the format prescribed by FPA.

b. The FPA shall require the applicant laboratory to correct its non-compliance(s).

c. Request for reassessment shall be entertained when the applicant laboratory provided the FLRC with a letter stating that they have already corrected their non-compliance(s) accompanied by supporting documents, if applicable, and paid the reassessment fee amounting to ten thousand pesos (P10,000).

***6) Granting of Recognition***

a. The FPA Laboratory Recognition Certificate shall be issued, signed and approved by the FPA Executive Director after the laboratory has been validated to comply with the appropriate requirements set by FPA.

   The Certificate shall, among others, contain the following information: name and address of the recognized laboratory, recognition number, recognition status, names of the authorized signatories, effectivity of recognition, and signature of the Chair of FLRC and FPA Executive Director.

b. Scope of Recognition shall also be issued accompanying the FPA Laboratory Recognition Certificate listing those tests/analysis that FPA considers the recognized laboratory can perform effectively.

c. The FPA Laboratory Recognition Certificate shall not be transferable.

***7) Extension of the Scope of Recognition***

The FPA Recognized Laboratory requesting for the extension of its Scope of Recognition shall submit the prescribed FPA application form supported with the necessary data/information and pay the laboratory accreditation fee of ten thousand pesos (P10,000.00). This application shall undergo the same procedure as the application for laboratory recognition.

Upon the approval of the request for extension, the revised Scope of Recognition shall be issued to the Recognized Laboratory.

***8) Directory of FPA Recognized Laboratories***

All recognized laboratories shall be listed in a directory of official fertilizer and/or pesticide laboratories or in another suitable publication or in records maintained by Secretariat.

***9) Monitoring and Surveillance of Recognized Laboratory***

FPA shall institute monitoring mechanisms within the period of effectivity of Recognition to ensure that the recognized laboratories continuously comply with the requirements. The FLRC shall conduct periodic monitoring and surveillance of the Recognized laboratory. This includes but limited to the following:

a. Scheduled/unscheduled laboratory inspection; and
b. Provision of quality control/inter-comparison samples for analysis by the Recognized laboratory.

## D. RESPONSIBILITIES OF THE RECOGNIZED LABORATORY

### *1) Compliance to Laboratory Recognition Requirements*

a. The Recognized Laboratory shall continuously comply with the appropriate requirements in the FPA Guidelines and other requirements that may be specified by FPA.

b. The Recognized Laboratory shall pursue to comply or align with requirements of ISO 17025 “General Requirements for the Competence of Testing and Calibration Laboratories” and the “Guidelines on Good Laboratory Practice (GLP) in Pesticide Residue Analysis” set by Codex Alimentarius Commission.

### *2) Cooperation of Recognized Laboratory*

a. The Recognized laboratory shall cooperate with the FLRC for the Laboratory Recognition Program to enable the latter to perform their duties conveniently during assessment and surveillance visits.

b. The Recognized Laboratory shall:

i. Allow access of FPA assessors to the following: premises, records and analysis;
ii. Conduct tests required by the FPA; and
iii. Allow FPA assessors to interview the laboratory staff.

### *3) Proficiency Testing*

a. The laboratory shall participate in inter-laboratory proficiency tests at least two (2) for residue and at least three (3) for formulation per year as part of the surveillance in the performance of the recognized laboratory.

b. Results of inter-laboratory exercises shall be submitted to FPA before it can renew its laboratory recognition. (Check guidelines of PAB on PT)

### *4) Payment of Fees*

The applicant laboratory shall pay the laboratory recognition fee amounting to ten thousand pesos (P10,000.00) for new application, renewal, reassessment or extension of the scope of recognition.

### *5) Notification of Change*

The Recognized Laboratory shall inform immediately the FLRC Secretariat (and in no case shall this be beyond one week) of significant changes in the laboratory that would affect the quality of its test results or compliance with laboratory recognition requirements. FPA may conduct reassessment, suspend, or withdraw recognition depending on the severity of effect of changes on quality of test results.

Significant changes that should be reported immediately include the following:

a. the Recognized Laboratory's technical staff, equipment, facilities, or laboratory location;
b. the Recognized Laboratory's organization, policies and procedures; and
c. the Recognized laboratory's authorized signatories.

### *6) Reference to FPA Laboratory Recognition*

a. The Recognized Laboratory may cite in communication media such as brochures or any other advertising material its recognition by FPA. However, such reference shall be done only during the validity of recognition, and shall claim recognition to specific scope of tests for which it has been recognized.

b. The Recognized Laboratory shall not use the FPA Laboratory Recognition Certificate in such a manner as to bring FPA into disrepute, and shall not make any statement relevant to its recognition that FPA may reasonably consider to be misleading.

c. The Recognized Laboratory, in making reference to its recognition status, shall use the following phrase as appropriate: "FPA Recognized Laboratory for specific tests and identified by FPA Recognition Number(s)…..".

### *7) Cooperation with FPA*

a. The Recognized Laboratory shall perform tests (for a fee) requested by FPA with respect to test data for registration or confirmation of test data submitted for registration and shall give priority to these tests.

b. The Recognized Laboratory shall participate in at least one (1) program of FPA on monitoring of fertilizer and pesticide formulations and residues under mutually agreed conditions (compensations, due dates, etc.).

c. The Recognized Laboratory shall participate in inter-laboratory tests programs run by FPA in its studies on sample handling, test procedures or other areas concerning fertilizer and pesticide residues or formulations.

## E. MISCELLANEOUS REQUIREMENTS

### *1) Suspension, revocation of laboratory recognition certificate and reduction in the scope of recognition*

a. FPA may suspend or revoke the FPA Laboratory Recognition Certificate, reduce the scope of recognition, or require re-assessment, on the following grounds:

i. Changes in personnel, equipment, or scope of activity of a recognized laboratory that will render the laboratory to be non-compliant;
ii. Non-submission/delay in the submission of annual reports;
iii. Violation of the terms and conditions for the recognition;
iv. Failure to provide reasonable cooperation to FPA and its assessment team; and
v. Deliberate falsification of documents and test results.

b. Should there be ground for suspension or revocation, the FPA shall issue a notice to the recognized laboratory requiring it to submit an explanation letter, within fifteen (15) calendar days from receipt, to show cause why the FPA Laboratory Recognition Certificate should not be suspended or revoked.

c. Upon receipt of the response of the show cause letter, the same shall be referred to the FLRC who shall evaluate and recommend to the FPA Executive Director the corresponding action.

### *2) Renewal*

Application for renewal shall be filed at least three (3) months before the expiration of Certificate.

### *3) Handling of Complaints*

a. FLRC shall act immediately on a complaint.

b. All complaints shall be recorded. The record shall include the name of complainant, nature of complaint, action taken, and the person who took charge of the complaint.

c. Complaints that are not resolved immediately shall be put in writing by the complainant. The letter of complaint shall be addressed to the FPA Executive Director. FLRC shall study or investigate and resolve the complaints. The complainant shall be provided with the resolution on their complaint(s).

***4) Confidentiality***

All information gained by FPA and its authorized agents in processing, granting, maintenance and renewal of laboratory recognition will be treated as confidential between FPA and the laboratory. Such information will be handled on a strict "need to know" basis and will not be divulged without written instructions from the FPA. The FLRC shall be made aware of and abide to this requirement of confidentiality. Moreover, the Recognized laboratory shall sign a contract or memorandum of agreement with FPA assuring that all laboratory information such as data and test reports shall not be disclosed or released to others without consent and approval from FPA.

### 4.5.7 Procedure for Revocation of Accreditation, Certification and Licenses

All types of accreditation, certification and licenses may be revoked or suspended by the FPA on the basis of the following:

1. False statements in the documents submitted to the FPA or any acts of dishonesty, fraud or deceit.

2. Violation of PD 1144 or failure to observe FPA Rules and Regulations.

3. Ignorance, negligence, poisoning or death in the community by his direct action or through persons under his supervision.

4. Application, or supervision of the use, of any restricted pesticide in a manner inconsistent with its labelling.

5. Non-compliance with the required use of safety equipment and/or operation of faulty or unsafe equipment causing injury or death of the applicator.

6. Refusal to allow inspection of premises and records or to give information requested by FPA.

The licensee will be notified of the revocation/ suspension/cancellation of his accreditation, certification or license through registered mail. Opportunity for a hearing before the FPA must be requested formally within ten (10) days after receipt of notice. Punitive action is enforced until the final outcome of the hearing.

For accredited researchers, first offense will be dealt with a written reprimand. Succeeding violations will be dealt with in the same way as the PCO or CPA.

**Table 9. SCHEDULE OF REVISED FEES AND CHARGES FOR ACCREDITATION/LICENSING OF PESTICIDE HANDLERS***

**FERTILIZER AND PESTICIDE AUTHORITY**

| ITEM | Fees and Charges (in Pesos) |
|---|---|
| **I. LICENSING OF FERTILIZER AND PESTICIDE HANDLERS, FERTILIZER & PESTICIDE DEALERS & WAREHOUSES** | |
| A. Fertilizer and Pesticide Handlers other than Dealers (annually) | |
| Over P 5M capitalization | |
| 1st activity | 8,500.00 |
| Additional activities | 5,000.00 |
| P 1M to 5M capitalization | |
| 1st activity | 5,500.00 |
| Additional activities | 4,000.00 |
| P 500T to 1M capitalization | |
| 1st activity | 4,000.00 |
| Additional activities | 2,000.00 |
| P 500T & below capitalization | |
| 1st activity | 2,000.00 |
| Additional activities | 1,000.00 |
| Filling fee/activity for new applications | |
| Manufacturer | 7,500.00 |
| Formulator, repacker | 7,500.00 |
| Institutional Users | 7,500.00 |
| Other activities | 2,000.00 |
| B. Pest Control Operations (Annually) Members of PCO associations | 1,200.00 |
| C. Accreditation Fee for Certified Pesticide Applicator (Annually) | 600.00 |
| D. Accreditation of Researcher (Annually) | 600.00 |
| Additional disciplines | 200.00 each |
| E. Accreditation fee for Accredited Responsible Care Officer (Annually) | 300.00 |
| F. Accreditation of Laboratories | 10,000.00 |

* Subject to change

**Table 9. (continued)**

| ITEM | Fees and Charges (in Pesos) |
|---|---|
| G. Mango Contractors (Annually) | 1,200.00 |
| Members of accredited associations | 600.00 |
| H. Dealers (renewable every 3 years) | |
| Pesticide Dealers | 2,500.00 |
| Members of dealer's associations | 2,000.00 |
| mall hardware stores (with option to pay annually or every 3 years) | 1,800.00 /3 yrs. |
| mall outlet retailing Household pesticide with annual sales of less than P 50,000.00 (renewable every 3 years) | 450.00 /3 yrs. |
| Dealers of both Fertilizer and Pesticide | 4,000.00 |
| Members of dealer's associations | 3,200.00 |
| Cooperatives | 50 % of dealers fee |
| I. Accredited Pesticide Dispenser | 360.00 /3 yrs. |
| J. Accredited Professional Pesticide Adviser (Annually) | 300.00 |
| K. Warehouses (Annually) | |
| Pesticide | 2,000.00 |
| Both Fertilizer and Pesticide | 2,400.00 |
| **II. PROCESSING FEES** | |
| CAIP Issuance | |
| a. General Use | 750.00 |
| b. Red Labelled & Restricted Use | 3,000.00 |
| Amendment Certification | 750.00 |
| Export Permit | 1,500.00 |
| Permit to Purchase Restricted Pesticide | 450.00 |
| **III. ALL OTHER CERTIFICATIONS** | 350.00 |

# *Chapter 5*

# *PRODUCT STEWARDSHIP AND RESPONSIBLE CARE*

## 5.1 GENERAL INFORMATION

There is a great possibility that the majority of pesticide users might have been unduly exposed to pesticides during and after application due to inadequate appreciation and understanding of the hazards involved. In this regard and in the interest of the common good, the principle of pesticide company product stewardship has been adopted as a means of addressing the hazards and risks to human health and the environment associated with the use of pesticides. Pesticide companies shall exercise product stewardship to ensure that their products are properly handled and safely used. It covers the entire cycle from the introduction, manufacture, formulation, marketing, application to the use of the products including proper waste disposal.

The FPA recognized the fact that the Crop Protection Association of the Philippines (CPAP) and similar organizations have already adopted in their Code of Ethics the Product Stewardship Principle and this paved the way for the formulation and issuance of the following guidelines on product stewardship.

### 5.1.1 Policy Guidelines on Product Stewardship

1. The Company concerned shall ensure that its products are handled properly and workers protected during formulation, storage, transit, application and disposal. The Company concerned must submit a report covering the manufacturing or formulation process, the volume and quantity of products (imported, processed, marketed and sold), the number of workers involved, safety precautions employed, waste management and disposal methods, including the residue levels in the wastes emitted/ disposed, etc.

2. The Company concerned shall provide the necessary training on the safe handling and use of its product (including proper waste disposal) to dealers and users following FPA approved modules. A yearly report which includes annual training schedules shall be submitted to FPA.

3. The Company concerned shall provide, at cost, protective clothing such as aprons, gloves, masks and boots to users of its product especially those belonging to Categories I and II pesticides. The company shall ensure the continued supply of these protective clothing and equipment for as long as its products belonging to Categories I or II are marketed.

4. The dealers concerned shall make available first aid kits while the company shall provide antidotes for its product to the nearest medical facilities as determined by FPA. The provision of antidotes to medical facilities shall be made annually and reported to FPA.

5. All companies concerned shall provide information services to the public. The nature and scope of these services shall be subject to FPA approval.

6. The Company concerned is obliged to report to FPA any information adversely affecting the safe use of its product within the quarter that such information has become known.

7. The Company concerned shall stop the sale of and recall its product which has been found or deemed unsafe for use under any use directions or

restrictions by FPA. The Company concerned must shoulder all the expenses that might be incurred in the retrieval and proper disposal of the recalled products.

### 5.1.2 Performance Review

There shall be periodic review, at least once a year, of the stewardship activity and performance of the pesticide company.

### 5.1.3 Penalty for Violations

Any violations of the provisions of the preceding policy guidelines on product stewardship, including the clause performance review, shall be subject to punitive action in the form of fines, sanctions, suspensions, cancellations or revocation of registration permit and/or company license. Any Company cited for violation shall be given due process but the FPA reserves the right to impose the degree of penalty based on the provisions of PD 1144 and FPA rules and regulations.

## 5.2 RESTRICTIONS ON AVAILABILITY AND USE

### 5.2.1 General Information

Because of their inherently toxic nature, not all pesticides can be allowed for use by the general public. Some pesticides need to be restricted to avoid undue risk to the applicator and the general public or the environment. Generally, restriction is to a particular class of user, such as a certified applicator or an institutional user.

*A. Legal Basis*

According to Section 6, III (3) of PD 1144, FPA is vested with the following powers and functions:

> " To restrict or ban the use of any pesticide or the formulation of certain pesticides in specific areas or during certain periods upon evidence that the pesticide is an imminent hazard, has caused, or causing widespread serious damage to crops, fish or livestock, or to public health and the environment."

Further, Section 5 Art. II (c) of the FPA Rules and Regulations No. 1; Series of 1977, provides:

> "If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings, and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause without additional regulatory restrictions, unreasonable adverse effects on the environment, including

injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use;

2. ...the pesticide shall be applied only or under the direct supervision of a certified applicator.

3. ... the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation."

### 5.2.2 Basis for Restrictions

Restrictions on availability are based on assessment of hazards due to the toxicity of pesticides, exposure potential and phytotoxicity to crops. Adverse effects and risks involved in the use of a particular product shall be carefully weighed against the benefits. Each compound shall be considered on its own merits. Use patterns and the presence of "equivalent" compounds which are less hazardous for the same uses shall also be taken into consideration.

In toxicology, reliance on a single toxicological criterion especially acute toxicity is not advisable. A compound cannot be restricted solely because of high oral toxicity. Oral toxicity is more of a suicide or inadvertent intake problem. Other toxicological parameters as well as the physical and chemical properties of a compound shall also be considered.

### 5.2.3 Restriction Categories

For the purposes of FPA, four restriction categories have been adopted: (1) Banned pesticides; (2) Restrictions because of hazard; (3) Restriction of purposes of gathering more information; and (4) Restriction due to possible crop phytotoxicity in an ordinary farmer's cultural practice.

*A. Banned Pesticides*

Banned pesticides are those which cannot be brought into and used in the country under any circumstances. Included in this classification are pesticides which have been found unacceptable for use under normal situations whose registration have been cancelled by FPA or voluntarily withdrawn by the concerned company. Pesticides banned in other countries may be allowed to be brought into the country under the Principle of Prior Informed Consent (PIC).

*B. Restriction Due to Health Hazards*

It must be clearly understood that any pesticide under this category shall not be allowed under any circumstances or likelihood to be released for general use.

The following factors are considered in making this determination:

1. Acute, chronic and subchronic toxicity in relation to formulation and use patterns;

2. The absence of antidotes in cases of poisoning;

3. Suspected carcinogenicity, mutagenicity or teratogenicity; and

4. Environmental properties, e.g., long residual life, high bioaccumulation potential and high leachability in soil.

*C. Restriction to Gather More Information*

Compounds in this category are believed to have some potential adverse effects which shall be monitored under Philippine conditions. This category is used to obtain additional local experience and some benefits prior to general sale while under closely controlled conditions.

*D. Restriction due to Phytotoxicity to Crops*

This restriction is most applicable to herbicides. There are instances when the tolerance of a crop to a particular herbicide is dependent upon certain conditions which may not be followed under ordinary farmer's field conditions. Perfection of the technology together with farmer education may be requisites for general use.

### 5.2.4 Pesticides For Institutional Use Only

One of the restricted categories adopted by the Philippines is the limitation of the use of the pesticide to institutions only. While the adoption of this category of restriction is, in general, in accordance with international practice, the guidelines have been modified to be responsive to the specific situations in the country.

An institutional user differs from ordinary farmer with respect to being able to exercise close supervision of pesticide application during all phases of the activity. This means that occupational exposure can be limited to smaller and more homogeneous groups. Prohibitions and protective clothing requirements, exposure times and other factors in applicator safety can be more readily managed. Simple expediency of limiting exposure time of workers to nil-exposure situations may prevent some effects. There is a higher awareness level in institutional users than farmers, in general. It is also easier for FPA to reach, or even monitor, a large group of users through an arrangement with institutions.

Pesticide for institutional use only shall be made available directly from the Philippine distributor/importer to the institution solely and directly. There will be no over-the-counter sales through the regular dealership networks.

It is stressed that restrictions to institutional users may be made only if FPA is convinced that some advantage can be gained by such action, e.g., the compound is useful but has some demonstrated or potential adverse effects that make general use inadvisable. However, general prohibition of use in the country would be disservice to Philippine agriculture. If sufficient information is generated, and if upon examination of submitted evidence FPA warrants such action, the restrictions may be removed.

*FPA Requirements for Restrictions for Institutional Use Only*

The following requirements shall be met if a pesticide product has been restricted to institutional use only:

1. Access to a medical facility having capabilities to deal with poisoning or other potential adverse effects must be available;

2. Strict compliance with FPA requirements for protective clothing, safety devices, exposure limits and other safety precautions established for use of the compounds;

3. File periodic reports to FPA on the observed or lack of observed adverse effects;

4. A report on the disposition of all stocks must be submitted to FPA by the registrant;

5. In the case of “Restriction to Gather More Information”, a complete summary report on the areas with incomplete data shall be filed by the registrant at the end of the probation period;

6. “For Restriction Due to Phytotoxicity”, a summary report on advances in technology, training and evidence of phytotoxicity under restricted use shall be submitted to FPA by the registrant at the end of the probationary period; and

7. Other requirements deemed necessary for the particular pesticide and use conditions.

### 5.2.5 Use of Pilot Areas

In some cases, FPA may permit the use of pilot areas in lieu of institutions. This is particularly true for restrictions designed to gather more information and improve pesticide selectivity. This option may be exercised if FPA assesses that the pesticide is only of limited use to institutions so that the spirit and intent of the restriction cannot be fulfilled. In the case of gathering more information, the following shall be observed/required:

1. A demonstration by the registrant that proper medical facilities are available in the pilot area;

2. An extensive information campaign must be conducted in the area appraising users of the potential hazard of the pesticide and requiring them to immediately report any adverse effects to the medical facility staff;

3. An adequate monitoring and reporting system must be implemented with periodic reports submitted to FPA;

4. The registrant shall bind himself to compensate users for any adverse effects suffered from the pesticide in an amount to be determined by FPA; and

5. The registrant shall submit a summary and complete report on the adverse effects, technology improvement and training at the end of the observation period.

### 5.2.6 Pesticides for Certified Pesticide Applicator Use Only

PD 1144 provides that restricted pesticides should be used and applied only by and under the direct supervision of certified pesticide applicators, or under such conditions as the FPA may require.

Some pesticides need to be used throughout the country but can cause problems if misused. One predominant class is comprised of those pesticides used in and around the home to control termites. These compounds are highly toxic and persistent, but the untrained user can misuse them and may contaminate the environment with severe economic consequences or health problems.

For these reasons, such pesticides are restricted, for use solely by Certified Pesticide Applicators (CPAs). Distribution of such materials and their advertising shall also be controlled.

### 5.2.7 List of Banned and Restricted Pesticides

FPA shall publish from time to time a list of banned and restricted products to provide guidance to pesticide users and the public. The latest listing is included in this guide book as Annex IX. Since this can and will change on a short notice during the course of the registration process, interested parties should contact FPA for the most current information about a specific pesticide and its use. Attached, as Annex X are additional circulars on restrictions of specific pesticide products.

## 5.3 FORMULATION AND PACKING

### 5.3.1 Introduction

Formulation and packing are among the important processes in the production and distribution of pesticides that ensure the quality and stability of the product. This section describes the standard and requirements for the safe manufacture of pesticides particularly with regard to formulation and packing, as well as the health/safety and environmental aspects.

*A. Common Types of Formulation*

The three (3) common types of formulation are as follows:

1. Liquid Formulation - all materials are pre-weighed, and then charged into the mixing tank. It is blended for a certain period of time (approximately 30 min. or more) to attain a homogenous mixture.

2. Powder Formulation - all materials are pre- weighed, and then charged into a ribbon-type blender. It is then blended for a certain period (approx. 20 min.) depending on the batch size. If the specifications require that the product be pulverized to finer particles, it undergoes a milling process.

3. Granular Formulation - the carriers are pre-weighed, charged first into the mixer. The liquid technical materials are then sprayed inside. The rest of the materials are mixed to coat and dry the granules.

*B. Common Equipment Used in Formulation*

Any company engaged in the formulation of pesticides shall have the following minimum set of equipment:

1. *Liquid Formulation*

- Weighing Scales
- Pneumatic Pumps
- Blending/Mixing Tanks
- Storage Tanks
- Sandmill (Optional)
- Cooling/Heating Equipment (Optional)

2. *Wettable Powder Formulation*

- Weighing Scales
- Ribbon Blenders
- Pulverizing Equipment (Optional)
- Dust Collector
- Bucket Elevators (Optional)
- Storage Bins/Hoppers
- Densifiers (Optional)

3. *Granular Formulation*

- Weighing Scales
- Munson Blender
- Bucket Elevators
- Storage Bins/Hoppers
- Extruder} for extruded
- Dryers } granules

*C. Common Types of Packing*

1. Liquid Packing - the process of placing the liquid formulated materials into suitable containers, such as: glass bottles, plastic bottles or jugs, tin cans, plastic or steel drums, etc.

2. Powder Packing - the process of placing the powder-formulated materials into the suitable containers, such as: polyethylene bags, polypropylene sacks, paperboard boxes, fiber drums, etc.

3. Granular Packing - the process of placing the granular formulated materials into suitable containers, such as: polyethylene bags, paper bags, corrugated cartons, fiber drums, etc.

### 5.3.2 Safety, Health and Environmental Aspects

*A. Facilities*

1. Ventilation

a. General Ventilation

The building shall be well ventilated principally to provide agreeable working conditions. Open-sided buildings (if site security is good) will achieve this naturally.

Where there are walls, vents shall be placed in the roof or in the wall just below roof level, as well as near the floor. However, this system shall not be used to remove toxic dusts or fumes. Local exhaust (source) ventilation must be established for this purpose.

b. Local Exhaust (Source) Ventilation

Local exhaust (source) ventilation is the only effective way of stopping harmful dusts and fumes from being released into the workplace. To be effective, the intake to the ventilation system shall be placed as close as possible to the source of the contamination. All such sources shall be enclosed as far as possible.

c. Room Ventilation

Room ventilation shall be used where equipment cannot be ventilated locally because of its size, shape or function. It is essential that the source of contamination shall be between the operator and point of extraction, and, that all other openings to the room shall be reduced to a minimum.

d. Emission Control

Where ventilation is used to control dust sources, the discharged air must be filtered. In exceptional cases, vapors and odors may require specific treatment.

2. Lighting

The plant must be sufficiently lighted (natural or artificial) to permit safe operation.

3. Electrical Equipment

All electrical equipment (including electrically-driven forklift trucks) used in plants handling flammable materials must be approved from a fire-safety viewpoint and must be maintained to a safe standard. Permanent electrical installations shall be used whenever possible; flexible electrical leads, where used, shall be kept short.

*B. Formulation and Filling Equipment*

1. Liquids (Fire-explosion Precautions)

Many of the liquid pesticide formulations are based on flammable organic solvents. In liquid formulations and filling plants using such solvents, there is always the possibility of an explosive mixture of air and vapor building up. For this reason, all electrical equipment in the vicinity of the formulation and filling units must not produce sparks and must be approved from a fire and explosion viewpoint.

Naked flames and spark-producing tools and accessories must not be used in such areas, except with the special approval of the plant manager. This prohibition includes petrol or gas motor-driven vehicles such as forklift trucks.

To prevent build-up of static electricity, all equipment must be adequately earthed, with earth-bonding straps or cables being used where appropriate to maintain earth continuity. Drums should also be earthed during emptying and filling. Charge build-up through splashing should be minimized by the use of dip-pipes in drums and vessels. A particular risk exists when powders are being loaded into vessels containing flammable liquids, especially from conductive containers such as plastic bags. Loading should be done slowly and, if possible, from an earthed conducting container.

2. Solids (Fire/explosion Precautions)

If the PDS states that a solid product presents a dust explosions hazard, equipment must be protected with explosion-suppression, explosion-venting or inert-gas-blanketing system and the recommended formulation and mixing procedures must be strictly followed. Specialist's advice must be sought with respect to the adequacy of the equipment.

All parts of the equipment must be earthed, using earth-bonding straps where necessary to ensure earth continuity. Conductive materials must not, under any circumstance, be isolated from earth.

3. Industrial Hygiene Precautions

Exhaust ventilation with a minimum air velocity of 0.5 m/sec must be provided at the charging and discharging points. Empty packaging material should be carefully collected in a container to keep dust in the working area to a minimum.

4. Filling and Packing Equipment

Packaging equipment for filling liquids and solids shall be equipped with local exhaust (source) ventilation with a minimum air velocity of 0.5 m/sec.

Liquid filling equipment shall be free of leaks. It shall have a guard to prevent splashing on to operators, and a collection container for drips and spills.

All filling machines shall automatically close when de-energized.

Filling and packing machines shall have protective guards to prevent fingers or clothing being caught.

*C. Operational Procedures*

1. General

a. Supervision and line of responsibility

Operations within the formulation and packing plant shall be closely supervised by a trained and experienced supervisor. If there are several supervisors of different levels, the area and line of responsibility shall be clearly defined and understood.

b. Working instructions and procedures

The following written instructions and working procedures shall be readily available to the supervisor:

- Instructions for safe and correct operation of the equipment
- Formulation recipe, blending and packing procedures
- Product Data Sheets for ingredients and finished products
- Hygiene and safety instructions and procedures
- Equipment cleaning procedures.

c. Training

All personnel working in the formulation and packing plant shall be thoroughly trained at the beginning of their employment. Thereafter, regular training programs shall be held to prevent the development of bad working practices. A permanent record of the instruction received shall be kept. Safety and hygiene practices shall be part of the regular training program.

d. Constraints

Pesticides shall not be formulated or packed in equipment in which products for human or animal use, such as foodstuffs, cosmetics, etc., are also formulated and packed.

If non-pesticide products, for example, brake fluids, lubricants, etc., are blended and packed in the same

equipment as pesticides, precautions shall be taken to prevent cross contamination.

2. Hygiene and Safety

Before formulating any pesticide or packing it, the supervisor shall check that all necessary plant hygiene and safety equipment, such as exhaust ventilation equipment are operational. He must also ensure that operators are wearing the necessary personal protective equipment. If such equipment is being re-used, it must first be properly cleaned and inspected.

The supervisor shall also ensure that the working area is in a condition that permits safe working. For example, it should not be crowded with containers and unnecessary equipment.

Workers must avoid all contact with the products, but in the event of accidental contact, they must remove contaminated clothing immediately, wash the skin and treat it according to the specific instructions given in the PDS.

3. Formulation and Filling Procedures

Strict precautions shall be taken to prevent cross-contamination. For example, a fungicide contaminated with an insecticide could present hazard to the user, and an insecticide contaminated with a herbicide could cause crop damage.

An effective system shall be adopted for identifying the correct ingredients required by the recipe.

Strict procedures shall be laid down for dosing of ingredients into formulating equipment in order to avoid mistakes.

Accurate records shall be kept for the batch or lot numbers and weights of all ingredients used in each identifiable batch of formulated product.

Products shall be checked regularly for quality, and a reference sample system be established to enable investigation of possible complaints.

Because of the risk of operator contact, the filling and packing of pesticides can be one of the most hazardous operations in a pesticide formulation and packing plant. Equipment shall be well maintained to prevent leaks and drips. The supervisor shall ensure that all safety devices are operational and that safe and hygienic working procedures are being followed.

## 5.4. PACKAGING MATERIALS

This section describes the standards and requirements for packaging materials

### 5.4.1 Packaging Standards

*A. Packaging Standard Line*

| Formulation | *Packaging size* | Packaging unit |
|---|---|---|
| Liquids: | Small | Bottles (PE, glass, AL)<br>Canisters (tin, PE) |
| | Large | Barrels (Iron-steel) |
| Powders: | Small | Bottom Bags (PE, paper, AL)<br>Tubular bags<br>Sacks |
| | Large | Sacks (PE, paper)<br>Drums (Iron-steel) |

*B. UN Performance Tests on Packaging*

Any packaging material for pesticide shall pass the UN Performance Tests on packaging.

The main objectives of the UN performance test are the following:

1. To make the transport of the products feasible which will in turn encourage trade.

2. To ensure safety of people, property and environment.

3. To generate data for use as guide in the formulation of harmonized laws and regulations.

There are three (3) types of tests conducted on packaging:

1. Material and Packaging Testing

   The objective of this test is to determine the packaging design and specifications. Examples of materials being tested for packaging are the following:

   - Metal
   - Lacquer
   - Plastic
   - Paper and cardboard.

   Examples of packaging testing are the following:

   - Water absorption of corrugated cardboard boxes
   - Stress crack corrosion on PE-canisters
   - Lacquer quality on iron steel drums.

2. Compatibility Test

These tests are conducted in order to determine if the packaging will be able to store its contents under different conditions and for certain minimum length of time. Main tests include the following:

- Loss of a.i. content
- Water content loss
- Weight loss or gain
- Appearance of the packaging (including internal surface)
- Appearance of the closure.

3. Performance Test

This includes the following:

- Drop test
- Leakproofness test
- Hydraulic pressure test
- Stacking test

### 5.4.2 Regulatory Requirements

*A. Pesticide Containers*

1. Packaging containers and related outer packaging shall comply with all national standards and regulations which apply to packaging and, where required, with international transportation and safety regulations.

2. Pesticides shall only be packaged in containers designed to provide protection against product deterioration, compaction, weight change or any other form of spoilage. The container used shall be able to withstand all anticipated levels of handling, storage, stacking, loading and unloading conditions, and shall not be adversely affected by changes in atmospheric conditions such as pressure, temperature and humidity.

3. The inner surface of the container or closure may be coated or lined with substances or materials which have been tested to resist corrosion and to be inert toward the contents.

4. The outer surface of the container shall be made of or be coated with materials which resist corrosion or other forms of deterioration and are suitable for direct label printing or the attachment of a printed label.

5. The shelf life of the container and its contents shall not be less than two (2) years. In case the shelf life of the product and its active ingredient is less than two (2) years, the “best before date” (month, year) shall be clearly indicated on the label. In every case, however,

the date of formulation and batch number shall also be clearly indicated.

6. Containers of a specific design which have been tested and qualified for a particular product shall be retested if they are to be used for another product, or with a new formulation of the same product. Likewise, should there be any change in the design, or size and shape, or materials used in the manufacture of the container, then the test procedure shall be repeated.

7. Used containers or reconditioned packaging shall only be reused when its quality has been tested to be equal to that of the original packaging.

*B. Filling*

1. Strict quality control shall be instituted in the container filling sites to maintain the high standard of the pesticide containers and its contents.

2. All liquid containers shall have a headspace of at least 5%.

*C. Types and Specifications of Pesticide Containers*

1. Inside Containers

Inside containers are defined as those, which require an overpack to provide protection during shipment, handling and storage. Inside containers may be removed from overpacks for sale or display.

a. Bags containing not more than 10 Kg

Bags shall be constructed of one or more piles of paper film or aluminum foil. Bags shall be tested by approved procedures for compatibility and resistance to impact.

b. Bottles containing not more than 1 Kg or 1 L

Bottles shall be fitted with closures, which in the case of liquid will not exceed 63 mm. Polyethylene or other plastic bottles used shall be made from virgin materials and shall have high level of resistance to environmental stress cracking. Bottles shall be tested using approved procedures for compatibility and resistance to impact.

c. Metal containers containing not more than 10 Kg or 2 L

Metal containers shall be constructed from steel, coated with tin or other materials, to provide compatibility with the content and external protection. In addition, metal containers for liquids shall use a gasketing compound at seams, which are not joined by welding. Metal containers

shall be fitted with closures, which in the case of liquids will not exceed 63 mm. Metal containers shall be tested using approved procedures for compatibility and resistance to impact.

2. Overpacks

Overpacks are defined as containers, such as boxes or cartons, which provide essential levels of protection to one or more inside containers. Overpacks shall be sufficiently rigid to prevent compaction or other damage to contents. Where required, internal packaging materials shall be used to help protect the contents.

The quantity of board used for overpacks shall not be measured as less than 190 g/m² when tested by the approved procedure.

Overpacks shall be drop-tested while containing inside containers filled with water or other suitable inert material using the approved procedure.

3. Bulk Containers

Bulk containers are defined as rigid wall packages which may be metal, polyethylene or fiber drums or heavy duty corrugated paper boxes.

Drums containing not more than 250 Kg or 200 L. Drums shall be constructed from steel, which shall be coated internally and externally with a rust preventive or corrosion resistant medium. In addition, all seams not joined by welding shall use a gasketing compound. Polyethylene drums shall be manufactured from resins with known high level of resistance to environmental stress cracking. Fiber drums and corrugated boxes, manufactured from paper, shall be internally lined with sealed polyethylene bags having a thickness of not less than 0.05 mm. The size of closures for liquid containers shall not exceed 63 mm. Bulk containers shall be tested by approved procedure for compatibility and impact resistance.

*D. Selection of Appropriate Pesticide Containers*

1. Solid Products - Powders, Dusts or Granules

Small packages, usually up to 3 kilos capacity, can generally be selected from ready made packaging such as bags, pouches, canisters, cans, glass or plastic jars. Bags or pouches shall be leakproof. Canisters, cans, and glass or plastic jars shall have closures, which are of the screw-on type to prevent leaks.

2. Liquid Products

- Small containers size up to 5 liters capacity can generally be selected from available stock packaging. Types used are

cans, with necked bottle, flat or screw top, made of glass or plastic.

- Large liquid containers typically sized between 10 to 200 liters capacity are usually of standard varieties such as jerry cans and drums manufactured from steel and plastic. Liquids shall always be packed in containers with closed heads; in the case of drums, the head should be seamed or welded onto the body.

3. Pressure Packages

Containers which must contain the contents under pressure at ambient temperatures shall be packaged in containers designed to be pressure resistant. Particular attention should be given to the gauge of the metal used for the body and heads, the method of sealing and the construction of the valve.

4. Overpacks

Overpacks are used to hold one (1) or more containers together and often provide extra protection for the side containers from handling, stacking and shipping damage. They can be constructed from film bags, shrink wrappings, paper bags or corrugated boxes depending upon the level of protection required. The most commonly used overpack for pesticides is the box particularly due to its ability to provide low cost, economic protection.

5. Closures

Selection of the right closure is important to successful packaging in rigid containers, especially when they contain liquids. The closure size for liquid containers shall be determined based on the rate of pour required and the viscosity of the formulation. Closure size shall not exceed 63 mm, and it is useful to limit smaller sizes to 38 mm for the purpose of standardization.

Closures for rigid containers for powders or granules may be larger than 63 mm, often close to, or the same as the diameter of the jar or drum. Tamper-proof feature built into the closure which indicates whether the container has been opened is particularly useful. Closure liners shall be carefully selected since they influence greatly the overall performance. Inadequate liners are often found to be the cause of container defects.

Closures are not designed to be in constant direct contact with the product except in the vapor phase and shall not be expected to contain liquids when the container is inverted.

Closures shall be applied to containers at a torque sufficient to maintain a seal. It is customary for the torque originally applied to reduce with time, usually 24 hours. The correct method of determining the torque is to measure the opening force.

*E. Testing of Pesticide Containers*

The performance of tests on containers is a useful means of determining the probability of the container providing the level of protection established in these Container Requirements and Standards prior to initial shipments being made. Subsequent to production of the product, it is necessary to make confirmatory tests to determine the efficacy of the original work. The use of specific test procedures improves communication between interested parties, such as regulatory bodies and container manufacturers and users. Test procedures can be developed with varying levels of complexity, depending on the facilities and personnel available. The determination of successful pesticide packaging can usually be done by means of practical procedures. Certain procedures are required in these Pesticide Standards; other useful procedures can be adopted. However, for reference purposes, well-established test procedures, such as those published by A.S.T.M. or other internationally recognized bodies, should be used.

*F. Safety*

Development of new ways of packaging pesticides and choosing the correct one enhances the safety of the user and the environment. There are several problems in safety which can be alleviated if not solved by improvements in packaging. The following are some of the more common problems:

1. User Safety

    - User contamination during mixing
    - Incorrect dose measurement
    - Damage during transport and storage
    - Tampering by children

2. Environmental Safety

    - Waste disposal
    - Recycling

*G. Present Trends in Pesticide Packaging*

Packaging materials are increasingly selected with ease of disposal of used containers in mind. This is because it is becoming difficult for farmers to find safe and convenient methods for disposing agricultural chemical containers. In order to reduce waste, recyclable containers are being developed. The use of biodegradable containers helps reduce environmental pollution.

Packaging materials are also being designed in a way that makes it easy for the users to transport, measure, mix and apply the pesticide. Some innovations also reduce the exposure of the user to the pesticide aside from making it easy for his use.

Many small farmers buy pesticides only at the time when needed. Limited advance or bulk buying is practiced. The pesticide is quickly used once purchased. Empty containers may be rinsed and the rinsate added to the spray mixture. An opportunity exists to design packaging to assist the farmer in emptying, draining and rinsing the container in his traditional way.

Container disposal is a matter of concern related to its utility or commercial value. Those with neither utility nor commercial value are usually found in the corner of fields, in ditches or at roadsides. However, some find their way into local use for carrying kerosene and other substances or are into formal collection channels for recycling or re-use. Re-use by counterfeiters is a major worry, requiring vigilance. The use of seals, guarantee rings, shrink wrap on individual packages helps in deterring people intent on tampering and adulterating the product. Inclusion of embossing and other special features on the packaging discourage people intent on duplication. This still leaves opportunities for misuse of emptied containers for storage of foodstuffs and repacking of counterfeit products.

Typical strategies for packaging and packaging disposal for liquid formulations include the following:

1. The use of water-soluble bags, plastic or paper bags as primary packaging.

2. Development and introduction of refillable containers.

3. Replacement of glass and metal packaging by plastic containers.

4. Development of appropriate container designs which allow safe and economic recycling and/or disposal.

*H. Squeeze Bottle On or Squbo*

The squeeze bottle or Squbo was based on the need to reduce the risk of contamination for small farmers during measuring out small amounts of liquid insecticides. Very often, measuring cups are not available and farmers must use the bottle cap or a tablespoon to measure the product. The squeeze bottle offers several advantages:

1. Safer handling during mixing;

2. Accurate measurement of dose;

3. It actively implements Article 5 of the “FAO Code of Conduct” by reducing end user hazards; and

4. Helps create safety awareness in all levels.

*I. Water Soluble Bag or WSB*

Water-soluble bag is a bag or sachet containing pesticide usually in gel or liquid form. The bag or sachet dissolves when dropped in water, thus, releasing the contents. This system of packaging minimizes the risk of exposure since the user only handles the bag while it is still non-reactive and is not yet dissolving. Exposure is also minimized since the user handles the pack very briefly by retrieving it from its tray and dropping it into the mixing tank. This is in contrast to the use of bottles where the farmer is at risk since he has to measure and prepare the pesticide spray solution before using it.

*J. Closed Filling Systems (Farm-Pak/Venturi Pump, etc.)*

These systems are bulk containment which have the following advantages:

1. It is easy to operate and, therefore, reduces working time and the number of workers needed (one person can handle it).

2. There are no leftovers and error in measurement is unlikely since it uses a digital flow meter to dispense the pesticide into the mixing tank.

3. The large container is harder to steal than smaller containers.

4. Refilling under these systems is like filling up your car at the gas station. It uses a similar closed filling system, which is easy to use.

5. It is easy to control the stock inventory because of the digital flowmeter.

6. There is nearly no need to rinse containers.

## 5.5 TRANSPORT, STORAGE, AND DISPOSAL

### 5.5.1 Introduction

This section describes the guidelines and regulations for the transport, storage and disposal of pesticides, recommended methods for coping with leakage and spill problems, as well as method for disposing unwanted pesticides and pesticide containers.

### 5.5.2 Transport

Safety in transport, with minimum risk to people and to the environment, must be a primary consideration for everybody concerned with the distribution of pesticides. Many of the incidents involving pesticides, which occur during transport, can be avoided by the following good distribution practices.

*A. Movement and Means of Transport*

From the manufacturer or formulators' depot, pesticides are transported to distributors who then transport these to pesticide dealers or retailers.

*B. Transport Emergency Card*

Drivers of vehicles transporting pesticides shall be provided with a document (e.g. a Transport Emergency Card) giving information on the following in the event of an accident:

1. Name and address including telephone number of the dispatching company.

2. Products being carried.

3. Basic hazards posed by those products.

4. Precautions and actions to be taken in case of accident or an emergency.

*C. Labelling and Packing of Pesticide Containers*

All containers shall be properly labelled and packed in manufacturer's original container.

1. Since pesticides are often transported over long distances on bad roads, attention shall be paid to the quality of packaging. Faulty or unsuitable packaging can lead to accidental leakage of product during transport and presents hazard.

2. All products being transported shall be properly and correctly labelled in order to ensure that the potential risks are communicated to all who may handle the goods, in the course of distribution.

*D. Loading and Unloading*

1. Make sure that the correct product is being dispatched and the cargo is labelled correctly.

2. Under normal conditions, pesticides are stable. However, if subjected to climatic extremes of temperature or moisture during transport, decomposition of some products can occur and the stability of the packaging can be adversely affected.

   To avoid damage due to temperature and moisture extremes, the following shall be observed:

   a. Use only vehicles or transport units that are dry inside.

   b. Packaging, including pallets, should be dry when loaded.

   c. Use dry materials for cushioning and securing the load.

   d. Pesticides shall be covered during transport to protect them from rain or direct sunlight.

3. Pesticides shall not be loaded on the same vehicles as foodstuff and other materials destined for human or animal consumption and use. If this could not be avoided, be sure to load the pesticide away from these items.

4. Examine the product carefully before loading. Damaged or leaking containers shall not be loaded.

5. Load and unload pesticides carefully. Do not load pesticides on the roof of the vehicle. Watch over the pesticides during transport.

6. In case of accident (crash, fire or spillage), the driver should:

   a. Switch off the engine and should not light a cigarette.

   b. Send someone to call the police and the pesticide company, and warn other traffic to keep away.

   c. Try to contain the spill by covering it with an absorptive material like soil or dust. Be careful about his own and others' safety. Put on protective gear and avoid walking in splashes and fumes.

   d. Collect the absorbed spill, broken containers and all contaminated waste for disposal in a safe place.

### 5.5.3 Storage

Good storage of pesticides involves the control of all factors that may cause deterioration of the stored products. These factors may be physical (heat, humidity), biological (molds, insects), chemical (acidity, corrosion) or mechanical (pressure packing). Even under optimum storage conditions, some products may spoil after a period of time.

*A. Safe Storage System*

1. Pesticide storage areas shall be constructed and maintained so that the risk of contamination to other products is avoided. All pesticide storage areas shall be clearly marked with warning signs.

2. Storage systems shall be flexible in view of changing stock quantities. They shall also be adaptable to the storage structure.

3. The system shall provide for orderly stacking and shelving with sufficiently wide gangways to enable access to and easy movement of stocks and minimize the risk of contamination from handling pesticide containers.

4. Pesticides shall be stored in containers with original label, positioned so that the label is clearly visible. Stock shall be arranged so that the "first in, first out" policy is followed.

5. Keep floor space clear and uncluttered, with gangways between stacks and shelves for easy inspection and good ventilation.

6. Keep doorways and fire exits free from obstacles, also keep access to the washroom and fire station free.

7. Do not store pesticides and contaminated empty pesticide containers near food and animal feedstuffs, seeds and other plant materials, beverages, clothing and other such articles.

8. Separate pesticides into product types such as herbicides, insecticides and fungicides, and allocate separate stacking areas for each type.

9. Segregate the more toxic products and the combustible ones in separate sections of the warehouse, preferably separated by firebrick walls.

10. Stack solid products separately from liquid products.

11. Never place containers of pesticides directly on the floor. Use dunnage (bricks, pallets or timber) under the containers so that leaks may be discovered easily. Dampness from the floor or leaking pesticides will lead to corrosion of containers and more leakage.

12. Larger containers, such as drums, bags and boxes, may be stacked in a manner that the stacks are stable and sufficiently low to enable easy handling.

13. Dust, granule and wettable powder formulations may cake under pressure. Store and stack these formulations in their original cardboard or fiber containers to prevent compression. If such formulations are supplied in bags, they should not be stacked high.

14. Small containers may be stored on shelves, which should not exceed two (2) meters high; this precludes the use of ladders. One should not climb on pesticide containers to reach other stacks.

15. Mark all warehouse sections and stacks of products with waterproof sign indicating the contents.

16. Keep accurate account of all stock movements and inspection.

*B. Storekeeping*

1. Pesticide Shelf Life. Proper management shall always consider the shelf life of the products. The store manager or storekeeper shall only order stocks which can be sold or disposed within a reasonable period of time before the “best before date” of the product. He should avoid ordering too much of slow-moving items.

2. Inspection of Stocks. All stocks shall be regularly inspected for signs of deterioration or leakage. Points to watch out include:

   a. Strong odor, which often indicates leakage or product decomposition.

   b. Metal drums which are susceptible to rusting and leaking seams or dents.

   c. Plastic drums or bottles shall be inspected for deformation and leakage.

   d. Carton and boxes, and paper or plastic sacks shall be inspected for dampness and discoloration, holes and signs of leakage.

   e. Glass bottles shall be inspected for cracks or leakage.

   f. Missing lids or labels.

   Whenever deterioration or leakage is detected or suspected, all affected packs shall be removed and isolated. Neighboring packs shall be carefully inspected and removed for cleaning if they are contaminated.

3. Rotation. Pesticide stocks shall be rotated on a first -in-first-out basis. “Older” stocks shall be sold or disposed first before the newer stocks.

*C. Recording System for Stored Pesticides*

The basic principle in any storage operation is rotation of stocks on a first-in-first-out basis. Although the type of record system adopted will depend on the size and functions of the store, there are certain practices that must be followed in all pesticide stores.

1. Keep accurate record of all stock movements and inspection. Write the date of purchase or the date of receipt on each container immediately upon its arrival in the store.

2. Ensure that containers are properly labelled: that the labels remain on the containers, and that they are clean and readable. Labels in poor condition shall be replaced.

3. Outdated stocks. Information on shelf life shall be requested from the distributor at the time the pesticide is purchased.

4. Write-off. Pesticide products which have expired or have reached the end of their shelf lives shall be written-off or removed from the inventory of stocks. They shall be disposed in accordance with the section on disposal.

*D. Safety Requirements for Storage Personnel*

1. All personnel in a pesticide store shall receive proper instruction and on-the-job training before they are allowed to work in a storage area. Knowledge and skill levels need to be tested periodically.

2. Appropriate protective clothing shall be worn; a respirator shall be used whenever recommended. Protective apparel and instruction on its proper use shall be provided by the employer.

3. Do not work alone when handling very dangerous pesticides.

4. Do not permit smoking, eating or drinking in pesticide warehouses and storage areas.

5. Practice good personal hygiene; wash work clothes frequently. (Clean water and soap shall always be available for this purpose).

6. Inspect pesticide containers for leaks before handling them; avoid leaving containers open. In order to prevent damage, never handle containers roughly or carelessly.

7. Should leak or spill occur, keep people and animals away from the area and give priority to thorough decontamination of the area.

8. Always keep material use for dealing with spillage and decontamination on hand. For larger warehouses, have this equipment available at strategic points.

9. Always make available in the storage area dry-powder fire extinguishers or substitute such as sand buckets, for fighting small fires. Train all personnel in dealing with small fires.

*E. Recommendation for Safety in Shops*

1. Because pesticide shops are often located near the town center, attention shall always be given to fire prevention.

2. Highly poisonous pesticides shall be stored behind glass doors on shelves or in glass compartments or cupboards, preferably under lock and key.

3. Display a “DANGER, POISON” notice outside and inside the shop so that it can be seen immediately.

4. All containers, packs and bottles shall carry a complete label, preferably in the major national language(s), which can be understood at least by the shop manager.

5. Pesticide containers and bottles shall not be piled upon the sales - counter where they can be easily knocked over.

6. Do not keep too many containers of the same kind in the shop area. Keep your stocks in a separate store.

7. Customer shall not be allowed to open containers to smell the content because they might be poisoned by inhalation.

8. Ensure that pesticides taken by the customer from the shop to the farm are wrapped adequately and carried separately from food, drinks and other consumer articles. Do not sell pesticides in leaking containers.

9. Do not hand over dangerous pesticides to children sent by parents or others to collect such products.

10. Store adequate supplies of water, soap and towels ready for use by customers in case of contamination.

11. Do not allow customers to use pesticide shop as a place for lengthy conversations or friendly gatherings.

### 5.5.4 Leaks, Spills and Decontamination

*A. Leakage and Spills*

1. Leakage is a major problem in the storage and transport of pesticides. Causes of leakage are the following:

   a. Rough handling - dents weaken or split seams and weaken closure (lids, caps, stopper) of drums.

   b. Puncturing or abrasions during transport when containers rub against each other or against sides of truck. The use of hooks for unloading bags at inland ports may damage bags.

   c. Corrosion of the container, which may be accelerated as a result of physical damage.

   d. Strong sunlight may degrade some plastic containers including plastic bottles and plastic sacks.

2. Spills should be cleaned up immediately to prevent harm to people and animals, and to avoid contaminating the environment.

   As soon as spillage occurs, or a leak is noticed;

   a. Keep unauthorized persons, children and animals away from the affected area.

   b. Prevent further waste by closing the container properly, or shifting its position to stop a leakage, or placing into another container.

   c. With dry waste, such as powders and granules, cover with dry sand or soil and sweep up and shovel into containers with cover for safe disposal. The use of damp sand or water may release toxic or flammable gasses from certain products. Consult the label.

   d. With liquid waste, use lime, sand, soil, or any other absorbent material to soak up the spillage. Shovel this into containers with cover for disposal.

   e. Wash the contaminated spillage area thoroughly with water. Do not allow the wash water to run off into any sewer, stream, well or pond and if necessary soak it up with more absorbent material for disposal.

   f. Make sure that all other containers near the spillage area are thoroughly decontaminated by thorough washing. Dispose off the washings properly.

3. During all handling operations of spillage and leaks, protective clothing such as gloves, boots and eye protection, as recommended on the product label, shall be worn.

   Protective cleaning gear shall always be kept ready in warehouses, stockyards and shops for dealing rapidly and effectively with spillage and leaking containers.

   The following list of equipment shall be sufficient to enable someone to deal with common accidents of spillage and leakage:

   a. Two pairs of neoprene or PVC gloves (elbow length)

   b. Two pairs of rubber boots

   c. Two neoprene or PVC aprons; 1 meter wide and l.5 meters long

   d. Two respirators, canister type

   e. Two face shields, helmet type covering eyes and face or at least two pairs of well-fitting goggles

f. Fifty Kg. of powdered lime (as a general purpose absorbent for liquid pesticides), or sawdust, or sand, or other absorbent material

g. Five liters of Teepol, or washing soda (sodium carbonate) or strong soap

h. Two-yard brooms

i. Two shovels

j. Some empty decontaminated drums of various sizes for waste disposal and repacking

k. Paper labels and glue for marking drums and boxes

l. Funnels, buckets, drum spanners and earthen wire

*B. Decontamination of Personnel (Skin)*

The most common contamination to people in the case of leakage and spillage is skin contamination. Successful decontamination requires:

1. Washing with plenty of soap and water.

2. Extreme thoroughness in using the soap and water.

3. Great speed in washing with soap and water.

### 5.5.5 Disposal of Pesticide Wastes

As a general rule, empty container management shall be the shared responsibility of the pesticides companies, their network of dealers/distributors, farmers and their associations, plantation owners, local government units and accredited waste generators/transporters and treatment/storage/disposal entities.

The general guidelines in empty container management are as follows:

*1. Rinsing*

Strictly, all used pesticide containers shall be decontaminated before disposal. Cleaning must be undertaken immediately following the emptying of containers. It must be properly rinsed and the rinsate must be added to the spray tank as part of the make-up solution. The options that maybe adopted are:

a. Triple rinsing which are applicable for small holder farmers who do not have mechanical rinsing equipment. It follows the following stages: a) Empty the container of its contents into the mixing tank and drain for 30 seconds; b) Rinse container at least three (3) times

with a volume of water not less than 10% of the container's total volume; and c) add the rinsate each time to the mixing tank.

b. Pressure rinsing which are applicable for farmers and/or plantation-type operations which have mechanical equipment. The jets of water hit the internal surfaces of the container removing and dissolving the residues.

Whichever method of rinsing is used, the rinsate should be added directly to the spray solution and not to be thrown elsewhere.

2. *Burying or burning of empty containers or packaging is prohibited.*

3. *Collection of empty containers.*

a. The pesticide dealers are hereby designated as primary collection points of properly rinsed packaging. They are, therefore, mandated to provide properly sealed drums in a secured area in their premises as temporarily holding areas where their clients should bring their rinsed containers. The dealers shall maintain a record of rinsed containers they receive, by company. A report on such should be submitted to the nearest FPA office on quarterly basis.

b. Thereafter, the pesticide dealers shall bring the collected rinsed pesticide containers to the DENR-EMB accredited waste generator near their area. The waste generator which may be the Local Government Units, NGO's or the private sector, must be compliant with the provisions of Republic Act 6969 or *The Toxic Substances and Hazardous and Nuclear Waste Control Act and Its Implementing Rules and Regulations.* They are required to assign a Pollution Control Officer for this purpose.

c. Plantation owners are hereby mandated to collect their empty containers. They shall keep a record of empty containers by company and shall submit on such to the nearest FPA office on quarterly basis. They must seek accreditation with DENR-EMB as waste generator and are required to assign a Pollution Control Officer.

4. *Transport of empty containers*

The waste generator shall only engage the services of DENR-EMB accredited transporter. The consolidated volume of empty containers shall be brought to an accredited treatment, disposal, recycling and destruction facilities. Any movement of pesticides empty containers must be covered by a manifest showing the kind and volume of container, the companies to which they belong, the description of conveyances and the permit issued thereof.

5. *Treatment, Storage and Disposal*

The pesticides empty containers/packaging shall be brought by a DENR-EMB accredited facility that is trained in the treatment, recycling,

disposal and destruction of hazardous waste. A Certificate of Treatment/Disposal/Destruction shall thereafter be issued. The Fertilizer and Pesticide Authority, the pesticide company and their industry association shall be provided with a certified copy of the report.

6. The training of dealers and farmers, and LGU's on container management shall be the responsibility of the pesticide companies as part of their responsible care activities in cooperation with FPA and the DENR. Information dissemination on container management shall be made using face-to-face interaction, posters, brochures and other print, broadcast and digital media.

7. The funds for the implementation of the container management shall be the shared responsibility of stakeholders, as follows:

    a. The costs of decontamination shall be to the account of the farmers or plantation owners as the case may be;

    b. The costs of transporting the containers to the primary collection point shall be to the account of the farmers or plantation owners;

    c. The costs of operating and maintaining the primary collection point and the transport to the accredited waste generator shall be to the account of the dealer;

    d. The operation and other incidental costs at the level of the accredited waste generator shall be to their account;

    e. At the plantation type operation, the owner of the firm may act as the primary collection point and waste generator at the same time, hence the costs therein shall be to their account;

    f. The transport from the waste generator and other costs related to treatment, disposal, or destruction shall be to the account of the pesticide companies whether they are affiliated or not to any industry association. No company, big or small, shall be exempted. The cost sharing shall be based on the volume of empty container a company or entity has in each batch of transported items. Participation in this regard will be monitored by FPA and shall serve as requirement in the renewal of their respective licenses as manufacturers, importers, dealers, handlers or distributors.

8. To operate the orderly and systematic implementation of the container management program, all parties to be involved shall define the modus operandi through a Memorandum of Agreement with the guidance of FPA and DENR-EMB.

9. The pesticide companies including their network of dealers shall incorporate their container management in their stewardship activities, which shall include among others, the conduct of trainings, and information dissemination through print, audio visuals, broadcast and digital media. The industry associations are tasked to provide support for these activities.

10. Company's compliance with container management shall be a requirement in the renewal of license with FPA.

11. On an annual basis, the pesticide companies or their industry associations, shall submit a report to FPA on their container management activities as regulatory and stewardship compliance.

12. FPA shall exercise its power under existing laws and regulations related to empty container management.

13. All other rules promulgated by other competent agencies on hazardous and toxic materials shall be adopted in suppletory character.

## 5.6 OCCUPATIONAL HEALTH

Occupational health staffing and training of occupational health staff shall be in accord with Section 1963.02 of Department of Labor and Employment (DOLE) regulations for first-aid workers, nurses and physicians.

### 5.6.l Safety/First Aid Training

*A. Occupational Health Personnel*

Physicians and nurses working in establishments where pesticides are used shall be accredited by DOLE. The company shall submit certification to the FPA. Other paramedical staff shall be trained and accredited by the Philippine National Red Cross (PNRC) or by the Safety Organizations of the Philippines (SOPI).

*B. Workers*

All workers (regular, contractual, permanent and casual) handling pesticides shall undergo pre-placement and periodic training on the proper and safe handling of pesticides; proper use of personal protective clothing and equipment, basic knowledge of the chemicals they are handling and first aid procedures in cases of poisoning. Periodic general safety training shall be conducted for a period of eight (8) hours per year or two (2) hours per quarter. Specific workplace hazards shall be communicated to the workers to ensure compliance.

### 5.6.2 Health Examinations

Pre-placement, periodic and exit health examinations are required for all permanent, contractual and casual personnel working with pesticides. Health examinations shall consist of the following minimum requirements which shall be provided by the employer free of charge: a) complete physical examination which shall be properly recorded and kept in the clinic, b) laboratory tests, and c) biologic monitoring.

Workers exposed to Categories I and II pesticides shall have semi-annual examinations consisting of a complete medical examination, hematologic, liver and

kidney function tests. Workers exposed to Categories III and IV shall have annual medical and laboratory examinations.

To ensure the safety of the workers, only regular personnel shall be allowed to work in formulating/manufacturing plants and institutions handling Categories I and II pesticides. Casuals shall not be allowed to handle AI or technical materials.

### 5.6.3 First Aid

An emergency clinic shall be provided for all hazardous workplaces regardless of the number of workers. There shall be minimum personnel requirement for plants/plantations/pest control establishments handling Categories I and II pesticides.

### 5.6.4 Safety and Security in Plants/Plantations/Pest Control Establishments

Emergency equipment to meet accident needs shall be provided such as emergency showers and eyewash facilities. In plantations or in the field, there shall be provision of water at work area of 25 gallons/person or minimum of 100 gallons per area, whichever is greater.

Maintain safe work environment by requiring health personnel to conduct regular appraisal of workplace including all the facilities therein in order to detect occupational health hazards. The physician shall be informed of the exact time, place and the type of pesticide to be used including the number of workers exposed.

Fire-fighting equipment shall be provided and strategically located. Signs indicating smoking restrictions, access restrictions, the location of the emergency equipment, re-entry time, and all escape routes shall be prominently displayed.

Each team of workers shall have at least one (1) person trained on first aid treatment of poisoning.

All emergency and safety-related equipment shall be frequently and regularly checked and maintained. Records shall be kept of all inspection checks and maintenance carried out on the equipment. These records shall be made available and ready during inspections.

# *Chapter 6*

# *POST-REGISTRATION ACTIVITIES*

## 6.1 GENERAL INFORMATION

FPA has the authority to conduct a wide range of activities after a pesticide is registered to assure that it is being handled, distributed and used safely and in accordance with the applicable rules, regulations and product labelling. The more important functions for the registration and licensing programs are discussed. However, FPA post-registration activities are not necessary limited to these.

## 6.2 MONITORING ACTIVITIES

Monitoring activities to ensure enforcement of policies at the local level shall be done in coordination with the pertinent offices under the Local Government Units (LGUs) and community-based people's organizations.

The mayor and barangay captains shall be given police power to enforce these rules and regulations in behalf of FPA. The barangay secretary, agriculture or health sector representative of the Sangguniang Barangay shall keep records of monitoring activities, including but not limited to pesticide poisoning cases, and unusual environmental conditions that are directly attributable to pesticide use/ contamination. These data will be submitted to the Mayor's Office on a quarterly basis.

The Municipal Agriculture Officer (MAO) as defined by a Memorandum of Agreement shall be responsible for the collation of barangay data. In addition, the agriculture technicians shall monitor compliance with rules and regulations by the dealers in their area of jurisdiction. Violations shall be reported to the Provincial FPA Officer. In turn, the Provincial FPA Officer shall send the data to the FPA Regional Officer for transmittal to the FPA central office. This is to be done on a quarterly basis. The Field Operations Division, in coordination with the Planning and Information Division of FPA, shall create the database for the data coming from the field. Results of monitoring shall be presented during PPTAC meetings, whenever necessary.

A prescribed form (Annex XII) will be used for monitoring activities in the barangay and town/city levels. FPA shall deputize Provincial Agricultural Officer (PAO) and/or MAO to monitor the problem areas. Important data to be collected at the barangay level are popular types of pesticide used, report on incidence of pesticide poisoning in relation to specific pesticides and mode of use, extent of use of banned chemicals, extent of pollution in the environment measured by bird kill, fish kill, color of surface water, taste of ground/potable water, and other manifestations of pesticide effect on public health and the environment.

Data generated in monitoring food and environmental contamination shall be reported to the FPA on a quarterly basis by the laboratories around the country that are assigned for that purpose.

Regional FPA Officers are tasked to monitor compliance of distributors, manufacturers and importers regarding rules and regulations. Data generated in these monitoring activities shall be used as a basis for the renewal/revocation of licenses.

## 6.3 COMPLIANCE IN MONITORING OF PRODUCT STEWARDSHIP

### 6.3.1 Monitoring of Product Quality

FPA shall establish a mechanism to ensure that the product has not yet expired, not misbranded or adulterated.

Expired formulated products shall be recalled and collected by the company concerned. Adulteration/faking/misbranding/mislabelling of pesticide products are acts prohibited by P.D. 1144 and the Implementing Rules and Regulations and are subject to the penal provisions of the law.

### 6.3.2 Residue on Food and Feeds

FPA shall establish a rapid monitoring system of pesticide residues in food crops and feeds to provide information that shall be used to assess the safety of the consumers. Such residue data shall be the basis for modifying use patterns and taking regulatory action on the particular pesticide.

FPA network of residue laboratories shall monitor pesticide residues in food crops and feeds.

### 6.3.3 Environment

FPA and other concerned agencies (LGUs and NGOs) shall monitor pesticide movement to the farms and other areas to determine the potential polluting and contaminating effects on natural environments which may affect fish, wildlife and other non-target organisms. Evidence of such impact shall lead to regulatory action on the pesticide.

Monitoring shall also be required of the registrant as a condition for registration of a particular product when this presents a practical way of resolving technical or environmental issues.

### 6.3.4 Pesticide Poisoning

FPA shall institute a mechanism to monitor pesticide poisoning at the barangay level in coordination with the concerned agencies. A Memorandum of Agreement between the FPA and the concerned agencies shall be established.

Monitoring pesticide poisoning cases shall be done through the Municipal Health Officers, physicians and paramedical practitioners trained under the Agro-Medical Training Programme. Monthly reports which are collected annually shall be submitted to FPA. Institutions allowed to handle pesticides restricted to “For Institutional Use Only” are also required to submit monthly reports on pesticide poisoning cases.

FPA Provincial and Regional Officers and pesticide companies shall coordinate with the Department of Health (DOH), Regional Occupational Toxicology and Non-Communicable Disease Information Center (ROTNIC) as well

as with the Regional Strategic Tactical Operational Program on Disaster, Epidemics, Accidents, Trauma and Hazardous Substances (STOPDEATHS).

All pesticide poisoning cases shall be properly documented using the WHO-GCPF protocol. Data shall be submitted to the municipal health units.

### 6.3.5 Use Patterns

FPA shall actively involve the industry, NGOs, LGUs and civic organizations in monitoring pesticide use to ensure alignment with label directions.

## 6.4 PESTICIDE RESIDUES (MRL ESTABLISHMENT)

### 6.4.1 General Information

*A. Legal Basis*

Pursuant to Section 6, III (2) and (4) of the P.D. 1144, in order to protect the public against potential hazards of pesticide residues in food, FPA is mandated to establish a system of setting maximum residue limits (MRLs), applicable for both domestic and imported raw agricultural commodities. Special provisions shall apply to import and export crops, as well:

> " ... To establish and enforce tolerance levels and good agricultural practice for use of pesticides in raw agricultural commodities;
>
> xxx xxx xxx
>
> ..... To prevent the importation of agricultural commodities containing pesticide residues above the accepted tolerance levels and to regulate the exportation of agricultural products containing pesticide residue above accepted tolerance levels."

*B. Implementation Scheme*

Upon its development, the MRL system will be introduced on a trial basis for one (1) year to educate affected parties and to ensure its proper implementation. This is to avoid disruption of agricultural production and confusion among producers, food importers and exporters.

### 6.4.2 Guidelines for Establishing Maximum Residue Limits (MRLs) and Risk Assessment

The Fertilizer and Pesticide Authority shall adopt the CODEX MRLs until such time that FPA shall have developed an MRL system to protect the consumers from unhealthful levels of pesticide residues. However, for future uses

of pesticides on food crops, registration shall not be granted without a proposed MRL to cover residues of the pesticides in each commodity for which registration is requested.

MRLs are derived from data generated through Supervised Pesticide Residue Trial (SPRT) with a validated method for residue analysis following the "*FAO Manual in the Submission and Evaluation of Pesticide Residue Data for the Evaluation of Pesticide Residue levels in Food and Feed* ". Before an MRL is recommended for adoption as standard it undergoes risk assessment taking into consideration the dietary intake of pesticide residues and the consumption data taken in by an average body weight of 55 Kg. The highest residue detected at Maximum GAP is proposed as the Maximum Residue Level. It is accepted as the Maximum Residue limit (MRL) after assessing the risk of the proposed maximum residue level.

At national level, the CODEX process of estimating Dietary intake (EDI) is being followed but using the national consumption data. Likewise, before an MRL is recommended for adoption as national standard it undergoes risk assessment taking into consideration the dietary intake of pesticide residues and the consumption data taken in by an average weight of man which is 55 Kg for Philippines.

*Predicting Dietary Intake of Pesticide Residues*

There are two types of dietary exposures to pesticides:

1. Long term dietary intake - a lifetime intake of residues contained in a commodity without any appreciable risk throughout man's life.

2. Short Term Dietary Intake - the highest intake of food containing residues eaten in one sitting without any appreciable risk to human health.

The procedure for estimating dietary intake and proposing an MRL is shown as follows:

$$EDI = \frac{\sum MRL_{(mg/kg)} \text{ X } FFi_{mg}}{\text{body weight}_{(Kg)}}$$

where :

EDI - sum of estimated dietary intake of pesticides taken in by a 55-Kg man
MRL - the Maximum Residue Level
FFi - Food Factor or consumption data

*Risk Assessment*

*1. Long Term Dietary Risk Assessment*

Risk assessment is a process that will determine if the proposed MRLs will not cause any health concern to the consumers.

Risk assessment of long-term dietary intakes are expressed as a percentage of the ADI for a 55-Kg person for the Far East.

Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments.

The following is an example.

Pesticide Code: 196
Name: Tebufenozide
ADI = 0.02 mg/Kg b. w.

| Crop | FFi (g/day) | MRL (mg/Kg) | FFI x MRL (mg) |
|---|---|---|---|
| Grapes | 18.00 | 0.5 | 0.009 |
| Rice, husked | 12.00 | 0.1 | 0.0012 |
| Pome Fruits | 45.00 | 1.0 | 0.0450 |
| Potato | 240.00 | 0.5 | 0.1200 |
| Walnut | 1.00 | 0.05 | 0.0001 |
| | | | Total = 0.18 |
| | | | ADI = 16.5% |

$$NEDI = \sum \frac{\text{MRL or pesticide conc.}}{\text{body weight (Kg)}} \times FFi$$

$$NEDI = \frac{0.18 \text{ mg}}{55 \text{ Kg b.w.}} = 0.0033 \text{ mg/Kg b.w.}$$

Comparison of National EDI with ADI:

$$\frac{EDI}{ADI} \times 100 = \% \text{ of the ADI} = \frac{0.0033}{0.02} \times 100 = 16.5$$

where: FFi - Food consumption
NEDI - National Estimated Dietary Intake

Interpretation:

- If the National Estimated Dietary Intake (NEDI) of residues do not exceed the Acceptable Daily Intake (ADI) for that specific pesticide - it can be concluded that the long term intake of the residues of pesticide resulting from its use is unlikely to present any public health concern.

- If the NEDI exceed the ADI, the proposed MRL may not be accepted and should be modified in such a way that it will not exceed the ADI and should not pose risk to human health.

*2. Short Term Dietary Risk Assessment*

The estimated short term dietary intake of pesticide residue is compared with its Acute Reference Dose (ARfD) in the risk assessment. Acute RfD is the estimate of the amount of a chemical residue in food, expressed on a

body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation. Regarding the acute toxicity of pesticides, short-term intakes above the ARfD are of more concern because toxicity might be observed after one or only a few doses. The short-term intake is calculated for each food separately (large portion size × highest residue × a variability factor for some cases) and compared with the ARfD.

*National Estimated Short-Term Intake (NESTI)*

There are three cases in estimating short term intake of pesticide residues:

*Case 1 - Food commodity unit weight ≤ 25 g*

$$NESTI = \frac{LP \times HR}{b.w.}$$

where : LP = Large portion consumption (97.5th percentile of eater)
HR = Highest residue found from supervised trial data

*Case 2 - Food commodity unit weight > 25 g*

- *Case 2a unit weight, edible portion (U) < LP*

$$NESTI = \frac{(U \times HR \times V) + [(LP-U) \times HR]}{b.w.}$$

where : V = Variability factor (V = 3 )
U = Unit weight in edible portion, in Kg

- *Case 2b unit weight, edible portion (U) ≥ LP*

$$NESTI = \frac{LP \times HR \times V}{b.w.}$$

*Case 3. Processed Commodity is bulked or blended; including milk*

$$NESTI = = \frac{LP \times STMR\text{-}P}{b.w.}$$

where: STMR-P = Supervised trials median residue in processed commodity

Comparison of NESTI with ARfD : $\frac{NESTI}{ARfD} \times 100$

Interpretation :

- When an estimate of short-term exposure for a pesticide residue in a food commodity exceeds the ARfD, the risk assessors examine residue data from supervised trials with alternative GAPs to compare those alternative short-term exposures with the ARfD.

- If an estimated alternative short-term exposure does not exceed the ARfD, a maximum residue level is proposed based on the alternative GAP.

- If NESTI > ARfD, the proposed MRL may not be accepted. Rather, it should be further refined using alternative GAPs, consumption data, etc.

*2.4.2.A. Establishment of MRLs*

1. MRLs are initially to be established by these Guidelines.

2. MRLs may be modified as found necessary both during and after the trial period.

3. Group MRLs will be established when sufficient data on representative crops show sufficient similarity to permit extension. Crop groups are found in Annex XI.

4. Additional crops may be added to groups either by FPA initiative or upon petition by a registrant or user. Supporting information may be submitted with any petition.

5. Additional MRLs or exemption may be established in the future by FPA on its initiative or by petition of a registrant user, importer or exporter. The petitioner must propose an MRL or an exemption and must submit data or information with the petition which:

    a. demonstrate the adequacy of the proposed level or justifies exemption;

    b. demonstrate the safety to the public health of the proposed level or exemption; and

    c. show the need for the tolerance or MRL/exemption.

6. To the extent possible, MRLs shall be consistent with those established through the Codex Alimentarius.

7. Once MRLs have been established, no registration shall be granted for a pesticide product unless its active ingredients have MRL or exemptions.

8. Violations will be dealt with as any other violation of P.D. 1144.

9. Special provisions for export: Exports must meet the MRL requirements of the importing country.

*2.4.2.B. Establishment of MRLs for New Pesticides for Use on Food Crops*

The following data or information are required for establishment of MRLs:

1. All data required for registration.

2. A suggested MRL.

3. Information or data to support the proposed MRL. These shall be one or more of the following:

   a. Valid supervised pesticide residue trials conducted in the Philippines following "FAO Manual in the Submission and Evaluation of Pesticide Residue Data for the Evaluation of Maximum Residue Levels in Food and Feed." Accepted test protocols may be found in Codex Guidance on Field Trials by Bates, or the compatible US EPA Guidelines for Residue Trials.

   b. Valid supervised pesticide residue trials conducted, following the aforementioned FAO Manual, in the country of similar climate and agricultural practices and use pattern as those of the Philippines. Bridging data in the Philippines may be required for crops which are exported or which form a large proportion of the Philippine diet.

   c. Evidence that the proposed MRL is approved by the Codex Committee on Pesticide Residue (CCPR) at Step 6 or above and has not been grossly criticized. Bridging data in the Philippines may be required.

   d. Evidence that an MRL exists in another country with supporting information to demonstrate its applicability to the Philippines. Bridging data may be needed.

4. Information on residues that are likely to be found on the commodity, as consumed.

5. Information on methods of reducing the residues on the commodity if it is found to exceed MRL.

6. An analytical method capable of detecting the residue levels in the crop at the proposed MRL.

7. Information that may be requested:

   a. Toxicology data suitable for establishing ADI or NOAEL, or

   b. An ADI established by the Codex, WHO, IPCS or a country having an FPA accepted procedure for determining ADI. A list of such countries currently includes: US, UK, Canada, Germany and France. Others may be acceptable, however, a WHO value is preferred.

   These may be requested when FPA has no valid NOAEL or ADI currently available to it through normal registration process.

8. Crop definition for analysis is the Codex definition unless a waiver is requested and obtained to deviate for the crop and MRL in question.

9. Animal feeds also require a proposed MRL and supporting data for animal products - meat, milk, eggs, etc. - which may be expected to carry over residues from feeds. This may require large animal metabolism and residue studies.

*2.4.2.C. Clearance of Inert Ingredients*

Inert ingredients may not contribute to bioefficacy but may be toxic to humans. Clearances comparable to the pesticide active ingredients are required unless an exemption from the requirement is requested and granted.

### 6.4.3 Exemption from the Requirement for MRL

An exemption from the requirement for MRL may be granted upon acceptance by FPA of evidence that a material is of such toxicological nature, that MRL is not required to protect the public health and safety. This may be demonstrated by:

1. Toxicity data developed by acceptable protocols - OECD, FAO, US-EPA, etc.

2. Evidence of limited exposure no matter how it is used due to rapid degradation.

3. Evidence of minor incremental exposure when compared to general exposure of population for all sources.

4. Being in the exempt list of pesticides “generally regarded as safe” by WHO, or by a country having an FPA-accepted system for reviewing and granting exemptions.

### 6.4.4 Petition to Change Existing MRLs

The requirements are the same as those for Establishment of MRL for new pesticide except for those data that FPA already has.

### 6.4.5 Crop Groupings

Crops have been placed in groups to facilitate the extrapolations of MRLs and reduce the time and expenses for data gathering. When MRL exists for representative crops defined for each group, they may be extended to the whole group of commodities. Crop groupings and representative crops are found in Annex XI. Petition may be made to add new crops to these groups.

### 6.4.6 Proposed MRLs for the Philippines

The new list of the proposed MRLs shall be prepared and submitted for industry review and acceptance. Once accepted, the list shall be annexed and shall form part of these Guidelines.

## 6.5 INSPECTION OF HANDLERS

Handlers (dealers, distributors, formulation plant owners, manufacturers, importers and PCOs) shall be inspected periodically without notice to determine compliance with P.D. 1144 and its applicable rules and regulations. In particular, attention shall be paid to proper storage, unregistered products, fake products, maintenance of appropriate records, and sale of restricted pesticides.

Inspection shall be scheduled on a priority basis where violations have been reported and to establishments with history of violations. Random inspection shall be made of other facilities as time permits so that they are all visited within one(1) year.

All pesticide handlers and Pest Control Operators (PCOs) must make available to FPA upon request all books and records kept as a normal part of day-to-day business and related to pesticide purchases, sales and use.

Data, which are trade secrets, commercial or financial information, shall be protected from release by FPA. In addition:

1. Those selling pesticides must keep a record of all sales of restricted pesticides including name and address of purchaser and name and quantity of restricted product. Total record of sales must equal the total purchases by seller (adjusted for inventory charges and spillage).

2. CPAs shall keep records regarding treatments with restricted pesticides. Such records may be maintained in any format and must include name and address of treated property; type of treatment performed; name and amount of pesticide used (product name, active ingredient name, Kg a.i equivalent); and the date treatment was performed. A suggested format for reporting appears as Annex XII.

## 6.6 IMPORTATION

No pesticide shall be imported into the country without the appropriate Certificate Authorizing Importation of Pesticides (CAIP) issued by FPA. Pesticide Circular No. l, Series of l981 lists the following requirements for importation of pesticides:

1. The importer must be licensed by FPA.

2. The pesticide product(s) and active ingredient(s) must bear a registration number, or covered by an appropriate Experimental Use Permit.

3. The following must be specified in the request for importation:

    a. product, specifying % purity if technical material or active ingredient if formulated product
    b. unit price

c. quantity
d. payment terms
e. country of origin
f. destination
g. carrier/vessel

4. The pro-forma invoice must be attached. This shall enable FPA to correlate the source of supply to the registration of the product.

5. The bill of lading, which verifies that the above transaction transpired at the term(s) and price(s) stated on the pro-forma invoice, must be attached to the subsequent request for importation.

All unused CAIPs must be returned to FPA at the end of each quarter.

Processing of import permits by the FPA is based on registration and licensing policies. No importation of locally produced technical grade material and its corresponding finished products is allowed by the FPA. However, the manufacturer is required to submit proof that the price of the technical material locally produced is competitive with the world market price.

Banned pesticides, if procured through importation, shall be transported back to the country of origin. This shall be certified by the Philippine consulate in the receiving country as a proof that such products really arrived there.

## 6.7 STORAGE AND DISPOSAL OF BANNED PESTICIDES

FPA shall allow six (6) months, from the date of publication of banning order, to bring the banned pesticides to centralized warehouses in the regions and finally to Metro Manila. Banned products can either be disposed by employing high temperature combustion facility or exported depending on the volume. Banned pesticides shall be transported to another country provided that the Prior Informed Consent (PIC) principle is followed and that the FPA is the lead agency to do this. Companies that sold the banned pesticides shall have the responsibility to retrieve the products.

## 6.8 DATA COLLECTION

Collection of data on importation, production, sales and poisoning cases is one of the important activities of FPA. Through issuance of CAIP for all pesticides imported into the country, FPA has acquired a built-in mechanism for collection of data on imports of technical materials and finished products. In addition, the monitoring activities provide a feed-back mechanism for reports on sales, poisoning cases, and production in formulating plants. The pesticide companies shall submit annual sales statistics including sales volume and prices for each of their products to FPA on a regular basis.

The data are summarized on an annual basis and maybe released to interested parties, subject to conditions stipulated in Section 2, Article VI of the FPA Rules and Regulations No I, Series l977 on “Protection of Trade Secrets and Other Information.”

## 6.9 TRAINING AND EDUCATION

1, FPA shall promote Agro-Medical Training in coordination with DOH specifically on the management of pesticide poisoning cases.

2. FPA shall confer with the Department of Education (DepEd) to explore the possibility of introducing the safe use of pesticides in the elementary and secondary school curricula, through incorporation in agriculture-related subjects. Likewise, FPA shall also discuss with Commission on Higher Education (CHED) the possible inclusion of pesticide poisoning management in the regular medical school curriculum

3. FPA shall establish linkage with the Local Government Units (LGUs) in training the farmers, health workers and others. Likewise, it shall assist LGUs, DA, RFUs in the establishment and operation of plant health clinics where the farmers could refer their problems and also in the conduct of training of technicians by appropriate agencies.

# *Chapter 7*

# *PENALTIES FOR VIOLATIONS*

## 7.1 PRE-REGISTRATION

Failure of the manufacturer or company to submit all the required data and information on the product to be registered and failure to follow the prescribed pre-registration procedure is a valid reason for FPA not to accept the application for product registration.

## 7.2 GROUNDS FOR REVOCATION OF LICENSE

All types of licenses issued by FPA may be revoked, cancelled or suspended on the basis of any of the following:

1. False statements in the application or any required report or record.

2. False claims in advertisement.

3. Violation of or failure to observe FPA rules and regulations.

4. Refusal to allow inspection.

5. Commission of prohibited acts under PD 1144.

**Grounds for Revocation of Accreditation of Certified Pesticide Applicators (CPAs) and License of Pest Control Operators (PCOs)**

Licenses of PCOs and/or accreditation of CPAs are subject to revocation or suspension on the basis of any of the following:

1. Any of the reasons stated above for revocation of licenses in general.

2. Acts of dishonesty, fraud or deceit.

3. Ignorance or negligence resulting in poisoning or death of his client or harm to the public by his/her direct action or through persons under his/ her supervision.

4. Application or supervision of the use of any restricted pesticide in a manner inconsistent with its labelling.

5. Non-compliance with required safety equipment and/or operation of faulty or unsafe equipment causing injury or death of the client, applicators or service technicians.

The licensee shall be notified by certified delivery, of the revocation or suspension of his/her license. He/she shall be given a hearing before FPA gives its final revocation order. Such hearing must be requested formally within ten (10) days from the receipt of notice. A PCO or CPA may be suspended pending hearing for revocation of his/her license or accreditation.

## 7.3 POST-REGISTRATION

***Product Stewardship and Responsible Care Violations.*** Any violation of the provisions of the policy guidelines on Product Stewardship and Responsible Care shall be subject to revocation and cancellation of registration permit and/or company license.

## 7.4 ENFORCEMENT OF ACTION

When violations are discovered, appropriate actions ranging from issuance of a warning letter to administrative action such as compulsion to attend seminar to imposition of fines or cancellation of product registration and/or company license will be taken. Product recall, remedial advertising and similar requirements may also be imposed.

Violations of P.D. 1144 and the corresponding rules and regulations shall be governed by the penal provisions of Sec. 3, Article VIII of the FPA Rules and Regulations No. I, Series of l977, enacted in accordance with P.D. 1144.

# *Chapter 8*

# *MISCELLANEOUS PROVISIONS AND REQUIREMENTS*

Other FPA concerns that do not fit and were not covered in the previous chapters are treated under this heading. Also, a variety of special requirements and policies that do not clearly fit into the other categories are likely to appear from time to time. These are included in this chapter.

## 8.1 STOCKS OF ANTIDOTES AND FIRST AID SUPPLIES AND EQUIPMENT FOR CERTAIN PESTICIDES

Supplies of antidotes and/or first aid supplies and equipment necessary to save the lives of poisoning victims are often unavailable in hospitals and rural health centers. In order to alleviate the problem, companies distributing Toxicity Categories I and II pesticides are required to maintain stocks of materials recommended on the label for first aid treatment. Registrants of pesticides shall also provide a stock of necessary emergency medicines including antidotes at medical facilities designated by FPA. Regular quarterly inspection of these facilities will cover this aspect. Specific conditions may form part of the registration requirement.

## 8.2 INSPECTION OF BOOKS AND RECORDS

Article VI of the FPA Rules and Regulations No. 1, Series 1977 provides:

"Section I. Books and Records, Reports

A. Books and Records - The Administrator may prescribe regulations requiring any person or handler who manufactures, formulates, prepares, compounds, repacks or processes any pesticide or other agricultural chemicals, to maintain books and records with respect to their operation and the pesticide produced as determined to be necessary for the effective enforcement of the PD 1144.

B. Reports - any person or handler, or any other person who sells or offers for sale, delivers or offers for delivery, any pesticide or other agricultural chemical subject to PD 1144 shall, upon request of any officer or employee of the FPA, duly designated by the Administrator, furnish reports on the following:

1. Quantity/volume, value of each kind of pesticide or other agricultural chemicals exported, imported, manufactured, produced, formulated, repacked, stored, delivered, distributed, or locally sold.

2. In case of importation, all records showing the delivery and movement of pesticides or other agricultural chemicals, including quantity, active ingredients, contents, letters of credit, invoices and all documents relating to the importation of such products.

3. Other pertinent data/information that may be required by the Authority.

Section 2. Protection of Trade Secrets and Other Information

A. In general - In submitting data required by PD 1144, the applicant may (1) clearly mark any portion thereof which, in his opinion, are trade secrets or commercial or financial information; and (2) submit such marked material separately from other material required to be submitted under PD 1144.

B. Disclosure - Notwithstanding any other provision of PD 1144, the Administrator shall not make public, information which, in his judgement, contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential except, when necessary to carry out the provision of PD 1144. Information relating to formulas of products acquired by authorization of PD 1144 may be revealed to any government agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

C. Disputes - If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by registered mail.

The Administrator shall not, thereafter, make available for inspection such data until thirty (30) days after receipt of the notice by the applicant or registrant may institute an action in an appropriate court for a declaratory judgement as to whether such information is subject to protection under subsection (b).

Section 3. Inspection and Establishments

In General - For the purpose of enforcing the provisions of PD 1144, officers or employees duly designated by the Administrator are authorized to enter at any time, any establishment or other place where pesticides are held for distribution or sale, for the purpose of inspecting and obtaining samples of any pesticide packaged, and labelled, and released for shipment, and samples of any container or labelling for such pesticides.

Before undertaking such inspection, the officers or employees must present appropriate credentials to the owner, operator, or any agent in charge of the establishment, or other place where pesticides are held for distribution or sale. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a report on the results of such analysis shall be furnished promptly to the owner, operator or agent in charge."

## 8.3 PROHIBITED ADVERTISING PRACTICES

Advertising shall be regulated in cooperation with the Philippine Board of Advertising (PBA). The following are regarded as prohibited practices:

1. Advertising of pesticides as “safe”, including statements such as “nonpoisonous, harmless, non toxic” with or without qualifying phrase such as “when used as directed.”

2. Showing a pesticide being used with improper protective gear or with bystanders present.

3. Including uses or other claims, which are not in the label.

4. Promoting unregistered products.

5. Advertising restricted pesticides for CPA/Institutional Use Only through journals other than those catering for such operations, unless the statement “Restricted Pesticide: For CPA/Institutional Use Only” is clearly and prominently shown.

6. False or misleading comparison with other pesticides.

7. Any false statement or misleading advertising.

The pesticide industry shall also state in their advertisement: “This is an FPA-Registered Pesticide Product, Use it strictly in accordance with its label.”

Violations of these regulations on advertising shall be sufficient cause for imposition of a P50,000.00 fine and/or suspension/cancellation of the product’s registration.

## 8.4 PESTICIDE PRICING POLICY

Section 6, III (8) of PD 1144 lays down the basic policy on pesticide pricing:

> “Should there be any extraordinary and unreasonable increases in prices, or a severe shortage in supply of pesticides, or imminent dangers of either occurrences, the FPA is empowered to impose such control as may be necessary in the public interest, including but not limited to such restrictions and controls as the imposition of price ceilings, controls on inventories, of such pesticides or raw materials thereof as may be in short supply.”

## 8.5 TECHNICAL REVIEW/EVALUATION OF REGISTERED PRODUCTS FOR POLICY ACTION

A point scoring system will be used in identifying/prioritizing compounds for review. When a registered product has been identified as a cause of concern based on reported serious damage and/or imminent hazards on public health and environment because of its use/misuse, FPA Management shall schedule the product for technical review for policy action. A set of primary (Table 2 or Table 3.1 a or b) and secondary (Section 8.5.F) criteria as described herein will be used for this purpose.

A. Preparatory Action:

1. Reasonable period of notification of product registrants of the preliminary actions and schedule of meeting(s) with them.

2. Compilation and evaluation of the consultants' reports on registration evaluation and data from post-registration monitoring activities. Data gaps shall be identified and communicated to the concerned companies.

3. Presentation by concerned company on the latest development and new information relevant to the requirement.

B. Industry Dialogue

1. Industry dialogue shall be conducted in a confidential manner. Oath of confidentiality of all parties concerned shall be signed.

2. Authorized parties in the meeting are:

   a. FPA Management, technical persons and secretariat.

   b. PPTAC members including the registration consultants who reviewed the product.

   c. Registrant represented by company management and technical persons.

3. The areas of concern of FPA shall be deliberated upon during the meeting and the identified data gap(s) shall be requested from the registrant. The registrants may express their reactions.

4. The PPTAC secretariat shall record and prepare the minutes of the meeting.

5. PPTAC submits recommendation to management. FPA Management communicates with the respective company(ies) on the areas of concern; additional data required and proposed regulatory action. Registrant officially acknowledges receipt of FPA communication and may request for further deliberations.

6. FPA notifies concerned companies of the schedule of further deliberations one month in advance if necessary.

7. Whenever necessary, public hearing may be conducted to generate more opinions as valuable inputs to policy action.

*C. Decision*

When all issues have been deliberated upon during the review and dialogue, FPA Management may make a decision or refer the matter to the FPA Board for collective deliberation and final decision.

*D. Timetable*

1. Management and PPTAC evaluation of areas of concern and product review and identification of data gaps, within three (3) months.

2. Registrant consolidation of data required for resubmission, within three (3) months or as specified by FPA.

3. In cases where data have to be generated, the concerned company and FPA Management shall discuss the time frame required for the study(ies).

4. Evaluation and deliberation on data resubmitted, within three (3) months.

*E. Records*

Records of all proceedings shall be kept under strict confidentiality by the FPA Management. Only concerned companies shall be provided with the records of the proceedings.

*F. Parameters to be used when reviewing pesticide products for policy action.*

1. Public safety is of prime importance

   a. Risk consideration to man - acute and chronic
   b. Adverse effects on non-target organisms
   c. Negative environmental impact
   d. Pesticide residues in food
   e. Disposal problem

2. Availability of suitable alternatives

   a. Bio-efficacy
   b. Cost effectiveness
   c. Production equitability and availability
   d. Ease of application

3. Special need considerations

   a. Public health needs
   b. Industry/end-user needs

4. Resource considerations

   a. Implementation
   b. Manpower needs for policy action
   c. Facilities

# *GLOSSARY OF TERMS*

**Acceptable Daily Intake (ADI) of a chemical -** is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight.

**Accredited Pesticide Dispenser (APD) -** the owner of the FPA licensed store or sales person who attended a two-day training for agro-dealers and passed the written examination.

**Accredited Professional Pesticide Adviser (APPA) -** an individual who is a graduate of a four-year college course or a holder of a two-year diploma in agriculture who has undergone the training designed for such purpose by FPA in coordination with the Weed Science Society of the Philippines (WSSP), on the Philippine Entomological Society(PAE), on the PMCP Foundation Inc.(PMCPFI), passed the accreditation examination, has taken an oath of responsibility administered for such purpose and issued an FPA accreditation card.

**Accredited Responsible Care Officer (ARCO) -** one who is issued an accreditation card after having attended the required training program; passed the examination administered for the purpose; paid the required fee and who is currently or will be proprietor/employee of agricultural store.

**Adulteration -** the production of inferior products by use of less desirable ingredients.

**Animal Feed -** harvested fodder crops, by-products of agricultural crops and other products of plant or animal origin which are used for animal feeding and which are not intended for human consumption.

**Area Distributor -** a pesticide establishment, classified by the pesticide companies as their distributor but with specific area of coverage and need not register pesticide products.

**Biorational Pesticides -** are a distinct group of pesticide, inherently different from conventional pesticides. They comprise two major categories: (1) biochemical pest control agents (e.g. pheromones, hormones, natural insect and plant growth regulators and enzymes) and (2) microbial pest control agents (e.g., microorganisms). The relationships between conventional pesticides, biological control agents, and biorational pesticides are illustrated in Figure 3. Pesticides to be included in these categories must be naturally occurring, or if the chemical is synthesized by man, then it must be structurally identical to a naturally occurring chemical. Minor differences between the stereochemical isomer ratios (found in the naturally occurring compound compared to the synthetic compound) will normally not rule out a chemical from being classified as a biorational unless an isomer is found to have toxicological properties significantly different from those of another isomer.

**Certified Pesticide Applicator (CPA) -** one who has attended a four-day training course and passed an examination administered by the FPA.

**Extraneous Residue Limit (ERL) -** a pesticide residue or a contaminant arising from environmental resources (including former agricultural uses) other than the use of a pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue or contaminant that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed. The concentration is expressed in milligrams of pesticide residue or contaminant per kilogram of the commodity.

**Faking -** unlawful manufacture of a product to misrepresent the legitimately registered one.

**Formulator -** one engaged in a series of operations in formulating the active ingredient into a final product suitable for its proper application.

**Good Agricultural Practice (GAP) -** is the officially recommended or authorized usage of pesticides under practical conditions at any stage of production, storage, transport, distribution and processing of food, agricultural commodities, and animal feed bearing in mind the variations in requirements within and between regions, which takes into account the minimum quantities necessary to achieve adequate control, applied in a manner so as to leave a residue which is the smallest amount practicable and which is toxicologically acceptable.

**Household Pesticides -** any material or mixture of substances used for the control of pests (e.g. flies, mosquitoes, cockroaches, ants, rodents) found in places of human habitation, work and recreation. They include pesticides used for the control of pests in homes, yards and gardens but exclude chemicals used in commercial agricultural production, golf courses, maintenance, pest extermination in industrial products and related uses.

**Importer/End-User -** commercial plantations which import and use the pesticides directly and private research institutions or companies that import or use pesticides for testing purposes.

**Indentor/Trader -** any person/entity who acts as an agent or representative in behalf of another or who arranges business between two or more contracting parties.

**Institution -** agricultural establishments with personnel hired to do a task. In this particular case, the task refers to the application of pesticides. Further, the term “institution” connotes the availability of medical facilities or arrangements for medical attention, and the assignment by the institution or the sub-contractor of a skilled person to supervise pesticide users.

**Limit of Determination (LOD) -** the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity, or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

**Master Instructor-Responsible Care Officer (MI-RCO)** - refers to one who has attended the FPA-CPAP Master Instructor Course and officially can act as resource person on specific pesticide topics.

**Maximum Residue Limit (MRL) -** the maximum concentration of a pesticide residue resulting from the use of a pesticide according to Good Agricultural Practice that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed, the concentration expressed in milligrams of pesticide residue per kilogram of the commodity.

**Misbranding -** the illegal use of a duly registered brand name by another entity not authorized to do so.

**Pesticides for Institutional Use Only -** are pesticides to be made available directly from the Philippine distributor solely to the institution. There will be no over-the-counter sale through the regular dealership networks.

**Pesticide Company -** any entity/partnership corporation/cooperative/local representative/local subsidiary who engages in the importation, exportation, manufacture and formulation as well as supplying pesticides.

**Pesticide Dealer -** pesticide establishments authorized by the Pesticide Companies or Distributors to retail their products. Sale is directly to end-users/farmers.

**Pesticide Distributor -** one who sells pesticides to sales outlets like dealers, traders or other distributors. It includes pesticide companies that carry their own brand names, affix their company names in the label, reprint a foreign company name in the country and those who are classified by the pesticide companies as their distributors.

**Pesticide Handlers -** exporters, importers, manufacturers, formulators, distributors, suppliers, wholesalers, dealers, repackers, commercial applicators, warehouse owners and retailers of agricultural and household pesticides.

**Pesticide Exporter -** one who exports pesticide products for commercial and other purposes.

**Pesticide Importer -** one who imports pesticide products for commercial and other purposes.

**Pesticide Manufacturer -** one engaged in a series of operations to obtain active ingredient with pesticidal properties, including extraction of pesticide active ingredients from plant materials.

**Pesticide Repacker -** any pesticide company or its duly authorized representative who transfers a formulation into marketable packagings. The new packagings may carry a different brand name from the original formulation.

**Pesticide Residue -** any specified substances in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

**Pesticide Supplier -** one who manufactures or produces pesticides outside the country, is registered in the Republic of the Philippines, and offers pesticides for sale to local distributors on a wholesale basis. This application will also include all pesticide suppliers, local representatives or suppliers' subsidiaries/promoters.

**Plant Regulators -** compounds other than nutrients which, in small amounts, promote, inhibit or otherwise modify any physiological process in plants. Among the plant regulators are the growth regulators, flowering regulators, flowering hormones, auxins and anti-auxins.

**Regulatory Method of Analysis -** a method that has been validated and can be applied using normal laboratory equipment and instrumentation to detect and determine the concentration of a pesticide residue or contaminant in a food, agricultural commodity or animal feed for purposes of determining compliance with a maximum residue limit or extraneous residue limit.

**Responsible Care Officer (RCO) -** one who had attended the required four (4) days training program; passed the examination administered for the purpose and is currently or will be employed as field personnel of pesticide companies or field officers of FPA.

**Surfactants -** to surface-active agents or materials which facilitate and accentuate emulsifying, dispensing, spreading, wetting and other surface-modifying properties of pesticide preparations. Surfactants include but are not limited to activators, adjuvants, deflocculators , detergents, dispersants, drift control agents, emulsifiers, foam suppresants, spreaders, stickers, wetting agents and others.

**Synergists -** chemicals/materials which when **combined** with other chemicals that enhance potentiation or heightens efficiency of one or more components of the mixture such that the total effect is greater than the sum of the independent effects of the components of the mixture. These include, but shall not be limited to, piperonyl butoxide, propyl isomers, sulfoxide and sesamin.

**Transformation Event –** the instance of entry, stable integration and expression of an introduced gene into a cell, which then develops into a functional organism expressing the introduced gene.

**Wood Preservatives -** compounds applied or injected to prolong the service life of structural timber as well as all wooden articles and other cellulosic materials normally used in building construction. These include but shall not be limited to salts of heavy metals, copper arsenates, pentachlorophenol, creosote, dinitrophenol, sodium pentachlorophenate, chlorinated hydrocarbon and others.

# *Annex I*

# *APPENDIX A, ANNEXES 1 AND 2 OF THE MANUAL ON THE DEVELOPMENT AND USE OF FAO SPECIFICATIONS FOR PLANT PROTECTION PRODUCTS, FIFTH EDITION*

## APPENDIX A

## REQUIREMENTS AND PROCEDURES FOR DEVELOPMENT OF FAO SPECIFICATIONS

### Annex I: MINIMUM DATA PACKAGE

*Notes:*

*(1) In general, studies which fulfill the requirements of modern national registration systems will meet the needs for the development of FAO specifications.*

*(2) In cases where technical material (TC) is not normally isolated, the data and information marked with an asterisk (*) (i.e. in paragraphs 1.4, 1.5, 1.6, 1.8, 1.9, 1.10 and section 3) may be derived from the technical concentrate (TK).*

*(3) The requirements of this Annex will apply in most cases. Exceptionally, where a proposer believes that a requirement is not appropriate to the proposed specification, or that additional information should be considered by the Group on Specifications, the proposer must submit a reasoned case to support this opinion. In such a case, further progress of the proposed specification will depend on agreement (between the Group on Specifications and the proposer) on the data required for evaluation.*

*(4) Data submitted will be maintained on confidential files by FAO, for future reference as required.*

**1. Data Requirements for Technical Materials (TC)**

1.1 Identity of the active ingredient:
- ISO English common name (and its status)
- Chemical name (IUPAC and CA)
- CAS® No.
- CIPAC No.
- Structural formula
- Molecular formula
- Molecular mass

1.2 Physico-chemical properties of the pure active ingredient:
- Vapour pressure
- Melting point, boiling point or temperature of decomposition
- Solubility in water
- Octanol: water partition coefficient
- Hydrolysis/ degradation characteristics

1.3 Outline of the manufacturing process

1.4 Minimum active ingredient content*

1.5 Maximum limits for the content of impurities present at or above 1 g/Kg*, supported by batch analytical data (5 minimum). Relevant impurities (see glossary) in this category must be identified.

*Note to paragraphs 1.4 to 1.5:*

*The unidentified fraction of the technical material* must not exceed 20 g/Kg.*

1.6 Maximum limits for relevant impurities present at < 1 g/Kg*

1.7 Information on relevant impurities, with explanations of the effects observed (for example, toxicological effects, or effects on the stability of the active ingredient). Limits set by FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and/or registration authorities should accompany this information, identifying the authority responsible for setting the limit.

*Note to paragraphs 1.6 and 1.7:*

*Relevant impurities must be included in the specification but other impurities (including isomers, etc., of low activity) must not be included.*

1.8 Nominal content (g/Kg) of compounds intentionally added to the technical material* (e.g. stabilizers)

1.9 Toxicological summaries:

1.9.1 Toxicological profile of the technical material* based on acute oral, dermal and inhalation toxicity; skin and eye irritation, skin sensitization.

1.9.2 Toxicological profile of the technical material* based on repeated administration (from subacute to chronic) and studies such as reproductive and developmental toxicity, genotoxicity, carcinogenicity, etc.

1.9.3 Ecotoxicological profile of the technical material* based on toxicity to aquatic and terrestrial organisms (e.g. fish, *Daphnia*, algae, birds, bees), as appropriate to intended use.

1.10 Other information:

1.10.1 UN International Programme on Chemical Safety (IPCS) hazard classification.

1.10.2 References to JMPR evaluation on toxicology, environmental fate and ecotoxicology should be given, where these exist. The toxicological and ecotoxicological data supplied to the JMPR for evaluation should be cross-referenced to the batch analysis data of the technical materials used in those studies.

1.10.3 A letter of authorization granting competent authorities access to registration data on behalf of FAO. This is to enable such authorities to assess whether or not:

(i) the technical material for which an FAO specification is proposed is equivalent to that registered by the authority, as assessed by a comparison between the data submitted to FAO and those submitted for registration; or

(ii) their decision that technical materials from different manufacturers are equivalent, based on data similar to those provided to FAO.

## 2. Data requirements for formulations

2.1 Main formulation types available.

2.2 Main countries where these formulations are registered and sold.

2.3 Physico-chemical properties, as required by sections 4 and 5 of this Manual.

## 3. Methods for analysis and testing*

3.1 Methods for identity testing

3.2 Methods for determination of active ingredient content

3.3 Methods of analysis of impurities in the technical material*

3.4 Test methods for physico-chemical properties

*Notes to section 3:*

*(1) The methods used to generate data submitted in fulfillment of the requirements of paragraphs 1.4, 1.5, 1.6 and 2.3 of this Annex must also be identified, if they differ from those given under the requirements of section 3 and intended for checking compliance with the specification.*

*(2) Methods for determination of non-relevant impurities may be given in outline but, in cases of doubt, additional information may be required to support the validity of the method. Methods required to assess compliance with a specification must be independently validated and must be published or otherwise made publicly available. Where independent validation (collaborative study of the method of analysis for the active ingredient, or peer validation of a method for a relevant impurity) is in progress at the date of submitting the proposal, the estimated date of completion must be provided. Specifications will not normally be adopted and published prior to the completion of validation of methods and, if the validation is unlikely to be completed before the next informal meeting of the Group, consideration of the proposal may be deferred.*

## APPENDIX A

## REQUIREMENTS AND PROCEDURES FOR DEVELOPMENT OF FAO SPECIFICATIONS

### Annex 2: PROCESS FOR DETERMINATION OF EQUIVALENCE OF TECHNICAL MATERIALS (TC and TK)

*Notes:*

*(1) In cases where the technical material (TC) is not normally isolated, the data and information requirements marked with an asterisk (*) may be derived from the technical concentrate (TK). However, data submitted for the determination of equivalence are expected to correspond to the same form (i.e. TC or TK) of the technical active ingredient upon which the reference specification is based.*

*(2) The requirements of this Annex will apply in most cases. Exceptionally, where a proposer believes that a requirement is not appropriate to the proposed extension of specification, or that additional information should be considered by the Group on Specifications, the proposer must submit a reasoned case to support this opinion. In such case, further progress of the proposed specification will depend on agreement (between the Group on Specifications and the proposer) on the data required for evaluation.*

*(3) Data submitted will be maintained on confidential files by FAO for future reference, if required.*

**1. Data Requirements for the Determination of Equivalence**

1.1 Data requirements for technical materials* include the information required in paragraphs 1.1 to 1.7, 1.9.1, 1.10 and sections 2 and 3 of Appendix A, Annex 1.

1.2 Additional toxicological summaries:

The following additional information may be required, in cases where the equivalence cannot be determined from the data required by paragraph 1.1

1.2.1 Toxicological profile* corresponding to that of Appendix A, Annex 1, paragraph 1.9.2

1.2.2 Ecotoxicological profile* corresponding to that of Appendix A, Annex 1, paragraph 1.9.3.

**2. Determination of Equivalence**

2.1 Technical materials for different manufacturers of manufacturing processes are deemed to be equivalent if:

2.1.1 The materials meet the requirements of the FAO specifications; and

2.1.2 Assessments of the manufacturing process used and the impurity profile (together with assessments of the toxicological/ ecotoxicological profiles, if necessary) have been carried out with the result that the profiles meet the requirements of sections 2.3, 2.4 and 2.5 of this Annex.

2.2 Where a producer changes the manufacturing process for a technical active ingredient which has previously been evaluated and included in the reference specification, equivalence may be determined on the basis of paragraphs 2.1.1 and 2.1.2 of this Annex.

2.3 Equivalence of the impurity profile of a technical material*

2.3.1 Where the maximum levels of non-relevant impurities are not increased by more than 50% (relative to the maximum level in the reference profile), or the absolute level is not increased by more than 3 g/Kg (whichever represents the greater increase), and there are no new relevant impurities, the technical materials* will normally be considered sufficiently similar as to be equivalent.

2.3.2 Where these differences in maximum impurity concentration are exceeded, the proposer will be asked to provide a reasoned case, with supporting data as required, as to why these particular impurities remain “non-relevant” and the technical material* is equivalent. The Group on Specifications will evaluate the case to decide whether or not the technical material is equivalent.

2.3.3 Where new impurities are present at ≥1 g/Kg, the proposer will be asked to provide a reasoned case, with supporting data as required, as to why these impurities are “non-relevant” and the technical material* is equivalent. The Group on Specifications will evaluate whether or not the technical material* is equivalent.

2.3.4 Where relevant impurities are increased in maximum concentration, and/or where new relevant impurities are present, additional toxicological and/or ecotoxicological data will be required, as described in Appendix A, Annex 1, paragraphs 1.9.2 and 1.9.3

2.4 Equivalence of the toxicological profiles of a technical material*

2.4.1 The toxicological profile will be considered equivalent to that of the reference profile, where the data required by paragraph 1.1 of this Annex (referring to the requirements of Appendix A, Annex 1, paragraph 1.9.1) do not differ by more than a factor of 2 compared to the reference profile (or by a factor greater than that of the appropriate dosage increments, if more than 2).

2.4.2 Where necessary (see paragraph 1.2 of this Annex), additional toxicological data (see paragraph 1.2.1 of this Annex) will be assessed by the criterion applied in paragraph 2.4.1. of this Annex, provided that, where appropriate, the organs affected are the same. The “no observable effect levels” (NOELs) or “no observable adverse effect levels” (NOAELs) should not differ by more than the difference in the dose levels used. There should be no change in the assessment in those studies which produce either positive or negative results.

2.5 Ecotoxicological profiles for the technical materials (as appropriate to the intended use of the active ingredient)

Where required (see section 1.2 of this Annex), the ecotoxicological profile (paragraph 1.2.2 of this Annex) will be considered equivalent to that of the reference profile if the data do not differ by more than a factor of 5 compared to the reference profile (or by a factor more than that of the appropriate dosage increments, if greater than 5), when determined using the same species.

*Note to paragraph 2.3.1, 2.4.1, 2.4.2 and 2.5:*

*Reference profiles are defined by the information provided for the reference specification, according to the requirements of paragraphs 1.4, 1.5, 1.6, 1.8 and 1.9 of Annex 1, Appendix A.*

2.6 Where a technical material* proposed for inclusion in an existing specification does not comply strictly with the tests for equivalence given in this Annex, but it is otherwise considered by the Group on Specifications to be of acceptable or improved quality, a modification of the existing specification will be considered, according to the procedure outlined in Appendix A, Annex 4, Scenario 2, Case C. This procedure may follow evaluation of the data required under paragraphs 1.1 and/ or 1.2 of this Annex.

# *Annex II*

# *FAO SPECIFICATION (Sample)*

INFORMATION

| | |
|---|---|
| COMMON NAME: | Parathion (ISO) |
| EMPIRICAL FORMULA: | $C_{10}H_{14}NO_5PS$ |
| RMM: | 291.3 |
| CAS REGISTRY NUMBER: | 56-38-2 |
| CIPAC CODE NUMBER: | 10.b |

CHEMICAL NAME:

0,0-diethyl 0-4-nitrophenyl phosphorothioate (IUPAC)
0,0-diethyl 0-(4-nitrophenyl) phosphorothioate (CA)

**PARATHION TECHNICAL**
FAO Specification 10.b/TC/S (1989)

## 1 DESCRIPTION

The material shall consist of parathion together with related manufacturing impurities and shall be a brown liquid with a garlic-like odour free from visible extraneous matter and added modifying agents.

## 2 ACTIVE INGREDIENT

### 2.1 Identity tests

(CIPAC 1B, 10.b/TC/(M.1)/2, p.1875 and -/(M.2)/2, p.1876) (Note 1).

Where the identity of the active ingredient is in doubt, then it shall comply with at least one additional test.

### 2.2 Parathion

(CIPAC 1B, 10.b/TC/(M.1)/3, p.1875 or -/(M.2)/3, p.1877) (Note 2).

The parathion content shall be declared (not less than 950 g/kg) and, when determined, the content obtained shall not differ from that declared by more than +/- 20 g.

## 3 IMPURITIES

**Water**

(MT 30.1, CIPAC 1, p.897)

Maximum: 1 g/kg

## 4 PHYSICAL PROPERTIES

**Acidity**
(31.1.1, CIPAC 1, p.903)

Maximum: 3 g/kg calculated as $H_2SO_4$

---

Note 1. Alternatively, the method 10.b/1/M41.3, CIPAC 1, p.555 may be used.

Note 2. Alternatively, the method 10.b/1/M41.2, CIPAC 1, p.551 may be used.

# PARATHION WETTABLE POWDERS

FAO Specification 10.b/WP/S (1989)

## 1 DESCRIPTION

The material shall consist of a homogeneous mixture of technical parathion [complying with the requirements of FAO Specification 10.b/TC/S (1989)] together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

## 2 ACTIVE INGREDIENT

**Identity Tests**

(CIPAC 1, 10.b/3/M/1.4, p.558)

Where the identity of the active ingredient is in doubt, then the isolated active ingredient shall comply with at least one additional test.

**Parathion**

(CIPAC 1, 10.b/3/M/1.2, p.558)

The parathion content shall be declared (q/kg) and, when determined, the content obtained shall not differ from that declared by more than the following amounts:

| Declared Content | Permitted Tolerance |
|---|---|
| up to 100 g/kg | +/- 10% of the declared content |
| 100 to 250 g/kg | +/- 6% of the declared content |
| 250 to 400 g/kg | +/- 5% of the declared content |
| above 400 g/kg | +/- 20 g. |

## 3 PHYSICAL PROPERTIES

### 3.1 Acidity or alkalinity

(MT 31.1.2, CIPAC 1, p.903)

Maximum acidity: 5 g/kg calculated as $H_2SO_4$
Maximum alkalinity: 2 g/kg calculated as NaOH

### 3.2 Wet Sieve Test

(MT 59.3. CIPAC 1, p.981)

Maximum: 2% retained on a 75 µm test sieve

### 3.3 Suspensibility

(CIPAC 1, 10.b/3/M/1.6, p.559) (Notes 1 and 2)

A minimum of 60% of the parathion content found under .2.2 shall be in suspension after 30 minutes in CIPAC Standard Water C. (Notes 1 and 2).

Alternatively, if the buyer requires other CIPAC Standard Waters to be used, then this shall be specified when ordering.

**3.4 Persistent foam**
(MT 47, CIPAC 1, p.954) (Note 3)

Maximum: 25 ml after 1 minute.

**3.5 Wetting of the product**
(MT 53.3.1, CIPAC 1, p.967)

The product shall be completely wetted in 1 minute without swirling.

## 4 STORAGE STABILITY

**4.1 Stability at 54°C**
(MT 46.1.1, CIPAC 1, p.951)

After storage at 54 +/- 2°C for 14 days, the product shall continue to comply with .2.2, .3.1, .3.2 and .3.5.

---

Note 1. The product should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in the method MT 15.1, CIPAC 1, p.861.

Note 2. This test will normally only be carried out after the heat stability test .4.1.

Note 3. The amount of sample to be used in the test should be specified.

## PARATHION EMULSIFIABLE CONCENTRATES

FAO Specification 10.b/EC/S (1989)

## 1 DESCRIPTION

The material shall consist of technical parathion [complying with the requirements of FAO Specification 10.b/TC/S (1989)] dissolved in suitable solvents with any other necessary formulants. It shall be in the form of a stable liquid, free from visible suspended matter and sediment.

## 2 ACTIVE INGREDIENT

### 2.1 Identity tests

(CIPAC 1B, 10.b/EC/(M.1)/2, P. 1878 and -/(M.2)/2, P. 1878) (Note 1)

Where the identity of the active ingredient is in doubt, then the isolated active ingredient shall comply with at least one additional test.

### 2.2 Parathion

(CIPAC 1B, 10.b/EC/(M.1)/3, p.1878 o -/(M.2)/3, P. 1878 (Note 2)

The parathion content shall be declared (g/kg or g/1 at 20°C, (Note 3) and when determined, the content obtained shall not differ from that declared by more than the following amounts:

| Declared content | Permitted tolerance |
|---|---|
| up to 500 g/kg or g/l | +/- 5% of the declared content |
| above 500 g/kg or g/l | +/- 25 g. |

## 3 IMPURITIES

### 3.1 Water

(MT 30.1, CIPAC 1, p.897 or MT 30.2, p.899)

Maximum: 2 g/kg

## 4 PHYSICAL PROPERTIES

### 4.1 Acidity or Alkalinity

(MT 31.1.3, CIPAC 1, p.904 or 31.2.3, p.905)

Maximum acidity: 3 g/kg calculated as $H_2SO_4$
Maximum alkalinity: 1 g/kg calculated as NaOH

### 4.2 Emulsion stability and re-emulsification

(MT 36.1.1, CIPAC 1, p. 910)

After the heat stability test (5.2), the product, when diluted at 30°C, (Note 4) with CIPAC Standard Waters A and C, shall comply with the following:

| Time after dilution | Limits of stability |
|---|---|
| 0 h | Initial emulsification complete |
| 0.5 h | 'Cream', maximum: 2 ml |
| 2.0 h | 'Cream', maximum: 4 ml |
| | 'Free oil', nil |
| 24 h (Note 5) | Re-emulsification complete |
| 24.5 h (Note 5) | 'Cream', max: 4 ml |
| | 'Free oil', max: 0.5 ml |

In special cases, a test using CIPAC Standard Waters A and C before the heat stability test may be necessary.

Alternatively, if the buyer requires other CIPAC Standard waters to be used, then this shall be specified when ordering.

**4.3 Flash point**
(MT 12, CIPAC 1, p.846)

If required, the flash point of the product shall not be lower than the minimum declared flash point. A closed cup method shall be used and the method stated (Note 6).

## 5 STORAGE STABILITY

**5.1 Stability at O°C**
(MT 39.1, CIPAC 1, p.930)

After storage at 0 +/- 1°C for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.3 ml.

**5.2 Stability at 54°C**
(MT 46.1.3, CIPAC 1, p.952)

After storage at 54 +/- 2°C for 14 days, the product shall continue to comply with 2.2 and 4.1

---

Note 1. Alternatively, the method 10.b/5/M/I.4, CIPAC I, p.565 may be used.

Note 2. Alternatively, the method 10.b/5/M/1.3, CIPAC 1, p.563 may be used.

Note 3. If the buyer requires both g/kg and g/l at 20°C, then in case of dispute, the analytical result shall be calculated as g/kg.

Note 4. Unless another temperature is specified.

Note 5. These tests need only be carried out in case of doubt as to the emulsion stability result of the 2 hour test.

Note 6. Attention is drawn to the appropriate national and international regulations on handling and transport of flammable materials.

# *Annex III*

# *FPA BIOEFFICACY PROTOCOL*

# BIOLOGICAL EFFICACY TEST PROTOCOLS

## I. INTRODUCTION

Adequate data to support claims on the label for effectiveness of a pesticide against selected pest species should be provided by the registrant as an integral part of registration. Such efficacy data should comply with the basic requirements specified in these guidelines and should be generated from field trials under practical conditions of use. The trials should be conducted in accordance with the test protocols prescribed herein.

Although it is preferred that efficacy trials be conducted in the Philippines, relevant data from other countries with similar climatic and pest conditions shall be accepted for registration purposes, provided these data are obtained following FPA prescribed test protocols. Moreover, company in-house data will be accepted as supporting documents only and cannot be used as primary basis for registration.

The prescribed test protocols are designed to facilitate transportability of efficacy data and to provide a uniform, simplified format with built-in advantages in record keeping, reporting of results and evaluation of data. These bioefficacy test protocols are intended as guide to researchers and registrants and adherence should be to the principles of validity, randomness and lack of experimental bias rather than to any rigid set of requirements. Under complex situations and justifiable circumstances, procedural changes may be considered by FPA.

The specific protocols outlined herein cover trials on rice, corn, vegetables, turf, and plantation crops, such as banana and pineapple. A general requirement for household bioefficacy trials is also included. These are designed for FPA registration purposes. Efficacy data obtained from test protocols for other crops not included in these guidelines shall be accepted provided that these were granted EUP following the official procedures prescribed by FPA.

## II. GENERAL REQUIREMENTS

A. Experimental designs (any of the following depending on objectives)

1. Randomized Complete Block Design (RCBD)
2. Latin Square (LS)
3. Split-plot design
4. Factorial (for rodenticides)

B. Experimental data not older than three (3) years.

C. Statistical analysis and appropriate tests of means.

D. Data should be generated from at least two (2) season trials, preferably wet, for rice and corn, two (2) regular cropping seasons for all other crops and in exceptional cases, same season but from two (2) locations with different climatic conditions.

E. Additional information – amount (Kg a.i. per hectare) and timing of application of standard pesticides.

F. For granular formulation or sprayables to be applied as soil surface treatment, assessment of soil fauna before and after treatment is a must.

G. Effects on beneficials (pollinators and natural enemies) and other non-target species should always form part of the data to be generated.

H. Adequate infestation level as indicated by population or damage level in the unprotected control plots.

I. For vegetables and other upland crops, a bigger plot size is recommended (at least 40 $m^2$). Lowland rice experiments can be done at a minimum lot size of 20 $m^2$ per plot per treatment. Minimum number of replication should be at least three (3) replicates.

J. Phytotoxicity evaluation should be done following crop injury rating for herbicide on V.B.2.

## III. REQUIREMENTS FOR SPECIFIC CROPS

### *Specific Requirements for Rice*

*A.* *Insecticides*

| | |
|---|---|
| 1. Number of Trials | |
| a. Number of Seasons | 1 preferably wet |
| b. Number of Locations | 2 different climatic conditions |
| c. Number of Replications | 3 (preferably 4 to have a fall back set) |
| 2. Experimental Design | RCBD or LSD as appropriate |
| 3. Plot Size | Minimum of 20 $m^2$ (4m x 5m) |
| 4. Adequate Infestation Level | Adequate insect infestation of at least 10%. Artificial infestation may be introduced when necessary. |
| 5. Reference Plot | a. Untreated control plots<br>b. Reference treatment, currently registered similar product |

6. Method of Assessment

a. Phytotoxicity assessment to be taken 3 to7 days after treatment following the crop injury rating scale for herbicide (V.B.2).

b. Bioefficacy Assessment

The primary basis of effectiveness should be population count before and after treatment. In cases where population is difficult to take, damage rating may be used to measure treatment effects but should be done at appropriate time to really measure the effects of the treatments. Post treatment counts should be based on company recommended re-entry period after treatment.

b.1. Rice Whorl Maggot

Get percent leaf damage per hill based on the two (2) youngest leaves per plant. Data should be taken from at least 20 sample plants per plot or treatment and replicated at least 3 times.

b.2. Green Leafhoppers

b.2.1. Actual counts before and after treatment

- Net sweep for adults covering the front 180 degrees of the operator. Then count the number per 10-20 sweeps in each plot.
- Tap the tillers over a pan with water to collect the nymphs and count the actual number.

b.2.2. Estimating virus infection

- Sample at least 9 $m^2$ (3m x 3m) quadrat and count the infected hills.
- Compute for percent virus infected plants per plot using the following formula:

$$\% \text{ virus infection} = \frac{\text{no. of infected hills per quadrat}}{\text{total no. of hills per quadrat}} \times 100$$

b.3. Brown Planthopper

b.3.1. Do actual counts before and after treatment or do sweep net sampling as indicated for GLH.

- Compute for percent virus infected plants per plot following the formula for GLH.

b.4. Stemborer

b.4.1. Actual Population Counts

- This is relatively difficult to do but can be done through destructive sampling of plants within the plots. Take at least 20 tillers per plot per replication. Dissect and count the number of larva present per infested tiller. Estimate of damage is the more convenient measure of bioefficacy.

b.4.2. Estimate of Damage

- Estimate percent damage in the middle of a 9-m² sample area using the formula:

$$\% \text{ damage} = \frac{\text{no. of damaged tillers or panicles}}{\text{no. of sampled tillers or panicles}} \times 100$$

- Deadheart is assessed twice at 35 and 50 days after transplanting (Growth stage 2) while whiteheads at about 10 days before harvest (Growth stage 9).

b.5. Leaf Folder

b.5.1. Actual Population Counts

- Sample and open 50 folded leaves within the 9-m² quadrat and record the number of larva present. Counting should be done at vegetative stage (maximum tillering) and flag leaf stages when leaf folders are generally abundant in the field.

b.5.2 Estimate of Damage

$$\% \text{ Leaf folder damage (hills or tillers)} = \frac{\text{no. of hills w/ leaf folder damaged tillers}}{\text{total no. of hills}} \times 100$$

b.6. Rice Caseworm

- Do actual counts of larva in 10 plants per plot 1 day before and 3-7 days after treatment. Sample at least 20 plants per plot.
- Count the number of damaged hills and based on the actual number of hills, compute the percent damage.

c. Yield assessment is the same as in herbicide for rice (III.C.6.d)

*B. <u>Fungicides</u>*

1. Number of Trials
   a. Number of Seasons — 1 preferably wet
   b. Number of Locations — 2 different climatic conditions
   c. Number of Replications — 3 - 4

2. Experimental Design — RCBD, split plot

3. Plot Size — Minimum of 20 $m^2$ (4m x 5m)

4. Adequate Infestation Level — Natural disease infection of at least 10% in the control plot.

5. Reference Plot
   a. Untreated control plots
   b. Reference treatments:
      Currently registered products against the specific disease to be tested; e.g. Benomyl for rice blast; Iprodione for sheath blight, etc.

6. Method of Assessment

   a. Phytotoxicity, assessment to be taken 10-15 days after treatment following crop injury rating scale for herbicide (V.B.2).

   b. Bioefficacy Assessment

      b.1. Rice blast

         b.1.1. Foliar. Take 20 sample hills from 5 center rows randomly taken and determine average % leaf area infected following the rating scale (V.A.1.a).

         b.1.2. Neck and Node. Take 20 sample hills from 5 center rows at random and determine % infected plants (V.A.1.b).

      b.2. Sheath blight

         Take 20 sample hills from 5 center rows at random and determine the average sheath and leaf infection following the rating scale (V.A.2).

      b.3. Sheath rot

         Take 20 sample hills from 5 center rows at random and determine the average infected tillers following the rating scale (V.A.3).

b.4. Cercospora and Helminthosporium Spot

Take 20 sample hills from 5 center rows at random and determine the average % leaf area infected following the rating scale (V.A.4).

c. Reading to be taken twice during growth stage indicated in the rating scale (Appended).

d. Yield assessment is the same as in herbicide for rice.

C. *Herbicides*

1. Number of Trials
   a. Number of Seasons — 2 (1 wet and 1 dry)
      For rice grown only in one season,
      e.g. in Kabsaka - 1 season
   b. Number of Locations — 3 different geographic areas (with different climatic conditions)
   c. Number of Replications — 4

2. Experimental Design — RCBD or split plot

3. Plot Size — Minimum of 20 $m^2$ (4m x 5m)

4. Adequate Infestation Level — Natural weed infestation of at least 25% ground cover in the unweeded plot at 15-40 days after transplanting (DAT) or after direct seeding.

5. Reference Plot
   a. Control plots
      1. Unweeded control
      2. Handweeded control, 2-3x within 40 DAT (not applicable on direct seeded rice) or weed-free control (4-5x handweeding)

   b. Reference treatments:
      For Grasses - Butachlor, Thiobencarb, 2,4-D (pre-emergence), Oxadiazon, and/or any currently registered similar herbicides
      Broadleaves - 2,4-D (post-emergence) and/or any currently registered similar herbicides
      Mixed Populations of annual grasses, broadleaves, sedges - Butachlor + 2,4-D or any currently registered similar herbicides.

6. Method of Assessment

   a. Crop injury and weed control rating by species to be taken 1-3 weeks after treatment using the rating scale (V.B.2 and V.B.1).

b. Weed count and weed weight(dry or fresh weight) by species 40 days after transplanting/direct seeding taken once per plot. Use a 50 cm x 50 cm quadrat per plot.

c. Take 5 hills sample per plot at 45 days after transplanting/direct seeding and count the number of tillers.

d. Grain yield. For transplanted rice sample 5 center rows in the plot. For direct seeded rice sample 3 m x 4 m center area in the plot. Express yield in Kg/ha.

### *Specific Requirements for Corn*

*A. <u>Insecticides</u>*

1. Number of Trials
   a. Number of Seasons — 1 preferably wet
   b. Number of Locations — 2 different climatic regions/areas
   c. Number of Replications — Minimum of 3 (preferably 4)
2. Experimental Design — RCBD or LSD
3. Plot Size — 30 $m^2$ (3m x 10m)
4. Adequate Infestation Level — At least 10% infestation in the unprotected control plot.
5. Reference Plot
   a. Untreated control plots
   b. Positive control – use any currently registered similar insecticides.
6. Method of Assessment

   a. Phytotoxicity rating following crop injury rating for herbicides (V.B.2).

   b. Bioefficacy Assessment

      b.1. Corn Seedling Maggots

      Sample 9-$m^2$ quadrat per replication. Count the damaged seedlings (indicated by deadhearts) and compute for percentage damaged seedlings at 1-2 weeks after emergence.

      b.2. Corn Earworm

      Assess damage at late silking stage (before and after treatment) by taking the number of damaged ears.

$$\textbf{\textit{\% damaged ear}} = \frac{\text{No. of damaged ears}}{\text{total no. of ears sampled}} \textbf{\textit{ x 100}}$$

      For actual counts, examine at least 20 ears and count number of larvae.

Actual corn earworm count is expressed in terms of average number of worms per plot per replication.

b.3. Corn Borers

Corn borer counts maybe done at least twice and one(1) final damage assessment after harvest.

First count is recommended at whorl stage. Count larva in at least 20 sample plants before and after treatment (closest to whorl stage). Second counting can be done at application closest to tasselling stage. Randomly sample (destructive sampling) 20 tassels per treatment and examine for presence of corn borer larva.

Final damage rating is done by measuring the borer larval tunnels by splicing the stalks (at least 10 sample plants per treatment per replication) and counting and measuring the tunnels within the plant. Express data in terms of mean number of larval tunnels per plant and mean length (cm) of tunnels.

c. Yield Assessment

Take yield of the whole plant and express yield in terms of Kg/ha (grain or green corn). For green corn, number of marketable and non-marketable ears should be reflected as final bioefficacy parameter.

*B.* *<u>Fungicides</u>*

| | | |
|---|---|---|
| 1. | Number of Trials | |
| | a. Number of Seasons | 1 preferably wet |
| | b. Number of Locations | 2 |
| | c. Number of Replications | 3 - 4 |
| 2. | Experimental Design | RCBD or split plot |
| 3. | Plot Size | 30 $m^2$ |
| 4. | Adequate Infestation Level | Natural disease infection of at least 10% in the untreated control. Point source inoculations if necessary. |
| 5. | Reference Plot | a. Untreated control plots<br>b. Reference treatments:<br>Seed dressing - Metalaxyl for downy mildew, TMTD as general seed protectant |

6. Method of Assessment

a. Phytotoxicity rating following the crop injury rating for herbicides (V.B.2).

b. Bioefficacy Assessment

Sample plants per plot for observation should not be less than 30.

b.1. Downy Mildew

Compute for the percentage of infected plants or disease incidence (V.A.5b) using the formula: Number of infected plants divided by total number of samples x 100.

b.2. Other fungal diseases (leaf spots, rusts, blights)

Take the percent leaf area following the rating scale (V.A.5a) and compute for % disease severity using formula V.A.1a.

c. Get the actual yield from the whole plot converted to Kg/ha.

*C. <u>Herbicides</u>*

1. Number of Trials
   a. Number of Seasons — 2 (wet and dry)
   b. Number of Locations — 2 different climatic areas/regions
   c. Number of Replications — 4

2. Experimental Design — RCBD or split plot

3. Plot Size — 30 $m^2$

4. Adequate Infestation Level — Natural weed infestation of at least 25% ground cover in the unweeded plot at 15-40 days after planting.

5. Reference Plot
   a. Control plots
      1. Unweeded control
      2. Handweeded control, 2-3x within 40 days after planting or weed-free control (4-5x handweeding)
   b. Reference treatments:
      For annual grasses & broadleaves (*Excluding Rottboellia*) - Atrazine and/or any currently registered similar herbicides
      For broadleaves & sedges -MCPA, 2,4-D (post-emergence) and/or any currently registered similar herbicides
      For annual grasses including Aguingay (*Rottboellia*) - Pendimethalin (pre-emergence) and/or any currently registered similar herbicides

6. Method of Assessment

   a. Take weed control rating by species and crop injury rating 1-3 weeks after herbicides treatment using the rating scale (V.B.1 and V.B.2).

   b. Take weed counts and weed weights(fresh or dry weights) by species from 50 cm x 50 cm quadrat per plot at 4-6 weeks after planting.

c. Take the yield from the whole plot (excluding area sampled for weeds) transformed to Kg/Ha.

### *Specific Requirements for Vegetables*

A. *Insecticide*

1. Crucifers - Pechay and Cabbage

In general, insect pests seriously damaging crucifers are mostly under the *Lepidoptera* group (cutworm and diamond back moth) and occasionally cabbage worm. These insects are also observed throughout the crop growing stage.

Plot size should be at least 40 $m^2$ (8m x 5m). Sampling should be within the middle row plants to prevent border effects (drift from adjacent treatments). If trials are done in farmer's field where strips are narrow, efforts should be done to prevent treatment drift by deliberate use of barriers like plywood or sackcloth during actual spraying.

Insect counts (pests and beneficial organisms) are done 1 day before and 3-5 days after treatment (based on company suggested re-entry period).

Harvest data should include weight or number of marketable and non-marketable product.

2. For Legumes (particularly aphids, leafhoppers, thrips, mites and pod borers)

Arthropod monitoring should be done 1 day before and 3 days after spraying at a time not later than 10:00 in the morning or not earlier than 4:00 in the afternoon, in all plots, including the untreated plots.

Determine the extent of beanfly infestation by dissecting 20 plants per plot at 21 days after emergence and counting the number of larvae and pupae. In case the actual counts before and after treatment is desired, sample 20 seedlings before and after treatment and dissect the plants. Record the actual larval/pupal counts.

The number of leafhopper, thrips and mites should be determined from 3 selected trifoliate leaves, representing the upper, middle and lower foliage of 5 sample plants per plot.

The number of leaves per canopy level of each of the 5 randomly selected plants per treatment should be recorded at each monitoring date.

Count the number of aphid colonies in 3 youngest trifoliate leaves of a stalk of 10 plant samples in a plot. Bioefficacy is expressed in terms of mean number of aphid colonies per plant as well as % aphid infested plants. Determine the infestation level using the following formula:

$$\% \text{ Infestation} = \frac{\text{Total no. of infested plants}}{\text{Total number of plants}} \times 100$$

Observe the five youngest trifoliate leaves per 20 sample plants per plot and count the number of larvae and pupae of leafminers during the regular arthropod monitoring schedule.

Finally, for pod borer evaluation, at least 3 sampling dates are required (at flowering stage, at 2nd and 4th priming). Note that ideally, insect counts should be done before and after treatment. However, these may build-up so much data that may lead to difficulty in analysis. Thus, a minimum of 3 assessments for pod borer is acceptable. It is important that the level of infestation in the unprotected control plot is relatively high. Since leafhoppers and thrips can be very damaging at earlier crop stage, it is recommended that protection against these insects be done before the onset of flowering but without effects on the pod borer population.

Sample 50 flowers within the plot and dissect to count the number of pod borer larvae. For the pod borers on pods, take the harvest from 50 plants within the middle 2 rows, weigh and count the number of undamaged and damaged pods. Compute for percent damaged pods. Assess level of pod infestation by taking at least 20 damaged pods and split to expose the seeds and count the number of larva present in the pod. Compute for mean number of larvae per pod.

3. Eggplants (particularly aphids, leafhoppers, leafminers and shoot and fruit borers)

Arthropod monitoring should be done 1 day before and 3 days after spraying at a time not later than 10:00 in the morning and not earlier than 4:00 in the afternoon, in all plots, including the untreated ones.

Determine the number of leafhopper, thrips and mites from 3 randomly selected leaves, representing the upper, middle and lower foliage of 10 sample plants per plot. Use the same number and site of leaves in assessing aphid infestation. The aphid units should be expressed in colonies per plant. Determine percent infestation using the following formula:

$$\% \text{ Infestation} = \frac{\text{Total no. of infested plants}}{\text{Total no. of plants}} \times 100$$

The number of insects (colonies for aphids, actual number for thrips and mites) per plant of 5 randomly selected plants per treatment should be recorded at each monitoring data.

Damage assessment for leaf hopper is done at least once (when damage difference among treatments is obvious) by visual rating of the plot using the following rating scale:

| SCALE | DESCRIPTION |
|---|---|
| 1 | No damage or only few lower leaves turning yellow due to leafhopper feeding |
| 3 | About 25% of mature leaves turning yellow |
| 6 | About 50% of mature leaves turning yellow |
| 7 | About 75% of mature leaves turning yellow |
| 10 | All leaves yellowing and cupping due to leafhopper damage |

Assessment for shoot and fruit borer can be done at late vegetative stage (35-45 DAT), while percentage damaged fruits can be taken after every priming or at

harvest. The damage ratings should be supported by actual population counts by dissecting damaged fruits during harvest at least three times.

*B. Fungicides*

1. Number of Trials
   a. Number of Seasons — 1 preferably wet
   b. Number of Locations — 2
   c. Number of Replications — 4

2. Experimental Design — RCBD or split plot

3. Plot Size — 5-10 $m^2$ for non-vine crops
   15 $m^2$ for vine crops
   30 $m^2$ for green corn

4. Adequate Infestation Level — Natural disease infection of at least 10% at the untreated control plots. Point source inoculations if necessary.

5. Reference Plot
   a. Untreated control plots
   b. Reference treatments:
      For late blight on white potato & tomato - Chlorothalonil and/or any currently registered similar fungicides
      For downy mildew of cucurbits - Mancozeb, Metalaxyl and/or any currently registered similar fungicides
      For anthracnose of beans and pepper - Mancozeb, Benomyl and/or any currently registered similar fungicides
      For leaf mold of tomato and okra - Mancozeb, Benomyl and/or any currently registered similar fungicides
      For downy mildew of green/sweet corn - Metalaxyl and/or any currently registered similar fungicides
      For root knot nematodes - Carbofuran and/or any currently registered similar fungicides

6. Method of Assessment

   a. Phytotoxicity rating following the crop injury rating for herbicides (V.B.2).

   b. Percent infected plants and percent leaf area taken from no less than 20 randomly collected plants per plot following rating scale (V.A.5b and V.A.5a).

   c. For nematodes, take the percentage of total root system galled and transform to rating scale (V.A.6).

   d. Take the yield from whole plots and transform to Kg/Ha.

C. *Herbicides*

1. Number of Trials
   a. Number of Seasons — 2 (wet and dry)
   b. Number of Locations — 2 different geographic areas with different climatic conditions
   c. Number of Replications — 4

2. Experimental Design — RCBD or split plot

3. Plot Size — 20 $m^2$ (4m x 5m)
   30 $m^2$ for green corn

4. Adequate Infestation Level — Natural weed infestation of at least 25% ground cover in the unweeded plots at 15 days after planting/transplanting.

5. Reference Plot
   a. Control plots:
      1. Unweeded control
      2. Handweeded control, 2-3x before close-in time or weed-free control (4-5x handweeding)

   b. Reference treatments:
      For annual grasses (except *Rottboellia*) and broadleaves- Atrazine (pre-emergence) and/or any currently registered similar herbicides for green corn
      For annual grasses including *Rottboellia* - Pendimethalin as pre-emergence and/or any currently registered similar herbicides for green corn
      For broadleaves & sedges - MCPA, 2,4-D (post-emergence) applied at 15-20 days after transplanting and/or any currently registered similar herbicides for green corn
      Broad spectrum - Oxyfluorfen applied 7 days after transplanting and/or any currently registered similar herbicides for onion

6. Method of Assessment

   a. Crop injury and weed control assessment taken 1-3 weeks after herbicide application transformed to the rating scale (V.B.2 and V.B.1).

   b. Weed counts and weed biomass by species using a 50 cm x 50 cm quadrat at 30 to 45 days after planting or transplanting.

   c. Take the yield from the whole plots excluding sample area and transformed to Kg/Ha.

## *Specific Requirements for Other Crops*

A. *Insecticide* (Banana and Pineapple)

*The most common problem in banana is the flower thrips while mealybug appears to be significant in pineapple because of its being the vector of pink disease in pineapple.*

*For systematic comparison of treatments, an unprotected control should be the reference point (not only to establish comparative advantage but also to provide an idea on the level of pest pressure). However, in cases where an unprotected plot becomes a threat to the bigger field (due to pest migration), this requirement may be waived provided that counts or damage assessments (as may be applicable) are done before and after treatment.*

1. Banana – for the banana flower thrips

If an unprotected plot is not possible, a pre treatment count for all plots will suffice. For injectibles, post treatment count can be done at 5 days after injection when dead thrips are expected to be highest. For economic reasons, at least 3 buds per treatment per replication (hence a total of 9 buds per treatment) should be sacrificed (split into half and observed for actual dead or live thrips).

Final assessment of thrips damage is done at harvest on hands using the water soaked or corky scab damage as indicator of the level of protection accorded by the product against the thrips.

2. Pineapple Mealybugs

Just like in banana plantations, unprotected control plot requirement may be waived provided a pre treatment count is made to establish pest pressure prior to treatment. Efficacy is assessed based on actual counts after treatment expressed in terms of % mortality or % population reduction vis-à-vis the standard plantation practice. Minimum plot size should be not less than 500 $m^2$ per treatment and replicated at least 3 times.

B. *Herbicides* for turf/perennial crops (rubber, banana, pineapple)

1. Number of Trials

| | | |
|---|---|---|
| a. | Number of Seasons | 2 |
| b. | Number of Locations | 2 |
| c. | Number of Replications | 4 |

2. Experimental Design — RCBD

3. Plot Size — at least 4m x 5m

4. Adequate Infestation Level — at least 25% ground cover in the unweeded plots at 15-40 days after planting.

5. Reference Plot
   a. Control plots
      1. Unweeded control
      2. Handweeded (2-3x) or weed-free control (4-5x handweeding)

b. Reference treatments:
Grasses: posterm grass herbicides (Fluazifop, Cyhalofop) or currently recommended herbicides.
Broadleaf weeds and sedges: 2,4 – D, Bensulfuron, or currently recommended herbicides.
Mixture: Glyphosate, Glufosinate, Sulfonylurea or other currently recommended herbicides.

6. Method of Assessment

a. Same as in corn/vegetables.

b. No. of days to 30 % weed regrowth.

c. Yield or other yield parameters from 10 $m^2$ area or whole plots, expressed in Kg/ha.

## IV. Specific Requirements for Rodenticide Trials

*A. <u>Rodenticide</u> Trial - Field*

1. Number of Trials

| | |
|---|---|
| a. Number of Seasons | 1 preferably wet |
| b. Number of Locations | 2 in areas with at least moderate rat populations |
| c. Number of Replications | 3; treated and check plots should be separated at least by 300 m. |
| 2. Experimental Design | t-test, DMRT or other applicable statistical analysis |
| 3. Plot Size | Minimum of one (1) hectare/ replication/treatment.<br>Plots should be at least 300 m apart. |
| 4. Adequate Infestation Level | Average of 5-10% rat activity (from a 3-day data) |
| 5. Reference Plot | Untreated plot – (but sometimes farmers may use same rat control procedure, so this should be noted). |
| 6. Method of Assessment | Preferably a periodic assessment of rat damage and supplemented by activity tiles. |
| a. Pre-treatment | 4 WAT preferably 2 WAT for rice; or at least 1 month for corn; or 3-4 months after planting/ratoon crop (for sugarcane). |

b. Periodic assessment on the performance of the treatments at these following stages of the crop:

| | Rice | Corn | Sugarcane |
|---|---|---|---|
| 1st pre treatment | 2 – 4 WAT | 4 Weeks After Seeding (WAS) | 3 months Ratoon 4-5 months new planting |
| Periodic: | 8, 12 WAT | 8, 12 WAS | Every month thereafter |
| Before harvest | 2 weeks | 1-2 weeks | Assess damage on harvested canes |

c. Assess bait consumption
- 2 days after baiting
- periodically as long as baiting is going on

d. Take note of possible risks to non-target animals
- Interview people in community to find out if there are animals that were affected.
- Review records of local/municipal health centers/hospitals on poisoning cases.

e. Yield loss — Base it on yield without rat damage.

f. Cost/benefit analysis (optional) — Use partial budgeting.

*B.* *Rodenticide* – animal farm and establishments (buildings, hotels, supermarkets and houses)

1. Number of Trials

a. Number of Seasons — 1
b. Number of Locations — 2 in areas with at least moderate rat infestation
c. Number of Replications — Minimum of 2; preferably 3

2. Treatments — Treated vs. untreated

3. Experimental Design — A t-test may be sufficient

4. Adequate Population Pressure
a. Based on damaged structures, food, eggs (in poultry houses, etc.)
b. Based on activity data ≥ 5% rat activity

5. Reference Plot — Untreated establishment/house

6. Method of Assessment

a. Pre-treatment
- Take note of damaged counts, e.g. no. of eggs broken, chicks killed by rats
- Average of 3-day rat activity data

b. During treatment — The same as #a

c. Post treatment — The same as #a

7. Efficacy Results

a. Reduced number of damaged counts, e.g. broken eggs, etc. compared to the pretreatment assessment.

b. Clients' feedback

## *V. Standard Rating Scales for Evaluation of Pest Damage*

The currently differing rating scales adopted by researchers and research agencies in assessing pest damage have created difficulties in evaluating and comparing data sets. Thus, this standard rating scale system is addressed to answer the problem. The system uses a six or five-digit scale to facilitate rapid interpretation of scores to provide more intermediate scores and to discriminate treatment effects more readily.

### *A. Diseases*

#### A.1. Rice Blast

##### A.1.a. Foliar blast

| SCALE | DESCRIPTION |
|---|---|
| 0 | No lesion/infection |
| 1 | Small to larger brown specks, infecting 1-5 % of leaf area |
| 3 | Typical blast lesions, infecting 6-15 % of leaf area |
| 5 | Typical blast lesions, infecting 16-25 % of leaf area |
| 7 | Typical blast lesions, infecting 26-50 % of leaf area |
| 9 | More than 50 % leaf area affected |

Reading should be taken at growth stage 3 to 5.

Compute % disease severity using the formula:

$$\% \text{ D.S.} = \frac{n(0) + n(1)\ldots + n(9)}{N \times 9} \times 100$$

Where: n = number of infested plants classified by grade (scale)
N = total number of samples

A.1.b. Neck and Node blast – use actual count of infected plants and convert to % disease incidence (number of infected plants divided by total number of samples x 100).

Reading should be taken at growth 7-9.

A.2. Sheath Blight

| SCALE | DESCRIPTION |
|---|---|
| 0 | No incidence. |
| 1 | Lesion limited to lower than 20 % of the plant height. |
| 3 | Lesion limited to 20 – 30 % of the plant height. |
| 5 | Lesion limited to 31 – 45 % of the plant height. |
| 7 | Lesion limited to 46 – 65 % of the plant height. |
| 9 | Lesion limited to more than 65 % of the plant height. |

Reading should be taken at growth stage 5-9.

A.3. Sheath Rot

| SCALE | % INFECTED TILLERS |
|---|---|
| 0 | No incidence |
| 1 | Less than 1 % |
| 3 | 1 – 5 % |
| 5 | 6 – 25 % |
| 7 | 26 – 50 % |
| 9 | 51 – 100 % |

Reading should be taken at growth stage 7-9.

A.4. Helminthosporium and Cercospora Leaf Spot (at growth stage 5 – 9)

| SCALE | % LEAF AREA INFECTED |
|---|---|
| 0 | No incidence |
| 1 | Less than 1 % |
| 3 | 1 – 5 % |
| 5 | 6 – 25 % |
| 7 | 26 – 50 % |
| 9 | More than 50 % |

A.5. Diseases of Vegetables

A.5a. Rating Scale for diseases exhibiting localized symptom (leaf spots, blight, anthracnose, etc.)

| SCALE | % AREA INFECTED |
|---|---|
| 0 | None |
| 1 | 1 – 5 % |
| 3 | 6 – 12 % |
| 5 | 13 – 25 % |
| 7 | 26 – 50 % |
| 9 | More than 50 % |

Reading should be taken at least 15 days after inoculation.

A.5b. Rating scale for diseases exhibiting systemic symptoms (wilts and rots and downy mildew of corn).

Use actual count of infected plants and convert to % disease incidence.

A.6. Nematode Root Gall Scale

| SCALE | % OF TOTAL ROOT SYSTEM GALLED |
|---|---|
| 0 | No gall |
| 1 | Less than 1 |
| 3 | 1 – 10 |
| 5 | 11 – 30 |
| 7 | 31 – 60 |
| 9 | 61 and above |

*B. Weeds*

B.1. Weed Control Rating

| SCALE | % WEED CONTROL BASED ON THE UNTREATED CHECK |
|---|---|
| 1 | 91- 100 |
| 3 | 81 – 90 |
| 5 | 71 – 80 |
| 7 | 61 – 70 |
| 9 | 60 & below |

B.2. Crop Injury Rating

| SCALE | % CROP INJURY BASED ON THE UNTREATED CHECK |
|---|---|
| 1 | None |
| 3 | 1 – 10 |
| 5 | 11 – 20 |
| 7 | 21 – 30 |
| 9 | > 30 |

*C. Rat Damage*

| SCALE | % DAMAGE PLANTS (HILL) |
|---|---|
| 1 | 0 – 10 |
| 3 | 11 – 15 |
| 5 | 16 – 20 |
| 7 | 21 – 25 |
| 9 | 25 & above |

## VI. General Requirement for Household Bioefficacy Trials

Bioefficacy evaluation against common household pests like houseflies and cockroaches should be made using uniform laboratory reared insects. In case of field evaluation, every effort should be done to determine the level of pest before treatment application. Effect of treatments is based on per cent mortality (or moribund insects) after treatment. It is very important that positive (standard commonly used product) and negative controls (unprotected or blank solution) are included in the test.

For aerosols, the effect of the carrier should also be assessed (and should be used as the negative control set).

Foreign data maybe considered provided these are conducted in places with similar environmental/climatic conditions as the Philippines and against our specific species. In-house company data will be accepted as supporting data but not as sole basis of registration. The format of data presentation should also follow FPA required format.

APPENDIX I

## GROWTH STAGES OF RICE PLANTS

| Code | Description |
|---|---|
| 0 | Germination to emergence |
| 1 | Seedling or transplanting |
| 2 | Tillering |
| 3 | Stem elongation |
| 4 | Booting (beginning with panicle initiation) |
| 5 | Heading |
| 6 | Flowering |
| 7 | Milk stage |
| 8 | Dough stage |
| 9 | Mature grain |

# *Annex IV*

# *LABELLING GUIDE*

**KEEP OUT OF REACH OF CHILDREN**

# TRADE NAME

DESCRIPTIVE STATEMENT
ACTIVE INGREDIENT
SOLVENT

ART WORK

Registered by the Fertilizer and Pesticide Authority
Pursuant to P.D. 1144
FPA Registration No. _____ Lot/Batch No. _____
Net Content: _____ Date Formulated: _____
WARNING

PRECAUTIONS

SECONDARY HAZARDS

Babala

Symptoms

First Aid

Note to Physician

DIRECTIONS FOR USE
(Warning intended to prevent misuses)

| CROPS | PESTS | Tbs/lb per L* |
|---|---|---|
| | | |
| | | |
| | | |

* Table spoon = 10 ml

Frequency and Method of Application

Mixing

Compatibility

**FOR RESTRICTED USE ONLY**

Pre-Harvest Interval

Re-Entry

Storage & Disposal

Prohibition/Warranty

Manufacturer/Distributor & Address

HAZARD SYMBOL

2-Panel Label

WARNING

PRECAUTIONS

SECONDARY HAZARDS

BABALA

Symptoms of Poisoning

First Aid

Note to Physician

**KEEP OUT OF REACH OF CHILDREN**

TRADE NAME
DESCRIPTIVE STATEMENT

Active Ingredient
Solvent

ARTWORK

Registered by the Fertilizer and Pesticide Authority Pursuant to P.D. 1144

FPA Registration No. _____ Lot/Batch No. _____
Net Content _____ Date Formulated _____
Manufacturer/Distributor and Address

DIRECTIONS FOR USE
(Warning intended to prevent misuses)

| CROPS | PEST | Tbs/lb per L* |
|---|---|---|
| | | |
| | | |
| | | |

* Table spoon = 10 ml

FREQUENCY AND METHOD OF APPLICATION

MIXING

COMPATIBILITY

FOR REGISTRICTED USE ONLY

Pre-Harvest Internal

Re-Entry

Storage & Disposal

Prohibition/Warranty

# HAZARD SYMBOL

3-Panel Label

**KEEP OUT OF REACH OF CHILDREN**

FOR RESTRICTED USE ONLY

TRADE NAME
DESCRIPTIVE STATEMENT
Active Ingredient
Solvent

ART WORK

Registered by the Fertilizer and Pesticide Authority
Pursuant to P.D. 1144
FPA Registration No. _____ Lot/Batch No. _____
Net Content _____ Date Formulated _____

Pre-Harvest Interval

Re-Entry

Storage & Disposal

Prohibition/Warranty

DIRECTIONS FOR USE
(Warning Intended to Prevent Misuses)

| CROPS | PEST | Tbs/lb per L* |
|---|---|---|
| | | |
| | | |
| | | |

* Table spoon = 10 ml

FREQUENCY AND METHOD OF APPLICATION

MIXING

COMPATIBILITY

WARNING

PRECAUTIONS

BABALA

SYMPTOMS OF POISONING

FIRST-AID

NOTE TO PHYSICIAN

MANUFACTURER/ DISTRIBUTOR & ADDRESS

# HAZARD SYMBOL

4-Panel Label

# *Annex V*

# *GUIDELINES ON GOOD LABORATORY PRACTICES IN PESTICIDE RESIDUE ANALYSIS*

# GUIDELINES ON GOOD LABORATORY PRACTICES IN PESTICIDE RESIDUE ANALYSIS[1]

## 1. INTRODUCTION

The ultimate goal in fair practice in international trade depends, among other things, on the reliability of analytical results. This, in turn, particularly in pesticide residue analysis, depends not only on the availability of reliable analytical methods, but also on the experience of the analyst and on the maintenance of "good laboratory practice in the analysis of pesticides". These guidelines define such good analytical practice and may be considered in three inter-related parts:

The Analyst;
Basic Resources; and
The Analysis.

A discussion of each of these follows:

## 2. THE ANALYST

2.1 Residue analysis consists of a chain of procedures, most of which are known, or readily understood, by a trained chemist, but because the analyte concentrations are in the range mg/kg to Tg/kg, attention to detail is essential. The analyst in charge should have an appropriate professional qualification and be experienced and competent in residue analysis. Staff must be fully trained and experienced in correct use of apparatus and in appropriate laboratory skills. They must have an understanding of the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems. They must understand the purpose of each stage in the method being used, the importance of following the methods exactly as described and of noting any unavoidable deviations. They must also be trained in the evaluation and interpretation of the data which they produce.

A record of training and experience must be kept for all members of staff.

2.2 When a laboratory for residue analysis is set up, the staff should spend some of their training period in a well established laboratory where experienced advice and training is available. If the laboratory is to be involved in the analysis for a wide range of pesticide residues, it may be necessary for the staff to gain experience in more than one established laboratory.

## 3. BASIC RESOURCES

### 3.1 The Laboratory

3.1.1 The laboratory and its facilities must be designed to allow tasks to be allocated to well defined areas where maximum safety and minimum chance of contamination of samples prevail. Laboratories should be constructed utilizing

---

[1] Section 3.2, Volume 2A, Codex Alimentarius (1996)

materials resistant to chemicals that are used in the area. Thus, under such conditions, separate rooms would be designated for sample receipt and storage, for sample preparation, for extraction and clean-up and for instrumentation used in the determinative step. The area used for extraction and clean-up must meet solvent laboratory requirements and all fume extraction facilities must be of high quality. Receipt, storage and sample preparation can be handled in one and the same room if only work at residue levels is being performed. The minimum requirements for pesticide residue analytical facilities are maintenance of sample integrity and adequate provisions for personal safety.

3.1.2 Laboratory safety must also be considered in terms of necessary and preferable conditions as it must be recognised that the stringent working conditions enforced in residue laboratories in some parts of the world could be totally unrealistic in others. No smoking, eating or drinking should be permitted in the working area. The use or application of personal, domestic or industrial preparations for cleaning, decoration, etc., should be minimized as they may cause contamination or other problems. Only small volumes of solvents should be held in the working area and the bulk of the solvents stored separately, away from the main working area. The use of highly or chronically toxic solvents and reagents should be minimized whenever possible. All waste solvent should be stored safely and disposed of safely and in an environmental protective manner.

3.1.3 The main working area should be designed and equipped for utilisation of a range of analytical solvents. All equipment such as lights, macerators and refrigerators should be "spark free" or "explosion proof". Extraction, clean-up and concentration steps should be carried out in a well ventilated area, preferably in fume cupboards.

3.1.4 Safety screens should be used when glassware is used under vacuum or pressure. There should be an ample supply of safety glasses, gloves and other protective clothing, emergency washing facilities and a spillage treatment kit. Adequate fire fighting equipment must be available. Staff must be aware that many pesticides have acute or chronically toxic properties and therefore, great care is necessary in the handling of standard reference compounds.

### 3.2 Equipment and Supplies

3.2.1 The laboratory will require adequate, reliable, supplies of electricity and water and various gasses, either piped or from gas cylinders, of proven quality. Adequate supplies of reagents, solvents, glassware, chromatographic materials, etc., are essential.

3.2.2 Chromatographic equipment, balances, spectrophotometers etc. must be serviced and their performance validated regularly and a record of all servicing/repairs must be maintained for every item of equipment. Calibration is essential for equipment performing measurements.

3.2.3 Equipment performing absolute measurements, e.g., balances must be recalibrated regularly, and records should be kept.

3.2.4 Although equipment may require periodic updating in order to keep up with developments, the equipment should be sophisticated enough to do the job required.

3.2.5 All laboratories require an adequate range of reference pesticide standards of known and acceptably high purity. The range should cover all parent compounds for which the laboratory is monitoring samples as well as those metabolites which are included in MRLs.

3.2.6 All analytical standards, stock solutions and reagents must be clearly labelled with an expiry date and stored under proper conditions. Extra care should be taken to ensure the stability of standard reference compounds. Equal care must be taken that standard solutions of pesticides are not decomposed by the effect of light or heat during storage or become concentrated owing to solvent evaporation.

## 4. THE ANALYSIS

### 4.1 Avoidance of Contamination

4.1.1 One of the major areas in which pesticide residue analysis differs significantly from macro-analysis is that of the problem of contamination. Trace amounts of contamination in the final samples used for the determination stage of the method can give rise to errors such as false positive results or to a loss of sensitivity that may prevent the residue from being detected. Contamination may arise from construction materials, reagents, from the laboratory environment, from the procedure, or from a combination of these. All glassware, reagents, organic solvents and water should be checked for possible interfering contaminants before use, by running a reagent blank through the procedure.

4.1.2 Polishers, barrier creams, soaps containing germicides, insect sprays, etc., can give rise to interference problems and are especially significant when an electron-capture detector is being used. There is no real solution to the problem other than to ban their use in the laboratory.

4.1.3 Lubricants, sealants, plastics, natural and synthetic rubbers, protective gloves, oil from ordinary compressed air lines and manufacturing impurities in thimbles, filter papers and cotton-wool can also give rise to contamination of the final test solution.

4.1.4 Chemical reagents, adsorbents and general laboratory solvents may contain, adsorb or absorb compounds that interfere in the analysis. It may be necessary to purify reagents and adsorbents and it is generally necessary to use redistilled solvents. Deionized water is often suspected. Redistilled water is preferable. Although in many instances, tap water or well water may be satisfactory.

4.1.5 Contamination of glassware, syringes and gas chromatographic columns can arise from contact with previous samples or extracts. All glassware should be cleaned with detergent solution rinsed thoroughly with distilled (or other clean) water and then rinsed with the solvent to be used. Glassware to be used for residue analysis must be kept separate.

4.1.6 Pesticide reference standards should always be stored in a room separate from the main residue laboratory at a suitable temperature.

4.1.7 Apparatus containing plastics should be regarded as suspect and, if shown to be a source of contamination, should not be allowed in the residue laboratory. Other materials containing plasticisers should also be regarded as suspect but PTFE is usually acceptable and others may be acceptable in certain circumstances.

Analytical instrumentation should be housed in a separate room. The nature and importance of contamination can vary according to the type of determination technique used and the level of pesticide residue to be determined. For instance, contamination problems which are important with methods based on gas chromatography or high performance liquid chromatography, may well be less significant if a spectrophotometric determination is used, and vice versa. For relatively high levels of residues, the background interference from solvents and other materials may be insignificant in comparison with the amount of residue present, while many problems can be overcome by the use of specific detectors. Furthermore, if the contaminant does not interfere with the result being sought, its presence may be acceptable.

4.1.8 Residue and formulation analyses must be completely separated, and separate laboratory facilities provided for each activity. Samples and sample preparation should be kept separate from the main residue laboratory in order to preclude cross contamination.

## 4.2 Reception and Storage of Samples

4.2.1 Every sample received in the laboratory should be accompanied by information on the analysis required, on past and required storage conditions and on potential hazards associated with the handling of that sample.

4.2.2 Upon receipt of a sample, it must immediately be allocated a unique sample identification code which should accompany it through all stages of the analysis to the reporting of the results. The samples should be subject to an appropriate disposal review system and records should be kept.

4.2.3 Sample processing and sub-sampling should be carried out using procedures which have been demonstrated to have no effect on the concentration of residues present.

4.2.4. In an ideal situation, samples should be stored at chill (1-5$^0$C) temperature, away from direct sunlight, and analyzed within a few days. However, in many instances, samples may require storage for an extended period (up to 1 year) before analysis. Storage temperature should be approximately -20$^0$C, at which temperature degradation of pesticide residues by enzyme action is extremely low. If any doubt exists, the result should be checked by analyzing fortified samples stored under the same conditions for the same period.

4.2.5 When samples are to be frozen, it is recommended that analytical subsamples be taken prior to freezing in order to minimize the effect of water separation as ice crystals during storage. Extra care must still be taken to ensure that all of the subsample is used in the analysis.

4.2.6 Neither the containers used for storage nor their caps or stoppers should allow migration of the chemical being sought into the container. The containers must not leak. All samples should be labelled clearly with permanent labels and records must be kept. The extracts and final test solution should not be exposed to direct sunlight.

## 4.3 Standard Operating Procedures (SOPs)

4.3.1 An SOP should be available for all routinely used operations. The SOP should contain full experimental details as well as information on application, performance, attainable limits of determination and method of calculation of results. It should also contain information on any hazards arising from the method, from standards or from reagents.

4.3.2 Any deviations from the SOP must be recorded and authorized by the analyst in charge.

## 4.4 Validation of Methods

4.4.1 The amount of effort allocated to the validation of methods will vary considerably. In a routine laboratory monitoring, for compliance with Codex MRLs or national tolerances, standardized methods will be used in most instances. Satisfactory performance should be demonstrated initially and thereafter checked periodically.

4.4.2 Whenever a laboratory undertakes method development and/or method modification, the effects of analytical variables should be established, e.g., by using a ruggedness test. Rigorous controls must be adhered to in all aspects of methodology which may include sample size; partition volumes; variations in the performance of the clean-up systems used; the stability of reagents or of the derivatives prepared; the effects of light, temperature, solvent and storage on analytes in extracts; the effects of solvent, injector, separation column, mobile phase characteristics (composition and flow-rate), temperature, detection system, co-extractives, etc., on the determinative system. It is most important that the qualitative and quantitative relationships between the signal measured and the analyte sought is established unequivocally.

4.4.3 The performance of the analytical method should be checked, both during its development and during its subsequent use, meeting the following criteria:

- The overall average recovery of the method, determined by fortification of blank samples, should normally be within the range of 70-120%. For a few pesticide/substrate combinations, such recoveries may not be achievable.

- The reproducibility and repeatability of the method must be established by analysis of, e.g., blank samples fortified at appropriate levels, certified reference materials or samples with incurred residues. The relative standard deviation should normally be less than 20%, but may be greater at lower residue levels. Recovery of pesticides from "spiked" samples is commonly used as a measure of efficiency of an analytical procedure, but it must be recognized that such studies are of limited value. The evaluation of a method should include, where possible, the extraction of labelled compounds.

### 4.5 Maintenance of Overall Analytical Performance

4.5.1 The performance of methods in use should be regularly assessed along the lines indicated in section 4.4. Blank and spiked samples, both at the tolerance level and at the lower limit of determination should also be analyzed.

4.5.2 Regular analyses of substrates known to be free of pesticide residues is necessary in order to check that contamination is not occurring.

4.5.3 In all laboratories, regular checks should be made on the effects of changes in batches or sources of supply of chemicals, solvents, etc.

4.5.4 Extra care should be taken so that standard solutions of pesticides are not decomposed by the effect of light or heat during storage or become concentrated owing to solvent evaporation. Equal care must be taken to ensure the stability of reference standard compounds. Regular injection of standards during chromatographic analysis of a series of samples is essential.

4.5.5 Various national and international organizations now organize collaborative studies on particular methods and/or check sample programmes. The latter present an ideal way for laboratories to assess their own performance. If possible, check samples should be introduced as routine samples so that the analyst concerned does not attempt to "make a special effort" which would invalidate the samples as a test of laboratory performance.

### 4.6 Confirmatory Tests

4.6.1 When analyses are done for regulatory purposes, it is especially important that confirmatory tests are carried out before reporting adversely on samples containing residues of pesticides not normally associated with that commodity or where MRLs appear to have been exceeded. As a first step, the analysis should be repeated using the same method, if only one sample was taken through the procedure initially. Samples may contain non-pesticidal chemicals which in some chromatographic methods may be misidentified.

4.6.2 Confirmatory tests can be divided into two types: quantitative tests are necessary when MRLs appear to be exceeded whilst qualitative confirmation of identity is also needed in these cases, and when atypical residues are encountered. Qualitative tests may involve chemical reactions or separations where some loss of the residue occurs. Particular problems occur in confirmation when MRLs are set at or about the limit of determination. Although it is difficult to quantify residues at this level, it is essential to provide adequate confirmation of identity.

4.6.3 The need for confirmatory tests may depend upon the type of sample or its known history. In many substrates, certain residues are frequently found. For a series of samples of similar origin which contain residues of the same pesticide, it may be sufficient to confirm

the identity of residues in a random proportion of the samples. Similarly, when it is known that a particular pesticide has been applied to the sample material, there may be little need for confirmation of identity, although a random proportion of samples should be confirmed. Where control samples are available, these should be used to check the presence of possible interfering substances.

4.6.4 In quantitative confirmation, at least one alternative procedure should be used and the individual results reported. In qualitative confirmation, an alternative technique using different physicochemical properties and/or the use of spectral data is desirable.

4.6.5 The necessary steps to positive identification are a matter of judgment on the analyst's part and particular attention should be given to the choice of a method which would minimize the effect of interfering compounds. The chosen method would depend upon the availability of suitable apparatus and expertise within the testing laboratory. As a guidance to the analyst, some alternative procedures for confirmation are given in the following paragraphs.

4.6.6 Alternative gas chromatographic columns

The results obtained in the primary analysis should be quantitatively and qualitatively confirmed using at least one alternative column involving a stationary phase of different polarity. The quantitative results obtained should be within 20% of the primary analysis. Further quantitative confirmation is required if the results differ by more than 20%, except when the MRL is set "at or about the limit of determination" when a difference of up to 100% of the higher value may occur.

In choosing the alternative column material, consideration should be given to separating any pesticidal or interfering compounds known to have retention times on the primary column identical to that of the residue detected. The alternative column may be a packed column or, preferably, a capillary column because of its higher separation power. Whilst the use of an alternative gas-chromatographic column may not always give positive confirmation, it will often quickly disprove a suspected identity. In either case, further confirmation is required to identify the residue.

4.6.7 Use of selective detectors for gas chromatography

When pesticides containing several chemical elements are present, detectors showing enhanced response to these elements may be used for confirmation. Detectors such as flame photometric (sulphur, phosphorus and tin), alkali flame ionization (phosphorus and nitrogen), Atomic emission, Fourier-Transform Infra Red and coulometric/electrolytic conductivity (nitrogen, sulphur and halogens) can give valuable additional information on residues. The sulphur/phosphorus response ratio obtained by using a flame photometric detector can give useful information in the case of phosphorothioates.

4.6.8 High-performance liquid chromatography (HPLC)

HPLC can often be used advantageously for the confirmation of residues initially found by other techniques and may be in certain circumstances the preferred quantitative technique. Post or pre-column derivatization, the use of different detectors and/or the acquisition of spectra, are further options available to the analyst, especially when heat-sensitivity or low volatility make the compound to be analyzed less amenable to gas chromatography.

4.6.9 Thin-layer chromatography (TLC)

In some instances, confirmation of gas chromatographic findings is most conveniently achieved by TLC. Identification is based on two criteria: Rf value and visualization reaction. The quantitative aspects of thin-layer chromatography are, however, limited. A further extension of this technique involves the removal of the area on the plate corresponding to the Rf of the compound of interest followed by elution from the layer material and further chemical or physical confirmatory analysis. A solution of the standard pesticide should always be spotted on the plate alongside the sample extract to obviate any problems of non-repeatability of Rf. Over-spotting of extract with standard pesticide can also give useful information. The advantages of thin-layer chromatography are speed, low cost and applicability to heat sensitive materials; disadvantages include (usually) lower sensitivity than instrumental chromatographic detection techniques and frequent need for more efficient clean-up. In some countries, problems may be encountered when high humidity or temperature cause lack of repeatability.

4.6.10 Column fractionation

The order of elution from liquid chromatographic columns may help to verify the identity of a compound. Thus, an element of confirmation can be built-in to the extraction and clean-up procedure.

4.6.11 Derivatization

This area of confirmation may be considered under three broad headings:

a. Chemical reactions

Small scale chemical reactions resulting in degradation, addition or condensation products of pesticides, followed by re-examination of the products by chromatographic techniques, have frequently been used. The reactions result in products possessing different retention times and/or detector response from those of the parent compound. A sample of standard pesticide should be treated alongside the suspected residue so that both results may be directly compared. A fortified extract should also be included to prove that the reaction has proceeded in the presence of sample material. Interference may occur where derivatives are detected by means of properties of the derivatizing reagent. Chemical reactions have the advantages of being fast and easy to carry out, but specialized reagents may need to be purchased and/or purified.

b. Physical reactions

A useful technique is the photochemical alteration of a pesticide residue to give one or more products with a reproducible chromatographic pattern. A sample of standard pesticide and fortified extract should always be treated in a similar manner. Samples containing more than one pesticide residue may give problems in the interpretation of results. In such cases, preseparation of specific residues may be carried out using TLC, HPLC or column fractionation prior to reaction.

c. Other methods

Many pesticides are susceptible to degradation/transformation by enzymes. In contrast to normal chemical reactions, these processes are very specific and generally consist of oxidation, hydrolysis or de-alkylation. The products possess different chromatographic characteristics from the parent pesticide and may be used for confirmatory purposes, if compared with reaction products using standard pesticides.

4.6.12 Mass spectrometry

Residue data obtained using mass spectrometry can represent the most definitive evidence and, where suitable equipment is available, it is the confirmatory technique of choice. The technique can also be used for residue screening purposes. Mass spectrometric analysis of residues is usually carried out in conjunction with a chromatographic separation technique to provide retention time, ion mass/charge ratio and ion abundance data simultaneously. The particular separation technique, the mass spectrometer, the interface between them and the range of pesticides to be analyzed are usually interdependent and no single combination is suitable for the analysis of all compounds. Quantitative transmission of labile analytes through the chromatographic system and interface is subject to problems similar to those experienced with other detectors.

The most definitive confirmation of the presence of a residue is the acquisition of its "complete" electron-impact ionization mass spectrum (in practice, generally from m/z50 to beyond the molecular ion region). The relative abundance of ions in the spectrum and the absence of interfering ions are important considerations in confirming identity. This mode of analysis is one of the least selective and interference from contaminants introduced during the production or storage of extracts should be scrupulously avoided. Most mass spectrometer data systems permit underlying interference signals (caused by, e.g., column bleed) to be removed by "background subtraction" but, whilst very useful, this can sometimes produce misleading results.

Increased sensitivity can usually be achieved by means of limited mass range scanning or by selected ion monitoring but the smaller the number of ions monitored (especially if these are of low mass), the less definitive are the data produced. Additional confirmation of identity may be obtained: (1) by the use of an alternative chromatographic column; (2) by the use of an alternative ionization technique (e.g. chemical ionization); (3) by monitoring further reaction products of selected ions by tandem mass spectrometry; or (4) by monitoring selected ions at increased mass resolution.

For quantification, the ions monitored should be those which are the most specific to the analyte, are subject to least interference and provide good signal-to-noise ratios. Mass-spectrometric determinations should satisfy similar analytical quality control criteria to those applied to other systems.

4.6.13 Spectral measurements

At present, little use is made of infrared, Raman or nuclear magnetic resonance spectroscopy in pesticide residue analysis. Instrumental techniques using multiple reflection cells, microcells, microprobes, laser light, Fourier Transformation, etc., are being developed. These improve the quality of spectra and enhance the sensitivity and may enlarge the application of these techniques as detection methods for confirmation of compounds isolated by chromatographic techniques.

4.6.14 Bioanalytical techniques

Bioanalytical techniques involving inhibition of enzyme reactions, bio-assays using fungal spores or immunological techniques may be used as an initial screening to determine whether a residue is present before a sample is subjected to a more complex instrumental analysis. Immuno-assays can also be used as a quantitative method complementary to chromatographic analysis.

## 4.7 The concept of Lower Practical Levels (LPL) for the Determination of Residues of Pesticides

4.7.1 The continuing availability of improved clean up systems and more sensitive and selective detectors has enabled residue chemists to measure lower residues. However, the measurement of very low levels of residues may not be essential in some circumstances.

The residue chemist is frequently involved in measuring residues in samples in order to establish or to monitor residue levels of chemicals present in commodities moving in international trade. In these cases, residue methods should be sufficiently sensitive to establish and monitor against the MRL and to determine residues likely to be present in a food sample; they need not necessarily be so sensitive as to be able to determine residues two or more order magnitude lower than the MRL. Methods developed to measure residues at very low levels usually become very expensive and difficult to apply. However, it may be acceptable to define a lower practical level to be determined (LPL) in any sample. This would have the advantage of reducing the technical difficulty of obtaining the data and would also reduce costs. The following proposals for LPLs in various samples could be useful in enabling the residue chemist to devise suitable methods.

4.7.2 For registered active compounds with agreed MRLs, the LPL can be specified as a fraction of the MRL. For analytical convenience, this fraction will vary and could be as follows:

| MRL (mg/kg) | LPL (mg/kg) |
|---|---|
| 5 or greater | 0.5 |
| 0.5 up to 5 | 0.1 increasing to 0.5 for higher MRLs |
| 0.05 up to 0.5 | 0.02 increasing to 0.1 for higher MRLs |
| less than 0.05 | 0.5 x MRL |

When the MRL is set at the limit of determination of the analytical method, the LPL will also be at this level.

## 4.8 Expression of Results

For regulatory purposes, only confirmed data should be reported, expressed as defined by the MRL. Null values should be reported as being less than an experimentally-determined level, rather than less than a level calculated by extrapolation. Results should not be corrected for recovery. Where positive results derived from the analysis of several samples or duplicate measurements, the scientifically most sound result should be evaluated and reported.

Where the results are of equal reliability, the arithmetic mean of the values obtained should be reported. In general, for regulatory purposes, results below 1 mg/kg should be rounded to one significant figure, those from 1 to 10 mg/kg should be rounded to two significant figures and those exceeding 10 mg/kg should be rounded to the nearest whole number.

# *Annex VI*

# *CHECKLIST OF REQUIREMENTS AND PRESCRIBED APPLICATION FORMS*

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA FORM NO. P-180

# APPLICATION FOR COMMERCIAL APPLICATORS LICENSE

_____ Fumigator
_____ Drone Spraying Operator

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

**TIN No. :** _____

**Tel No. :** _____

**2. Business Address/es**

**a. Main** _____

**b. Branch/es (Use additional sheet if necesarry)**

_____

| **FPA USE ONLY** | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

| 3. **Capitalization** : (Attach most recent Financial Statement) | **4. Area of Coverage** (Province, Region) |
|---|---|
| | |

| **5. Activities** | **6. Equipment Use in Operation** | **Quantity** |
|---|---|---|
| _____ User | a. Storage _____ | |
| _____ Applicator | | |
| | | |
| | b. Actual Pesticide Applicator | |
| | | |
| | | |

**7. Chemical/s Used in Operation** (Use additional sheet if necessary)

| **Brand Name/s** | **Supplier/s** |
|---|---|
| | |
| | |
| | |

**8. Name/s of FPA Certified Pesticide Applicator Employed** (Use additional sheets if necessary)

| Title | Control / Ref. No. | Expiry Date of CPA ID |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

**9. PCO Association membership** (submit copy of certificate of membership)

_____
_____
_____

**10. Training Seminar/s Attended** (Related to Pest Control)

| Title | Place & Date | No. of Hours |
|---|---|---|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

**11. Years of Business**

| Inclusive Year | No. of Employee | Type of Operation |
|---|---|---|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

**12. What safety measures / equipment do you employ in handling pesticides.**

_____
_____
_____

I, hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA-PRD Form P-130

# APPLICATION FOR AGRICULTURAL PESTICIDE DEALERSHIP LICENSE

_____ Pesticide only
_____ Both Fertilizer & Pesticide

New
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

_____

Business Address:
a.) Main _____

_____

b.) Branch/es _____

_____

TIN No. : _____
Tel No. :

| FPA USE ONLY | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Name of Owner:** _____
(Family) (First) (Middle)
Sex: _____ Civil Status: _____ Age: _____

**3. Name of Authorized Representative:** _____

**4. Type of Ownership:**
_____ Single proprietorship _____ Corporation
_____ Partnership _____ Cooperative

**5. Capitalization:** P _____

**6. Name of Personnel who attended Agro-dealers/ retailers training:**

| Name | Date & Place of Training | Rating |
|---|---|---|
| | | |
| | | |

**7. List of Fertilizer and Pesticide Products:**

| | | |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

**8. List of Outlets (Business Name & Address:)**

_____ _____ _____
_____ _____ _____
_____ _____ _____
_____ _____ _____

**9. Physical Facilities:**

| **Warehouse** | | **Capacity** | **Store** | | **Capacity** |
|---|---|---|---|---|---|
| _____ | Rent | _____ | _____ | Rent | _____ |
| _____ | Own | _____ | _____ | Own | _____ |
| _____ | Others | _____ | _____ | Others | _____ |

Location:

| **Warehouse** | | **Store** | |
|---|---|---|---|
| _____ | Residential Area | _____ | Residential Area |
| _____ | Commercial | _____ | Commercial |
| _____ | Agricultural | _____ | Agricultural |

**10. What safety features do you have in the store/warehouse? Enumerate.**
(Use separate sheet if necessary.): _____
_____

**11. Did you have any training in pesticide handling?** _____

**12. Number of personnel employed:** _____

**13. Are you capable of extending credit to farmers in your area? Approximate loan ceiling per annum:**
_____

I HEREBY CERTIFY that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

IN WITNESS WHEREOF, I have hereunto set my hand this _____ day of _____ 20___ at _____, Philippines

Signature _____
Printed Name _____
Designation _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at _____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA FORM NO. P-150

# APPLICATION FOR AGRICULTURAL PESTICIDE NATIONAL DISTRIBUTORSHIP LICENSE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

Address : _____

_____

_____

_____

TIN No. : _____

Tel No. : _____

| FPA USE ONLY | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Capitalization** : (Attach most recent Financial Statement)

_____

3. **Supplier(s) Represented** (Use additional sheets if necessary)

_____

4. **List of Area Distributor(s) and addresses** (use additional sheet if necessary; update yearly)

_____

5. **Major Warehouse Points** (Give exact address: Use additional sheet if necessary)

_____

6. **List of Registered Products(s)** (Use additional sheet if necessary; update yearly)

_____

7. **Name of Accredited Responsible Care Officer (ARCO). Attach photocopy of Accreditation ID.**

_____

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

I hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA FORM NO. P-160-A

# APPLICATION FOR AGRICULTURAL PESTICIDE AREA DISTRIBUTORSHIP LICENSE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

Address : _____

_____

_____

_____

TIN No. : _____

Tel No. : _____

| FPA USE ONLY | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Capitalization** : (Attach most recent Financial Statement)

3. **Supplier(s) Represented** (Use additional sheets if necessary)

4. **List of Dealer(s) and addresses** (use additional sheets if necessary; update yearly)

5. **Major Warehouse Points** (Give exact address: Use additional sheets if necessary)

6. **List of Registered Products(s)** (Use additional sheets if necessary; update yearly)

7. **Name of Accredited responsible Care Officer (ARCO). Attach photocopy of Accreditation ID.**

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

I hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA PRD FORM NO. P-110

# APPLICATION FOR AGRICULTURAL PESTICIDE FORMULATOR / MANUFACTURER / EXTRUDER LICENSE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

Address : _____

_____

TIN No. : _____
Tel No. : _____

| **FPA USE ONLY** |
|---|
| Date Submitted: |
| Received by: |
| O.R. No. |
| Amount Paid: |
| Date: |
| Remarks: |

2. **Capitalization** : (Attach most recent Financial Statement)

_____

**3. Address of Formulation / Manufacturing / Extrusion Plant**

_____

**4. Environmental Compliance Certificate No.** _____
**Permit to Operate No.** _____
**Expiry Date** _____

**5. List of Pesticides Formulated / Manufactured / Extruded** ( Use additional sheets if necessary)

| Product | Formulation Type | Product Owner I/ | Volume / Year |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

I/ if formulation under contract, indicate date of expiry of contract. _____

| 6. Formulation Capability Rated Capacity | 7. No. of Employees | 8. Area of Compound | 9. Location of Plant |
|---|---|---|---|
| **Operating Capacity** | | | _____ Agricultural<br>_____ Residential<br>_____ Industrial<br>_____ Others (specify) |
| | | | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

**10. Occupational / Safety Arrangements**

In House Physician: _____ Clinic _____ Yes
Referrals: _____ No
Physician: _____
Hospital/ Clinic: _____
Address: _____

**11. Technical Staff: Name, PRC License No.**

**Plant Manager** _____
**PRC license #** _____
**Formulation Chemist** _____
**PRC license #** _____
**Quality Control Chemist** _____
**PRC license #** _____

**12. Name and Address of Laboratory, if not located within the plant.**

_____
_____

**13. Name of Accredited Responsible Care Officer (ARCO)**
**(Attached copy of Accreditation ID)**

_____
_____

I hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No._____

Original bears documentary stamps.

# ANNUAL CAPACITY AND OUTPUT

Company: _____
Activity : _____
Year : _____

| | | | | OUTPUT (in NT/KL) | | | |
|---|---|---|---|---|---|---|---|
| ANNUAL CAPACITY | COMMON NAME | PRODUCT NAME | USE | PRODUCTION PERIOD | VOLUME | VALUE | TOTAL |
| | | | | | | | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA FORM NO. P-120

# APPLICATION FOR AGRICULTURAL PESTICIDE REPACKER LICENSE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

Address : _____

TIN No. : _____
Tel No. : _____

| FPA USE ONLY | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Capitalization** : (Attach most recent Financial Statement)

**3. Address of Repacking Plant**

**4. Environmental Compliance Certificate No.** _____
**Permit to Operate No.** _____
**Expiry Date** _____

**5. Repacking Set-Up and Equipment**

| **6. Rated Capacity** | **7. No. of Employee/s** |
|---|---|
| | |

**8. List of Specific Products Repacked** (Use additional sheets, if necessary)

| Product | Repacking Type | Formulation Type | Importer / Distributor |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

| **9. Do you use your own brand name(s) for repacked products** | **10. Who Affixes or attached labels on repacked products?** | **11. Source of Labels** |
|---|---|---|
| _____ Yes | _____ Brand / Label owner | _____ Brand / Label owner |
| _____ No | _____ Repacker | _____ Repacker |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

| 12. Occupational Safety Arrangement | 13. Location of Plant | 14. Area of Compound |
|---|---|---|
| In Plant: _____ | _____ Agricultural | |
| Referrals: _____ | _____ Residential | _____ |
| | _____ Industrial | _____ |
| | _____ other (specify) | |

**15. Technical Staff: Name, PRC License No.**

**Plant Manager** _____
**PRC license #** _____
**Quality Control Chemist** _____
**PRC license #** _____

**16. Name of Accredited Responsible Care Officer (ARCO)**
(attach photo copy of Accreditation ID)

_____

I hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA PRD FORM NO. P-150

# APPLICATION FOR AGRICULTURAL PESTICIDE IMPORTER / INDENTOR / EXPORTER LICENSE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

Address : _____

_____

_____

_____

TIN No. : _____

Tel No. : _____

| **FPA USE ONLY** | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Capitalization** : (Write amount with denomination)

_____

**3. Mechanism of Payment**

_____ Letter of Credit
_____ Others, specify
_____ _____
_____ _____
_____ _____

**4. Type of Activity**

Importer _____
Indentor _____
Exporter _____
Others _____

**5. Pesticide imported** (Use additional sheets if necessary)

| Formulated | Technical | Name & Address of Supplier |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

**6. In country major warehouse point(s) (Use additional sheets if necessary)**

| Name of Warehouse / Address | Capacity |
|---|---|
| | |
| | |
| | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

**7. Form and package of imported material to be passed on to immediate recipient**

_____ As is
_____ Repacked
_____ Technical Material
_____ Formulated Products

**8. Name of Accredited Responsible Care Officer (ARCO) attach photocopy of Accreditation ID**

Name of ARCO _____

Expiry Date _____

I hereby agree to furnish FPA copies of importation documents after shipment/importation of pesticide/ agricultural chemical not later than 15 days upon arrival of shipment/importation.
Further, I, certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____ at _____, Philippines, affiant exhibited to me his/her Residence Certificate No. _____ issued on _____ at_____, Philippines.

Doc. No. : _____
Page No. : _____
Book No. : _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

NOT FOR SALE
FPA PRD FORM NO. P-170

# APPLICATION FOR AGRICULTURAL PESTICIDE SUPPLIER / SUPPLIER'S LOCAL REPRESENTATIVE / LOCAL SUBSIDIARIES

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Business Name of Applicant**

_____

Address : _____

_____

_____

TIN No. : _____
Tel No. : _____

| FPA USE ONLY | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No. | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

2. **Capitalization** : (Attach most recent Financial Statement)

_____

**3. Type of Activity**

_____ Supplier
_____ Supplier's Local Representative / Promoter
_____ Local Subsidiaries
_____ Others (specify)

_____

| **4. Name & Address of Parent Company** | **5. Name & Address of Local Distributors** |
|---|---|
| _____ | _____ |
| _____ | _____ |

**6. Pesticide Supplied:**

| Common / Chemical Name | Brand Name | Technical | Formulated | Type of Formulation |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Applicant Representative:
Signature _____
Printed Name _____
Position _____

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

I hereby certify that the foregoing data and information including those in the annexes hereof are true and correct to the best of my knowledge.

IN WITNESS WHEREOF, I have Hereunto set my hand this_____ day of _____,
at _____, Philippines.

_____
Name & Signature of the Applicant

_____
Name & Signature of Firm's
President/ Manager or
Authorized Representative

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____
at _____, Philippines, affiant exhibited to me his/her Residence Certificate
No. _____ issued on _____ at_____, Philippines.

Doc. No.: _____
Page No.: _____
Book No.: _____
Series No.: _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

# APPLICATION FOR AGRICULTURAL PESTICIDE WAREHOUSE REGISTRATION CERTIFICATE

_____ Conventional
_____ PIP

New _____
Renewal- License No _____
FPA Control No. _____
Expiry Date: _____

**1. Name of Applicant and Address**

_____

_____

**2. Names, Address(es) and storage capacity(ies) of Warehouse(s). Please indicate the Street No./ Barrio/ Town/ City & Province**

| **Name of Warehouse** | Address | **Storage Capacity & total Floor Area for Fertilizer / Pesticide** | |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| **FPA USE ONLY** | |
|---|---|
| Date Submitted: | |
| Received by: | |
| O.R. No.: | |
| Amount Paid: | |
| Date: | |
| Remarks: | |

Date of Application : _____

_____
Name & Signature of Owner or
Authorized Representative

REPUBLIC OF THE PHILIPPINES)
PROVINCE OF _____)S.S.
MUN/CITY OF _____)

SUBSCRIBED AND SWORN TO before me this _____ day of _____, at _____, Philippines, affiant exhibited to me his/ her Residence Certificate No. _____ issued on _____ at _____, Philippines.

Doc. No.: _____
Page No.: _____
Book No.: _____
Series No.: _____

NOTARY PUBLIC
Until December 31, _____
PTR No. _____

Original bears documentary stamps.

| Document title | Form no. | FPA-PMID - 01 |
|---|---|---|
| **APPLICATION FOR ACCREDITATION ASD / ARCO** | Revision no. | 0 |
| | Date | 09.13.2019 |
| | Author | A.D Gonzales |
| | Approved by | D.M De Leon |
| | Page | 1 of 1 |

Latest 1 x 1 Picture

Control No. _____

**Please check:**

☐ **New** ☐ Accredited Safety Dispenser **(ASD)**

☐ **Renewal** ☐ Accredited Responnsible Care Officer **(ARCO)**

| Date of training/last symposium attended: | Venue : |
|---|---|

| | |
|---|---|
| NAME | |
| EMAIL ADDRESS | |
| CONTACT NUMBER | |
| COMPANY | |
| COMPANY ADDRESS | |

*I hereby certify that the above information is correct to the best of my knowledge.*

_____
Signature

| **Requirements to be attached to this application** | | **ARCO** | **ASD** |
|---|---|---|---|
| | 1. Certificate of attendance to training/symposium | ✓ | ✓ |
| | 2. Recently issued Certificate of Employment | ✓ | |

**PRIVACY NOTICE AND CONSENT TO USE DATA**

*We respect your privacy and keep your personal information confidential unless we are lawfully required or allowed to disclose it or that you give your written consent to such disclosure.*

**FOR FPA USE ONLY:**

Received by / Date:

_____

Date Issued :_____

Amount Paid :_____

Official Receipt No. :_____

Place :_____

| | Document title | Form no. | FPA-PMID - 03 |
|---|---|---|---|
| DEPARTMENT OF AGRICULTURE FPA 1898 | **APPLICATION FOR ACCREDITATION CERTIFIED PESTICIDE APPLICATOR** | Revision no. | 0 |
| | | Date | 09.13.2019 |
| | | Author | A.D Gonzales |
| | | Approved by | D.M De Leon |
| | | Page | 1 of 1 |

Latest 1 x 1 Picture

Control No. _____

**Please check:**

☐ **New** ☐ **Agricultural Fumigator**

☐ **Renewal** ☐ **Agricultural Exterminator**

| Date of training/last symposium attended: | Venue : |
|---|---|

| Name | | |
|---|---|---|
| Email Address | Contact Number | Age |
| Citizenship | Educational Attainment | |
| Company Name | | |
| Company Address | | |

*I hereby certify that the above information is correct to the best of my knowledge.*

_____
Signature

| **Requirements to be attached to this application** | 1. Certificate of attendance to training/symposium<br>2. Recently issued Certificate of Employment<br>3. Monthy Pest Control Operations Report (in-house renewal)<br>4. List of Chemicals Used (in-house renewal) |
|---|---|

**PRIVACY NOTICE AND CONSENT TO USE DATA**

*We respect your privacy and keep your personal information confidential unless we are lawfully required or allowed to disclose it or that you give your written consent to such disclosure.*

**FOR FPA USE ONLY:**

Received by / Date:

_____

Date Issued :_____

Amount Paid :_____

Official Receipt No. :_____

Place :_____

| | Document title | Form no. | FPA-PMID - 04 |
|---|---|---|---|
| DEPARTMENT OF AGRICULTURE FPA 1898 | **APPLICATION FOR ACCREDITATION** | Revision no. | 0 |
| | | Date | 09.13.2019 |
| | **DRONE CONTROLLER / CREW** | Author | A.D Gonzales |
| | | Approved by | D.M De Leon |
| | | Page | 1 of 1 |

Latest 1 x 1 Picture

Control No. _____

**Please check:**

☐ **New** ☐ **Renewal**

☐ **Drone Controller** ☐ **Spray Operation Crew**

| | |
|---|---|
| Date of training/last symposium attended: | Venue : |
| Name | |
| Company | |
| Company Address | |
| Email Address | Contact Number |
| CAAP License No. | Valid Until |
| CPA / ARCO No. | Valid Until |

## CERTIFICATION

**Drone Controller**

*I hereby certify that I have competence and knowledge in the use of pesticide, as follows:*

a. Appropriateness of pesticide formulation to be applied.
b. Correct dose/rate and manner of application.
c. Awareness of hazards in the use of product.
d. First aid procedure.
e. All information provided in this form are true and correct.

_____
Signature

**Spray Operation Crew**

*I hereby certify that:*

a. I am knowledgeable and fully conversant with drone operation.
b. I had undergone training in safety on pesticide handling and the use of PPEs.
c. I have knowledge and fully conversant with precedures in case of pesticide exposure.
d. All information provided in this form are true and correct.

_____
Signature

**Requirements to be attached to this application**

☐ 1. Certificate of attendance to training/symposium
☐ 2. Copy of Civil Aviation Authority of the Philippines (CAAP) license

**PRIVACY NOTICE AND CONSENT TO USE DATA**

*We respect your privacy and keep your personal information confidential unless we are lawfully required or allowed to disclose it or that you give your written consent to such disclosure.*

**FOR FPA USE ONLY:**

Received by / Date:

_____

Date Issued :_____
Amount Paid :_____
Official Receipt No. :_____
Place :_____

| Document title | Form no. | FPA-PMID - 02 |
|---|---|---|
| **APPLICATION FOR ACCREDITATION**<br>**Fertilizer and Pesticide Researcher** | Revision no. | 0 |
| | Date | 09.13.2019 |
| | Author | A.D Gonzales |
| | Approved by | D.M De Leon |
| | Page | 1 of 1 |

Control No. _____

Latest 1 x 1 Picture

☐ **New** ☐ **Renewal**

Date of training/last symposium attended: _____ Venue : _____

**FIELD OF DISCIPLINE:**

- ☐ Plant Nutrition/Fertilizer
- ☐ Plant Pathology
- ☐ Weed Science
- ☐ Entomology
- ☐ Supervised Pesticide Residue Trial (SPRT)
- ☐ Others (Pls. specify)_____

| | |
|---|---|
| NAME | |
| EMAIL ADDRESS | |
| CONTACT NUMBER | |
| COMPANY NAME/ UNIVERSITY AFFILIATION | |
| COMPANY / UNIVERSITY AFFILIATION ADDRESS | |

*I hereby certify that the above information is correct to the best of my knowledge.*

_____
Signature

**Requirements to be attached to this application**

1. Certificate of attendance to training/symposium
2. Latest Resume which includes academic specialization, training, published research or current research undertakings, and years of research experience for the discipline being applied for (Greenbook, Chapter 4.5.5.B)
3. Approved protocol (*New Application*)
4. Authorship of one (1) publication in a refereed journal or two(2) publications in non-refereed journals along the discipline being applied for in case of expansion of accreditation for additional research discipline (Greenbook, Chapter 4.5.5.B)

**PRIVACY NOTICE AND CONSENT TO USE DATA**

*We respect your privacy and keep your personal information confidential unless we are lawfully required or allowed to disclose it or that you give your written consent to such disclosure.*

**CONSENT TO PROCESS AND SHARE DATA**

*In compliance with the Data Privacy Act, I hereby give my consent to the Fertilizer and Pesticide Authority to share my contact details to its registered clients who need researchers with my field of discipline to conduct field experiment to support fertilizer or pesticide product registration.*

_____
Signature of Researcher

**FOR FPA USE ONLY:**

Received by/Date:

_____

Date Issued :_____

Amount Paid :_____

Official Receipt No. :_____

Place :_____

# ANNEX C

## APPLICATION FOR FPA LABORATORY RECOGNITION

A. Name of Laboratory: _____

B. Address: _____

C. Tel./Fax. Nos.: _____

D. Email Address: _____

E. Name of Laboratory Head: _____

F. Scope of Recognition

| TYPE OF ANALYSIS (FERTILIZER OR PESTICIDE) | TEST PARAMETER / ANALYTE | ANALYTICAL METHOD |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

I HEREBY CERTIFY that the foregoing data and information including the relevant attachments for this application are true and correct to the best of my knowledge.

IN WITNESS WHEREOF, I have hereunto set my hand this ___ day of _____, _____ at _____, Philippines.

_____
Printed Name & Signature of Authorized Representative

REPUBLIC OF THE PHILIPPINES
PROVINCE OF _____)S.S.
MUNICIPALITY/CITY OF_____)

SUBSCRIBED AND SWORN to before me this ____ day of _____, _____ at _____, Philippines. Affiant exhibited to me his/her Government Issued ID (number) _____, issued on _____, _____ at _____, Philippines.

**WITNESS MY HAND AND SEAL,** this ____ day of _____, _____.

Doc. No. ____
Page No. ____
Book No. ____
Series of ____

ANNEX "D"

# SAMPLE TRANSMITTAL FORM

**Name of Sample:** _____

**Type of Sample:** _____

**Analyte/Test Parameters to be Analyzed:** _____

_____

_____

_____

**Remarks:** _____

_____

_____

**Requested by:**

_____
**Client's Name & Signature/Date**

**Prepared & Reviewed by:**

_____
**FRD/PRD Personnel/Date**

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE MANUFACTURER/FORMULATOR/REPACKER/EXTRUDER | FPA-PRD-CL-7<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-110 for manufacturer, formulator, & extruder and/or form No. P-120 for repacker, with documentary stamps
_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI
_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statements (FS)
_____ 4. Copy of Environmental Compliance Certificate (ECC) and Permit to Operate (PTO) with DENR
_____ 5. Production Process/Flow Chart
_____ 6. Recommendation/Inspection report from FPA Regional/Provincial Officer
_____ 7. Written authority to repack/formulate/extrude/manufacture from the supplier
_____ 8. Pre/post-licensing inspection report by the Pesticide Audit Team
_____ 9. Registration of Pesticide Warehouse/s
_____ 10. Photo copy of Accredited Responsible Care Officer (ARCO) ID
_____ 11. Product Registration/contract/certification from the manufacturer/supplier
_____ 12. Compliance of FPA Manual on Occupational and Technical Safety of Pesticides manufacturing, formulation, repacking and extrusion plant
a. Occupational Health and Safety Program (OHSP)
b. Medical Health Examinations and certificate of "Fit to Work" of Workers
_____ 13. Annual Capacity Output
_____ 14. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with <u>incomplete</u> requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE IMPORTER LICENSE | FPA-PRD-CL-8<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-150 with documentary stamps

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration.
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statements (FR)

_____ 4. Distributorship agreement/certification from the pesticide supplier/s

_____ 5. Recommendation / Inspection Report from FPA Regional / Provincial Officer

_____ 6. Registration of Pesticide Warehouse/s

_____ 7. Photo copy of Accredited Responsible Care Officer (ARCO) ID

_____ 8. Product Registration/contract/certification from the manufacturer/supplier

_____ 9. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with <u>incomplete</u> requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE EXPORTER | FPA-PRD-CL-9<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-150 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration.
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statements (FS)

_____ 4. The exporter submits to the Authority the supply-demand analysis of the product/s intended to be exported to insure that exportation is made only after satisfaction of local demand.

_____ 5. The exporter submits a letter from the Department of Agriculture or relevant Regulatory Agency of the importing country to justify that the product to be exported is not a banned or restricted and allowed to be exported to the importing country.

_____ 6. Product Registration/contract/certification from the manufacturer/supplier

_____ 7. Photo copy of Accredited Responsible Care Officer (ARCO) ID

_____ 8. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE INDENTOR | FPA-PRD-CL-10<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-150 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statements (FS)

_____ 4. Photocopy of contract/certification with Manufacturer / Supplier

_____ 5. Corresponding fees (See attached scheduled of fees)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE IMPORTER END-USER / INSTITUTIONAL USER | FPA-PRD-CL-11<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-150 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration.
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statements (FS)

_____ 4. Compliance of FPA Manual on Occupational Health and Technical Safety of Pesticides Institutional Users / End-User
a. Occupational Health and Safety Program (OHSP)
b. Medical Health Examinations and Certificate of "Fit to Work" of workers

_____ 5. Copy of Environmental Compliance Certificate (ECC) and Permit to Operate (PTO) from DENR

_____ 6. Recommendation / Inspection Report from FPA Regional / Provincial Officer

_____ 7. Photo copy of Accredited Responsible Care Officer (ARCO) ID

_____ 8. Product Registration/contract/certification from the manufacturer/supplier

_____ 9. Registration of pesticide warehouse/s

_____ 10. Authorization letter from the pesticide company who register the product.

_____ 11. Authorization letter from the pesticide company who register the product

_____ 12. Pre/post-licensing inspection report by the Pesticide Audit Team

_____ 13. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-44 1-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF COMMERCIAL APPLICATOR - DRONE SPRAYING OPERATOR | FPA-PRD-CL-12 Revision 00 |
|---|---|

**I. For New Application:**

_____1. Duly accomplished and notarized FPA application form No. P-180
_____2. a. For Corporation / Partnership - Copy of SEC Registration and Articles Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship- Copy of Certificate of Registration of Business Name with DTI
_____3. Copy of latest Income Tax Return (ITR) and Financial Statement (FS)
_____4. License Fee: ₱1,200.00/year
_____5. Recommendation / Inspection report from FPA Regional / Provincial Officer.
_____6. Photocopy of Drone Controller and Spray Operation Crew ID.
_____7. Compliance on the Occupational Health and Safety Standards for Drone Controller and Spray Operation Crew:

a. Complete and thorough physical examination.
b. Laboratory tests which shall include:

- Hematology (Hemoglobin, Hematocrit, Leucocyte count, and differential, reticulocyte and platelet count)
- Chest X-ray
- Urinalysis
- Fecalysis
- Biochemical monitoring (BUN, creatinine, uric acid, total protein, alkaline phosphatase, total cholesterol, SGOT and SGPT)

c. Certificate of "Fit to Work".

**II. For Renewal (Additional Requirement):**

Renewal of application shall be filed at least one (1) month before its expiry date. Application for renewal filed within one (1) month after the expiry date of its license shall be subjected to a 50% surcharge while those filed after the said period shall be subjected to a 100% surcharge. In addition, the following has to be submitted:

_____ 1. Monthly Pest Control Operation Report.

Note:

Application with <u>incomplete</u> requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE DEALER | FPA-PRD-CL-13<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA form No. P-130 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. To be secured from the FPA Provincial Officer:
a. Report on inspection of facilities/Good Housekeeping Compliance
b. Recommendation

_____ 4. Proof of Training/Accreditation - Copy of Accredited Safety Dispenser's (ASD) ID

_____ 5. For members of the Agro-Dealers - Certificate of membership from the association in the province

_____ 6. List of registered pesticide products to be sold

_____ 7. Payment of license fee for three (3) years in money order & check. (Personal and out-of-town checks are not acceptable)

a. Agricultural Pesticide Dealer ---------- P 2, 500.00
Member of dealer association ---------- P 2, 000.00
b. Dealer of both Fertilizers / Pesticides ---------- P 4, 000.00
Member of dealer association ----------P 3, 200.00
c. Cooperative – 50% of license fee

Notes:

- A license is required for each dealership branch / outlet.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE SUPPLIER'S LOCAL REPRESENTATIVE/SUBSIDIARY | FPA-PRD-CL-14<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-170 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statement (FS)

_____ 4. Product Registration/contract/certification from the manufacturer/supplier

_____ 5. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PEST CONTROL OPERATOR - FUMIGATOR | FPA-PRD-CL-15<br>Revision 00 |
|---|---|

**I. For New Application:**

_____1. Duly accomplished and notarized FPA application form No. P-180
_____2. a. For Corporation / Partnership - Copy of SEC Registration and Articles Incorporation
b. For Cooperative - Copy of CDA Registration.
c. For Single Proprietorship- Copy of Certificate of Registration of Business Name with DTI
_____3. Copy of latest Income Tax Return (ITR) and Financial Statement (FS)
_____4. License Fee: ₱1,200.00/year
_____5. Recommendation / Inspection report from FPA Regional / Provincial Officer
_____6. Photocopy of Certified Pesticide Applicator (CPA) ID
_____7. Compliance on the Occupational Health and Safety Standards for CPA & technicians:

a. Complete and thorough physical examination.
b. Laboratory tests which shall include:

- Hematology (Hemoglobin, Hematocrit, Leucocyte count, and differential, reticulocyte and platelet count)
- Chest X-ray
- Urinalysis
- Fecalysis
- Biochemical monitoring (BUN, creatinine, uric acid, total protein, alkaline phosphatase, total cholesterol, SGOT and SGPT)

c. Certificate of "Fit to Work".

**II. For Renewal (Additional Requirement):**

Renewal of application shall be filed at least one (1) month before its expiry date. Application for renewal filed within one (1) month after the expiry date of its license shall be subjected to a 50% surcharge while those filed after the said period shall be subjected to a 100% surcharge. In addition, the following has to be submitted:

_____ 1. Monthly Pest Control Operation Report.

Note:

Application with <u>incomplete</u> requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSNG OF PESTICIDE NATIONAL DISTRIBUTOR | FPA-PRD-CL-16<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-160 with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of Latest Income Tax Return (ITR) and Financial Statements (FS)

_____ 4. Distributorship Agreement / Third Party Authorization (TPA) from the pesticide supplier(s)

_____ 5. Recommendation / Inspection Report from FPA Regional / Provincial Officer

_____ 6. Photo copy of Accredited Responsible Care Officer (ARCO) ID

_____ 7. Product Registration/contract/certification from the manufacturer/supplier

_____ 8. Registration of Pesticide Warehouse/s

_____ 9. List of Area Distributors

_____ 10. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR LICENSING OF PESTICIDE AREA DISTRIBUTOR | FPA-PRD-CL-17<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. 160A with documentary stamp

_____ 2. a. For Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation
b. For Cooperative - Copy of CDA Registration
c. For Single Proprietorship - Copy of Certificate of Registration of Business Name with DTI

_____ 3. Copy of latest Income Tax Return (ITR) and Financial Statement (FS)

_____ 4. Distributorship Agreement / Certificate from the pesticide supplier(s)

_____ 5. Recommendation / Inspection Report / Good Housekeeping Compliance from FPA Regional / Provincial Officer

_____ 6. Photocopy of Responsible Care Officer (RCO) / Accredited Responsible Care Officer (ARCO) ID

_____ 7. Registration of Pesticide Warehouse/s

_____ 8. List of Dealers

_____ 9. Corresponding fees (See attached schedule of fees.)

Notes:

- A license good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR CERTIFICATE AUTHORIZING IMPORTATION OF PESTICIDES (CAIP) | FPA-PRD-CL-18<br>Revision 00 |
|---|---|

____ 1. Photocopy of importer license
____ 2. Photocopy of Certificate of Product Registration (CPR) or Experimental Use Permit (EUP)
____ 3. Request letter specifying the:

a. Product, % purity if technical material or active ingredient if formulated product
b. Unit price
c. Quantity
d. Payment terms
e. Country of origin
f. Destination

____ 4. Pro-forma invoice
____ 5. Bill of lading
____ 6. Processing fee

CAIP Issuance
a) General Use---------- P 750.00
b) Red Labelled & Restricted Use---------- P 3,000.00
Amendment Certification ---------- P 750.00
Certification ---------- P 350.00

Note: Application with <u>incomplete</u> requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR EXPORT PERMIT | FPA-PRD-CL-19<br>Revision 00 |
|---|---|

——1. Photocopy of exporters license

——2. Photocopy of Certificate Product Registration (CPR) or Experimental Use Permit (EUP)

——3. Request letter specifying the:

a. Product, % purity if technical material or active ingredient if formulated product
b. Quantity
c. Batch number
d. Country of origin
e. Destination

——4. The exporter submits to the Authority the supply-demand analysis of the product/s intended to be exported to ensure that exportation is made only after satisfaction of local demand.

——5. The exporter submits a letter from the Ministry of Agriculture or relevant Regulatory Agency of the importing country to justify that the product to be exported is not banned nor restricted and allowed to be exported to the importing country.

——6. Processing Fee: P 1,500.00

Note: Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR OTHER CERTIFICATIONS | FPA-PRD-CL-20<br>Revision 00 |
|---|---|

____ 1. Request letter indicating the use / purpose of the product

____ 2. Safety Data Sheet (SDS) of the product

____ 3. Product brochure

____ 4. Processing Fee: P 350.00

Note: Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail add: fpacentral77@gmail.com Website: http://fpa.da.gov.ph

| CHECKLIST OF REQUIREMENTS FOR WAREHOUSE REGISTRATION | FPA-PRD-CL-21<br>Revision 00 |
|---|---|

_____ 1. Duly accomplished and notarized FPA application form No. P-140 with documentary stamp

_____ 2. Recommendation/Inspection report from FPA Regional/Provincial Officer

_____ 3. Corresponding fees (See attached schedule of fees.)

Notes:

- A warehouse registration good for one (1) year shall be issued upon approval of application.
- Application with incomplete requirements will NOT be accepted.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

## Documentary Requirements for the Licensing of Pesticide Handlers / PCO / DSO / Dealers / Warehouse Registration

| REQUIREMENTS | Dealer | Importer-Distributor | National Distributor | Area Distributor | Indentor | Pesticide Supplier Local Subsidiary/ Representative | Exporter | Manufacturer | Formulator | Repacker | Extruder | End-User/ Institutional User | *PCO | DSO | Warehouse Registration |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Duly accomplished and notarized application form (original copy) with documentary stamps. | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 2. For:<br>a. Corporation/Partnership - Copy of SEC Registration and Articles of Incorporation.<br>b. Cooperative - copy of CDA Registration.<br>c. Single Proprietorship - copy of certificate of Registration of Business Name with DTI. | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | |
| 3. Copy of latest Financial Statements (FS) and ITR | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | |
| 4. Recommendation / Inspection report / Good House Keeping Compliance from FPA Regional / Provincial Officer. | ✔ | ✔ | ✔ | ✔ | | | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |
| 5. Proof of training / Accreditation<br>- copy of Accredited Safety Dispenser (ASD) ID | ✔ | | | | | | | | | | | | | | |
| 6. For members of Agro-Dealers Association<br>- Certificate of membership from the association. | ✔ | | | | | | | | | | | | | | |
| 7. List of registered agricultural pesticide products to be sold. | ✔ | | | | | | | | | | | | | | |
| 8. Distributorship agreement / Certification from the pesticide supplier / Third Party Authorization (TPA) pesticide supplier. | | ✔ | ✔ | ✔ | | | | | | | | | | | |
| 9. Photo copy of Responsible Care Officer (RCO) / Accredited Responsible Care Officer (ARCO) ID | | ✔ | ✔ | ✔ | | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 10. Registration of pesticide warehouse/s | | ✔ | ✔ | ✔ | | | | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 11. Product Registration / contract / certification from the manufacturer / supplier. | | ✔ | ✔ | | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 12. List of Area Distributors. | | ✔ | ✔ | | | | | | | | | | | | |
| 13. The supply-demand analysis of the product/s intended to be exported to ensure that exportation is made only after satisfaction of local demand. | | | | | | | ✔ | | | | | | | | |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
FERTILIZER AND PESTICIDE AUTHORITY
FPA Bldg. B.A.I. Compound Visayas Ave. Diliman, Quezon City P.O. Box 2582, Q.C.
Tel. Nos. 920-8173*920-8573*922-3368-441-1601
E-mail address: fpacentral77@gmail.com
Website: http://fpa.da.gov.ph

| REQUIREMENTS | Dealer | Importer-Distributor | National Distributor | Area Distributor | Indentor | Pesticide Supplier Local Subsidiary/ Representative | Exporter | Manufacturer | Formulator | Repacker | Extruder | End-User/ Institutional User | *PCO | DSO | Warehouse Registration |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 14. Letter from the Department of Agriculture or relevant Regulatory Agency of the importing country to justify that the product being exported is not banned nor restricted - allowed to be exported to the importing country. | | | | | | | ✔ | | | | | | | | |
| 15. Copy of Environmental Compliance Certificate (ECC) and Permit to Operate (PTO) with DENR. | | | | | | | | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 16. Production process / Flowchart. | | | | | | | | ✔ | ✔ | ✔ | ✔ | | | | |
| 17. Written Authority to repack / formulate / extrude from the supplier. | | | | | | | | ✔ | ✔ | ✔ | ✔ | | | | |
| 18. Compliance of FPA Manual on Occupational and Technical Safety of Pesticide.<br>a. Occupational Health and Safety Program (OHSP)<br>b. Medical Health Examinations and certificate of "Fit to Work" of workers | | | | | | | | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 19. Pre/Post-licensing inspection by the Pesticide Safety Audit Team. | | | | | | | | ✔ | ✔ | ✔ | ✔ | ✔ | | | |
| 20. Annual Capacity and Output. | | | | | | | | ✔ | ✔ | ✔ | ✔ | | | | |
| 21. Authorization letter from pesticide company who register the product. | | | | | | | | | | | | ✔ | | | |
| 22. Monthly Pest Control Operation Report - Renewal | | | | | | | | | | | | | ✔ | ✔ | |
| 23. Compliance on the Occupational Health & Safety Standards for CPA & Technicians. | | | | | | | | | | | | | ✔ | | |
| 24. Compliance on the Occupational Health & Safety Standards for Drone Controller & Spray Operation Crew | | | | | | | | | | | | | | ✔ | |
| 25. Photo copy of CPA ID | | | | | | | | | | | | | ✔ | | |
| 26. Photocopy of Drone Controller and Spray Operation Crew ID | | | | | | | | | | | | | | ✔ | |
| 27. List of Dealers | | | | ✔ | | | | | | | | | | | |
| 28. Filing / license fee (see attached scheduled and fees) | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ | ✔ |

*Pest Control Operator (PCO)

*Drone Spraying Operator (DSO)

## *Annex VII*

## *RISK APPRAISAL CHECKLIST FOR "GOOD HOUSEKEEPING COMPLIANCE CERTIFICATE"*

## RISK APPRAISAL CHECKLIST FOR WAREHOUSE/ STORES

Name of Establishment:_____ Date:_____

Address:_____ Auditors:_____

| APPRAISAL ITEM | SCORE 1 | ✓ | 2 | ✓ | 3 | ✓ | 4 | ✓ |
|---|---|---|---|---|---|---|---|---|
| **MAJOR** | | | | | | | | |
| Capability for dealing with leaks/spills i.e. does he carry absorbent material, PPE, care cart? Containment of contaminated water or firewater run-off? | All the necessary equipment is in good condition; readily accessible; adequate containment of spills, fire water or runoff | | All the necessary equipment is in good condition; not readily accessible; partial containment of spills, firewater or runoff water. | | Some necessary equipment available; poor containment of spills, firewater or runoff water. | | No capability at all | |
| Ventilation | Good | | Fair | | Marginal | | Poor | |
| Housekeeping/tidiness | Good | | Fair | | Marginal | | Poor | |
| Product storage/ stacking/ display | Ordered, neat, stable, easily accessible | | Room for improvement | | Not very well ordered | | Generally haphazard. Poor stack stability | |
| Capability for fighting small fires, i.e. availability of handheld extinguishers. Number, positioning and maintenance Okay? | Sufficient No. of extinguishers positioned and serviced. Personnel trained to use them. | | Insufficient No. but adequately serviced with at least one person trained to use them. | | Extinguishers available but inadequately serviced. Access difficult; doubts about ability to use them. | | No extinguishers available. | |
| General Attitude towards health and safety i.e. appreciation of hazard/ safety awareness. | Good | | Fair | | Marginal | | Poor | |
| Hygiene standard i.e. facilities for washing, consumption of food/ drink in work area | Washing facilities that are used. Separate eating area. | | Washing facilities that are used. No separate eating area. | | Inadequate washing facilities. No separate eating area. | | Poor | |
| Waste disposal (presence of water e.g. broken bottles/ packages/ spills etc.) | None | | Small amount | | Moderate | | Poor | |
| Animal feeds/ fertilizers/ foodstuff/etc. | Such products not stored | | Stored in a physically separate area. | | Stored in the same area but not adjacent to pesticides. | | Stored adjacent to pesticides. | |
| TOTAL SCORE: MAJOR ITEMS | | | | | | | | |

ASSESSMENT: (MAJOR APPRAISAL ITEMS)

| | |
|---|---|
| 9-18: | Generally acceptable standard; can be further improved by attention to specific aspects. |
| 19-24: | Minimum acceptable standard; remedial action or improvement maybe required to be done within 6 months to one year one specific aspect |
| 25-30: | Less than acceptable standard; immediate remedial action or improvements required for continued operation. |
| 31-36: | High risk. Definitely not acceptable. Immediate closure/suspension of operations should be recommended until significant improvements in standards are achieved. |

| APPRAISAL ITEM | SCORE 1 | ✓ | 2 | ✓ | 3 | ✓ | 4 | ✓ |
|---|---|---|---|---|---|---|---|---|
| **SUPPLEMENTARY** | | | | | | | | |
| Emergency exit | Exits clearly marked, accessible and easily operable | | Exits accessible and easily operable but not clearly marked | | With exits but obstructed or locked | | Does not have exits | |
| Response time of fire service | Less than 10 min | | Less than 30 min. | | More than 30 min. | | No realistic response | |
| Security when closed | Premises securely locked. Windows guarded, etc. | | Premises securely locked but access could be achieved e.g. via unguarded windows | | Premises locked but access could be achieved with relatively little effort | | No realistic security whatsoever | |
| Floor construction | Impermeable to liquids, no open drains | | Predominantly impermeable to liquids, no open drains | | Predominantly impermeable to liquids, with open drains | | Permeable to liquids and/or open drains | |
| Environmental risk i.e. proximity to homes/ shops/ schools/ waterways/ etc. | More than 100 meters away | | 15-100 meters away | | Not directly adjacent but less than 15 meters away | | Directly adjacent | |
| Materials of construction | Non-combustible | | More than 70% non-combustible | | Less than 70% non-combustible | | Combustible | |
| TOTAL SCORE: SUPPLEMENTARY ITEMS | | | | | | | | |

ASSESSMENT: (SUPPLEMENTARY ITEMS)

| | |
|---|---|
| 6-12: | Generally acceptable standard, can be further improved by attention to specific aspects. |
| 13-18: | Minimum acceptable standard, remedial action or improvement maybe required within 6 months to one year |
| 19-24: | Not acceptable standard, immediate remedial action on major improvements required. |

RECOMMENDATIONS: (Indicate specific improvements needed, timetable, etc. Use separate sheet if necessary)

_____

_____

_____

_____

_____

_____

CONFORME: _____

Owner/ Authorized Representative
Signature above printed name

# *Annex VIII*

# *LIST OF BANNED AND RESTRICTED PESTICIDES*

## BANNED AND RESTRICTED PESTICIDES IN THE PHILIPPINES[1]

## RATIONALE

Pesticides have been of great benefit to agriculture. They have minimized crop damage by insects, weeds, plant diseases, rodents and other pests. They have saved lives through control of disease-carrying insects. Generally, they have provided a higher quality of life for man.

Pesticides, however, are poisons that, if used improperly or without sufficient knowledge of their side effects, can endanger man and animals. Moreover, potential hazards to human health and wildlife can be created by residues from some persistent pesticides that may build-up in the food chain and cause contamination of the environment.

Given the benefits of pesticides, the critical challenge now is to institute strong and extensive mechanisms to prevent pesticides from harming human health and the environment. The primary purpose of Presidential Decree 1144, creating the Fertilizer and Pesticide Authority (FPA), is to address this challenge. It does so through a process of pesticide registration.

Registration of pesticides, active ingredients and formulations, is one of the most basic operations of pesticide regulatory agencies. This mechanism ensures that any pesticide made available to the end-users is considered safe for use through the examination of the data in support of its registration submitted by the manufacturers through their distributors. Biological efficacy, chemical, physical and toxicological data are evaluated.

As a result of this evaluation process, compounds have been classified into **banned** and **restricted pesticides**.

BANNED PESTICIDES are not to be brought into, and used, in this country, under any circumstances.

---

[1]As amended by Pesticide Circular No. 4, Series of 1989, and FPA Board Resolution Nos. 01 (1993) and 01 (1999).

## GUIDELINES ON RESTRICTED PESTICIDES

A restricted pesticide is covered by two basic guidelines:

A. They may not be allowed for distribution, sale and use in certain crops and/or areas of the country, and;

B. They may be used only by and under the supervision of certified applicators, or under such conditions as the FPA Administrator may require.

## CLASSIFICATION OF RESTRICTED PESTICIDES

The list of restricted pesticides is categorized as follows:

1. Those which are not for importation except in cases of emergency. Such cases are to be determined by the Authority.

2. Those to be used for ***termite control only***.

3. Those to be used under ***specific limitations***.

4. Fumigants and other chemicals for use only by ***certified fumigators***.

**STOP SALE**
**STOP USE**
**REMOVAL AND**
**HOLD ORDER**

When a pesticide is being offered for sale or used in violation of this Restriction Notice, the FPA through its authorized representative, may issue and enforce stop sale, stop use, removal or hold order to the owner or custodian of said pesticide, offering it to be held at a designated place until the law or the Rules and Regulations of this Authority shall have been complied with; or until all said violations have been disposed by the proper authorities.

The provisions of Presidential Decree 1144 and the FPA Rules and Regulations and their penal provisions shall apply for violations of this circular.

**BANNED AND RESTRICTED PESTICIDES IN THE PHILIPPINES**

## I. Banned Pesticides

1. Parathion-ethyl
2. Copper aceto-arsenite (Paris Green)
3. DDT containing mosquito coil
4. DBCP
5. Nitrofen
6. Leptophos
7. EPN
8. Endrin
9. Mercuric fungicides
10. Toxaphene
11. Elemental phosphorus (white and yellow)
12. Thalium sulfate
13. 1-Naphthylthiourea (ANTU)
14. Gophacide
15. Sodium fluoroacetate
16. Sodium fluoroacetamide (1081)
17. Strychnine
18. 2, 4, 5-T
19. Aldrin
20. Dieldrin
21. Heptachlor
22. Chlorodimeform
23. EDB
24. HCH/BHC
25. Methyl parathion
26. Organotin compounds
27. Azinphos Ethyl
28. Chlordane

## II. Restricted Pesticides

### A. Importation Not Allowed Except in Cases of Emergency as Determined by the Authority

1. Aldicarb
2. Chlorobenzilate

### B. For Use Under Specific Limitations

1. DDT - All uses cancelled except for malaria control purposes by the Department of Health.

2. Endosulfan - Not for use near aquatic system and in paddy rice. The concentration will be reduced to 5% EC or lower for other uses (FPA Board Resolution No. 01, 1993).

3. Monocrotophos – Allowed use is for beanfly control on legumes only (FPA Board Resolution No. 01, 1993).

4. Too Hazardous for General Use
(For Institutional Use Only)

   a. Paraquat - Restricted for Institutional Use Only. Approval of use will be based on strict compliance by the importer/end-user of the requirements set for its use.

   b. Phenamiphos - For use in banana and pineapple plantations only.

   c. Ethoprop - For use in banana plantations only.

   d. Methidathion - For use in banana plantations only.

   e. Inorganic Arsenicals (Arsenic Trioxide) - For use by FPA accredited wood treatment and wood preserving plants only.

   f. Lindane (Gamma/BHC) - The only allowed use to date is on pineapple plantations by soil pre-plant application.

   g. Pentachlorophenol - For use in wood treatment only by FPA accredited wood treatment plants and institutions.

**C. Fumigants and Other Chemicals for Use Only by Certified Fumigators**

Adequate time for aeration after treatment is required before commodities are processed into food or feed.

1. Methyl bromide
2. Carbon disulfide
3. Phosphine generating compounds
4. HCN-generating materials
5. Carbon tetrachloride
6. Chloroform
7. Ethylformate

# *Annex IX*

# *ADDITIONAL CIRCULARS ON RESTRICTIONS OF SPECIFIC PESTICIDE PRODUCTS*

Republic of the Philippines
FERTILIZER AND PESTICIDE AUTHORITY
6th Floor Raha Sulayman Building
Benavidez Street, Makati, Metro Manila

Pesticide Circular No. 1
Series of 1981

T O : All Pesticide Importers

SUBJECT Pesticide Importation Requirements

* * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * * *

Effective January 31, 1981 no request for importation of pesticide shall be processed unless the following requirements are fully satisfied.

1. The importer must be licensed by FPA.
2. The pesticide product(s) and active ingredient(s) must bear either full or provisional registration, or covered by the appropriate Experimental Use Permit.
3. The following must be specified in the request for importation:

   a. Product
   b. Unit Price
   c. Quantity
   d. Payment Terms
   e. Country of Origin
   f. Destination
   g. Carrier/Vessel

4. The pro-forma invoice must be attached. This shall enable FPA to correlate the source of supply to the registration of the product.
5. The bill of lading, verifying that the above transaction transpired at the term(s) and price(s) stated on the pro-forma invoice must be attached to the subsequent request for importation.

Please be guided accordingly.

MIGUEL M. LOSA
Administrator

December 15, 1989

Pesticide Circular No. 04
Series of 1989

To: : All Concerned

Subject : REVISED LIST OF BANNED AND RESTRICTED PESTICIDES IN THE PHILIPPINES

Pursuant to its declared regulatory policy of conducting a periodic evaluation of the existing list of Banned and Restricted Pesticides in the Philippines (Pesticide circular No. 9 Series of 1981 is amended and superceded by Pesticide Circular No. 5 Series of 1983) this Authority hereby releases this newly revised list.

This new list specifically addresses the so-called Dirty Dozen issue. The policy recommendations were discussed with the agricultural pesticide industry in consonance with existing protocols on regulatory actions by this Authority.

With the concurrence of the Chairman of the Board, Secretary Carlos G. Dominguez, this list is being issued and shall be effective immediately. It supercedes all previous lists, specifically Pesticide Circular No.9 Series of 1981 and Pesticide Circular No. 5 Series of 1983.

For your immediate compliance.

(SGD)
LUIS T. VILLA-REAL, JR.
Executive Director III

## FPA REGULATORY POLICY ON THE DIRTY DOZEN PESTICIDES[2]

| PESTICIDE | PREVIOUS REGULATORY STATUS | NEW REGULATORY POLICY |
|---|---|---|
| 1. PARATHION (Ethyl) | BANNED | CONTINUE BAN STATUS |
| 2. 2,4,5-T | - RESTRICTED FOR EMERGENCY CASES ONLY AS MAY BE DETERMINED BY THE AUTHORITY<br>- NO EXISTING REGISTRATION WITH FPA | BANNED |
| 3. PARAQUAT | RESTRICTED FOR INSTITUTIONAL USE ONLY | RESTRICTED FOR INSTITUTIONAL USE ONLY. APPROVAL OF USE WILL BE BASED ON STRICT COMPLIANCE BY THE IMPORTER/ END-USER OF THE REQUIREMENTS SET FOR ITS USE. |
| 4. DDT | RESTRICTED FOR USE ONLY BY THE DEPARTMENT OF HEALTH FOR MALARIA CONTROL | RESTRICTED<br><br>ALL USES CANCELLED EXCEPT FOR MALARIA CONTROL PURPOSES OF THE DEPARTMENT OF HEALTH |
| 5. ENDRIN<br><br>DIELDRIN<br><br>ALDRIN | BANNED<br><br>RESTRICTED<br><br>RESTRICTED FOR TERMITE CONTROL ONLY | CONTINUE BANNED STATUS<br><br>BANNED<br><br>BANNED |
| 6. CHLORDIMEFORM | - NO EXISTING REGISTRATION WITH FPA<br>- NO CURRENT RESTRICTION | BANNED |
| 7. DBCP | BANNED | - CONTINUE BANNED STATUS |

[2] Attachment to Pesticide Circular No.4, Series of 1989

| PESTICIDE | PREVIOUS REGULATORY STATUS | NEW REGULATORY POLICY |
|---|---|---|
| 8. CHLORDANE | RESTRICTED FOR TERMITE CONTROL ONLY BY FPA CERTIFIED APPLICATORS | BANNED |
| HEPTACHLOR | - RESTRICTED FOR TERMITE CONTROL ONLY BY FPA CERTIFIED APPLICATORS<br>- RESTRICTED USE IN PINEAPPLE PLANTATIONS FOR CONTROL OF WHITE GRUBS | BANNED |
| 9. HCH | RESTRICTED FOR DIRECT IMPORTATION IN SUGAR PLANTATION | BANNED |
| LINDANE/ GAMMA BHC | NO CURRENT RESTRICTION | RESTRICTED<br>THE ONLY ALLOWED USE TO DATE IS ON PINEAPPLE PLANTATIONS BY SOIL PRE-PLANT APPLICATION |
| 10. ETHYLENE DIBROMIDE (EDB) | RESTRICTED | BANNED |
| 11. CAMPECHLOR/ TOXAPHENE | - NO CURRENT RESTRICTION<br>- NO EXISTING APPLICATION FOR REGISTRATION WITH FPA | BANNED |
| 12. PCP (PENTACHLOROPHENOL) | NO CURRENT REGULATORY ACTION | SEVERELY RESTRICTED FOR WOOD TREATMENT ONLY BY FPA ACCREDITED WOOD TREATING PLANTS AND INSTITUTIONS. |

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
**FERTILIZER AND PESTICIDE AUTHORITY**
4TH FLOOR, BUILDING B, NIA COMPLEX, EDSA, QUEZON CITY
Tel Nos. 929-6071 LOC 123, 922-3362, 922-3364, 922-3368, 922-3371
Tel/Fax Nos. 922-3355, 922-3368
P.O. Box 2582 QUEZON CITY

We the members of the Board of Directors of the Fertilizer and Pesticide Authority, through our authorized representatives, at the meeting held on 20 April 1999 at the OSEC Conference Room, Department of Agriculture, do hereby ratify the following Resolutions as indicated by the signatures appearing below.

## RESOLUTION NO. 01-99

Approving the Recommendation of the Pesticide Policy and Technical Advisory Committee (PPTAC) banning the use of Chlordane and its formulated products in the Philippines. Such a recommendation was duly endorsed by the Fertilizer and Pesticide Authority (FPA). Companies engaged in the formulation, distribution and marketing of Chlordane or any product containing Chlordane are given fifteen (15) days after publication of this notice to dispose of their stocks.

Chlordane or any product containing Chlordane found in the possession of distributors or dealer fifteen (15) days after the publication of this notice shall be confiscated by the government for proper disposal at the expense of the importer/dealers as part of their product stewardship responsibility. Pest Control Operators who may have stocks of Chlordane in their possession are given three (3) months from publication to phase-out their stocks. Thereafter, the remaining stocks shall be confiscated for proper disposal at the expense of the holder.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
**FERTILIZER AND PESTICIDE AUTHORITY**
4TH FLOOR, BUILDING B, NIA COMPLEX, EDSA, QUEZON CITY
Tel Nos. 929-6071 LOC 123, 922-3362, 922-3364, 922-3368, 922-3371
Tel/Fax Nos. 922-3355, 922-3368
P.O. Box 2582 QUEZON CITY

# IMPLEMENTING GUIDELINES ON FPA BOARD RESOLUTION NO.01 (1993) ON ORGANOTIN, AZINPHOS ETHYL, METHYL PARATHION, ENDOSULFAN AND MONOCROTOPHOS

CONSISTENT WITH THE FPA PESTICIDE REGULATORY POLICIES AND THE IMPLEMENTING GUIDELINES AND PROCEDURES, SPECIFICALLY SECTION VI UNDER THE HEADING "RESTRICTIONS ON AVAILABILITY AND USE". THIS IMPLEMENTING GUIDELINES ON FPA BOARD RESOLUTION NO. 01 (1993) ARE HEREBY PROMULGATED.

## GENERAL INFORMATION

ALL PESTICIDES ARE INHERENTLY TOXIC IN NATURE; THEREFORE NOT ALL OF THEM SHALL BE ALLOWED FOR USE BY THE GENERAL PUBLIC. SOME PESTICIDES NEED TO BE BANNED OR RESTRICTED TO AVOID POSSIBLE UNSAFE SITUATIONS FOR THE APPLICATOR AND THE ENVIRONMENT.

SECTION 6, III (3) OF P.D. 1144, VESTED FPA WITH THE POWERS AND FUNCTIONS:

" TO RESTRICT OR BAN THE USE OF ANY PESTICIDE OR THE FORMULATION OF CERTAIN PESTICIDE IN SPECIFIC AREAS OR DURING CERTAIN PERIODS UPON EVIDENCE THAT THE PESTICIDE IS AN IMMINENT HAZARD, HAS CAUSED, OR IS CAUSING WIDESPREAD SERIOUS DAMAGE TO CROPS, FISH OR LIVESTOCK OR TO PUBLIC HEALTH AND THE ENVIRONMENT. "

FURTHER, ARTICLE II SECTION 5 OF THE FPA RULES AND REGULATIONS NO.1 SERIES OF 1977, PROVIDES ADDITIONAL LEGAL BASIS FOR RESTRICTIONS ON AVAILABILITY AND USE OF PESTICIDES.

## FPA BOARD RESOLUTION AND IMPLEMENTATION

ON SEPTEMBER 29, 1993, THE FPA BOARD OF DIRECTORS, MEETING *EN BANC*, UNANIMOUSLY APPROVED THE FOLLOWING PESTICIDE POLICY DECISIONS:

BAN FROM ALL USES IN AGRICULTURE

1. ORGANOTIN COMPOUNDS
2. AZINPHOS ETHYL
3. METHYL PARATHION

RESTRICT FROM BEING USED IN PADDY RICE

1. ENDOSULFAN- THE CONCENTRATION WILL BE REDUCED TO 5% E.C. OR LOWER FOR OTHER USES.
2. MONOCROTOPHOS- THE ALLOWED USE IS FOR BEANFLY CONTROL ON LEGUMES ONLY;

THIS PESTICIDE POLICY DECISION WILL BE INCLUDED IN THE EXISTING FPA LIST OF BANNED AND RESTRICTED PESTICIDES IN THE PHILIPPINES (PESTICIDE CIRCULAR NO. 04 SERIES OF 1989, DECEMBER 15, 1989)

CHANGE OF LABEL

LABEL OF ENDOSULFAN AND MONOCROTOPHOS AND MIXTURES THEREOF I OTHER FORMULATIONS WILL BE CHANGED TO CONFORM WITH THE PRODUCT RESTRICTIONS AS STATED IN THIS GUIDELINES.

## FORMULATIONS WITH MORE THAN ONE ACTIVE INGREDIENTS

1. ANY MIXTURES OF AZINPHOS ETHYL AND/OR METHYL PARATHION WITH OTHER ACTIVE INGREDIENTS IN ANY FORMULATION IS NOT ALLOWED.
2. ANY COMBINATION OF ENDOSULFAN WITH OTHER ACTIVE INGREDIENTS IN ANY FORMULATION MAY BE ALLOWED IF THE ENDOSULFAN CONCENTRATION IS 5% OR LOWER PROVIDED THAT IT DOES NOT INCREASE THE INHERENT TOXICITY OR HAZARD OF THE COMBINATION AND MUST NOT BE USED IN PADDY RICE.
3. ANY COMBINATION OF MONOCROTOPHOS WITH OTHER ACTIVE INGREDIENTS IN ANOTHER FORMULATION MAY BE ALLOWED FOR BEANFLY CONTROL ON LEGUMES ONLY PROVIDED THAT IT DOES NOT INCREASE THE INHERENT TOXICITY OR HAZARD OF THE COMBINATION.

## PHASE OUT PERIOD

1. AZINPHOS ETHYL AND METHYL PARATHION MAYBE ALLOWED I THE MARKET WITHIN THE SIX MONTH PERIOD ENDING MARCH 29, 1994.

   AT THE CONCLUSION OF THE SIX MONTH PHASE OUT PERIOD, COMPANIES DISTRIBUTING THE AFORENAMED BANNED PRODUCTS SHALL WITHDRAW THEIR RESPECTIVE COMMODITIES FROM THE DEALER'S SHELVES FOR INCINERATION OR EXPORTATION IN THE CASE OF ORGANOTIN COMPOUNDS. FPA CIRCULAR NO.1 SERIES OF 1990, DATED OCTOBER 4, 1990 PROVIDING FOR THE IMMEDIATE SUSPENSION OF THE SALE AND USE OF ORGANOTIN COMPOUNDS SHALL CONTINUE TO BE IN FORCE AND IN EFFECT.
2. FOR ENDOSULFAN, ONLY 5% E.C. OR LOWER FORMULATIONS SHALL BE ALLOWED IN THE MARKET UPON COMPLIANCE OF FPA REGISTRATION REQUIREMENTS. FORMULATION HIGHER THAN 5% SHALL NOT BE ALLOWED. THE SALE OF STOCKS OF REGISTERED FORMULATIONS HIGHER THAN 5% MAYBE ALLOWED WITHIN THE SIXMONTH PHASE OUT PERIOD.
3. MONOCROTOPHOS SHALL BE RESTRICTED FOR BEANFLY CONTROL. THE SALE OF MONOCROTOPHOS MAYBE ALLOWED FOR ITS REGISTERED USE WITHIN THE SIX MONTH PERIOD EFFECTIVE SEPTEMBER 29, 1993.

## IMPORTATION

PROCESSING OF ALL REQUESTS FOR CERTIFICATE AUTHORIZING IMPORTATION OF PESTICIDE (CAIP) FOR AZINPHOS ETHYL AND METHYL PARATHION SHALL BE DISCONTINUED EFFECTIVE SEPTEMBER 29, 1993. APPROVAL OF REQUESTS FOR CAIP FOR MONOCROTOPHOS AND ENDOSULFAN SHALL BE BASED ON THE STOCK INVENTORY OF THE PRODUCTS AND THE PROJECTED ALLOWED USAGE.

## STOCKS INVENTORY

ALL CONCERNED COMPANIES SHALL CONDUCT INVENTORY OF ALL EXISTING WAREHOUSE STOCKS AT THE START AND THE END OF THE PHASE OUT PERIOD. A CERTIFIED TRUE COPY OF THE INVENTORY SHALL BE SUBMITTED TO FPA SUBJECT TO VERIFICATION.

## ADVERTISING, PROMOTIONAL AND PERIPHERAL MATERIALS

ALL EXISTING ADVERTISING, PROMOTIONAL AND PERIPHERAL MATERIALS ON THE FOLLOWING BANNED PESTICIDES: ORGANOTIN COMPOUNDS, AZINPHOS ETHYL AND METHYL PARATHION. SIMILAR ACTIVITIES ON THE RESTRICTED PESTICIDES: ENDOSULFAN AND MONOCROTOPHOS NOT IN ACCORD WITH THEIR ALLOWED USE SHALL BE PROHIBITED.

## PRODUCT AND COMPANY COVERAGE

THE FOLLOWING BRAND NAMES AND COMPANIES REGISTERED WITH FPA ARE COVERED:

| GENERIC NAME | BRAND NAME | COMPANY |
|---|---|---|
| ORGANOTIN | BRESTAN | HOESCHT |
| ORGANOTIN | AQUATIN 20 EC | PLANTERS PRODUCTS |
| ORGANOTIN | TELUSTAN 60 WP | SHELL CHEMICALS |
| AZINPHOS ETHYL | GUSATHION 400 EC | BAYER |
| AZINPHOS ETHYL | MARSATHION 40 EC | MARSMAN |
| AZINPHOS ETHYL | BIONEX 40 EC | PLANTERS PRODUCT |
| AZINPHOS ETHYL | TELOTHION 40 EC | SHELL CHEMICALS |
| METHYL PARATHION | FOLIDOL M 50 EC | BAYER |
| METHYL PARATHION | METHYL FOSFERNO 50 EC | JARDINE DAVIES |
| METHYL PARATHION | METHION 50 EC | MARSMAN |
| METHYL PARATHION | MEPTOX 50 EC | SHELL CHEMICALS |
| METHYL PARATHION | PARAPEST M 50 EC | PLANTERS PRODUCT |
| METHYL PARATHION | PENNCAP M (ENCAP) | ALDIZ |
| METHYL PARATHION | WOFATOX 50 EC/ 80 EC | CHEMIE INTERNATIONAL |
| METHYL PARATHION | WOFATOX KONZENTRAT 50 EC/ 80 EC | TOMAS YAP TRADING |
| ENDOSULFAN+ BPMC | THIOCARB 47 EC | HOECHST |
| ENDOSULFAN | THIODAN 35 WP | HOECHST |
| ENDOSULFAN | THIODAN 35 EC | HOECHST |
| ENDOSULFAN | ENDOSULFAN 35 EC | MARSMAN |
| ENDOSULFAN | ENDOX 35 EC | PLANTERS PRODUCT |
| ENDOSULFAN | THIODAN 2.5 G | HOECHST |
| ENDOSULFAN | ENDOSULFAX 35 EC | ALDIZ |
| MONOCROTOPHOS | NUVACRON 30 SCW | CIBA-GEIGY |
| MONOCROTOPHOS | AZODRIN 16% | SHELL CHEMICALS |
| MONOCROTOPHOS | AZODRIN 202 R | SHELL CHEMICALS |
| MONO+FENVALERATE | AZODRIN 150 | SHELL CHEMICALS |
| MONO+MEVINPHOS | AZODRIN 202 | SHELL CHEMICALS |
| MONO+CYPERMETHRIN | AZODRIN137 | SHELL CHEMICALS |

## PENAL PROVISIONS

ANY VIOLATIONS OF ANY OF THE PROVISIONS OF THESE IMPLEMENTING GUIDELINES ISSUED OR PROMULGATED BY FPA COMMITTED BY ANY PERSON, CORPORATION, FIRM, PARTNERSHIP, COOPERATIVE, ASSOCIATION OR ANY OTHER ENTITY, SHALL BE COVERED BY PENAL PROVISIONS UNDER SECTION 8 (C) OF P.D. 1144 AND ARTICLE IV SECTION 1 (A) OF THE RULES AND REGULATIONS.

(SGD)
FRANCISCO C. CORNEJO
EXECUTIVE DIRECTOR III
SEPTEMBER 30, 1993

*" Better harvest, health and environment through safe and judicious use of fertilizers and pesticides"*

# *Annex X*

# *CROP GROUPINGS*

## CROP GROUPINGS[1]

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **GROUP 1 - ROOT AND TUBER VEGETABLES** | |
| Root and tuber vegetables are starchy foods derived from the enlarged solid roots, tubers, corms or rhizomes, mostly subterranean, of various species of plants. The underground location usually protects the edible portion from pesticides applied during the growing season. The entire vegetable may be consumed. | |
| ***Root and tuber vegetables:*** | Whole commodity after removing tops. Wash the roots or tubers in cold running water, brushing gently with a soft brush to remove loose soil debris, if necessary, and then dab lightly with clean tissue paper to dry. For carrots, after drying the tops are carefully cut off with a knife by cutting through the bottom of the stem at the lowest point of attachment of the outer petioles. If an annulus of root tissue is thereby severed from hollow-crown roots, the material should be re-combined with the roots. |
| Arrowroot<br>Beets, Sugar<br>Carrot<br>Cassava, Bitter or Sweet<br>Ginger<br>Parsley<br>Parsnips<br>Potato<br>Potato, sweet<br>Radish<br>Taro<br>Tugui<br>Turmeric<br>Turnip<br>Water chestnut<br>Yam, True (ubi)<br>Yam Bean (Singkamas) | |
| ***Representative Commodities*** | |
| Carrot<br>Radish<br>Potato | |

[1] Adopted from FAO Manual on Submission and Evaluation of Pesticide Residues Data for the Estimation of MRL (Appendix VI).

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 2 - BULB VEGETABLES** | |
| Bulb vegetables are pungent flavorful foods derived from the fleshly scale bulbs, or growth buds of alliums of the lily family (*Liliaceae*). Subterranean growth protects the bulb from the direct application of pesticide during the growing season. The entire bulb may be consumed following the removal of the parchment-like skin. | |
| ***Bulb Vegetables:***<br>Garlic<br>Leek<br>Onion, Green and bulb<br>***Representative Commodities***<br>Onion, Green and bulb | Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity).<br>Bulb/dry onions and garlic:<br>Whole commodity after removal of roots and whatever parchment skin is easily detached.<br>Leeks and spring onions:<br>Whole commodity after removal of roots and adhering soil. |
| **Group 3 - LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES)** | |
| Leafy vegetables (except Group 4 vegetables) are foods derived from the leaves of a wide variety of edible plants including leafy parts of Group 1 vegetables. These leaves are fully exposed to pesticides applied during the growing period. The entire leaf may be consumed. Leafy vegetables of the brassica family are grouped separately. | |
| ***Leafy Vegetables:***<br>Alugbati<br>Celery<br>Kangkong<br>Lettuce, Head and leafy<br>Melon, Bitter, leaves<br>Pepper leaves<br>Saluyot<br>Spinach<br>Squash<br>Beets, sugar, leaves<br>Carrot, leaves<br>Cassava, Bitter or sweet<br>Parsnips, leaves<br>Potato, Sweet, leaves<br>Radish, leaves<br>Taro, leaves<br>Turnip, leaves<br>Malunggay<br>***Representative Commodities***<br>Lettuce<br>Spinach<br>Potato, sweet, leaves | Whole commodity after removal of obviously decomposed or withered leaves. |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 4 - BRASSICA (COLE) LEAFY VEGETABLES** | |
| Brassica (cole) leafy vegetables are foods derived from the leafy parts, stems and immature inflorescences of plants commonly known and botanically classified as brassicas and also known as cole vegetables. The edible parts are fully exposed to pesticides applied during the growing season. The entire vegetable may be consumed. | |
| ***Brassica leafy vegetables:***<br>Brocolli<br>Brussel sprouts<br>Cabbage<br>Cabbage, Chinese<br>Cabbage, Savoy<br>Cauliflower<br>Mustard<br>Mustard, Chinese (Pechay)<br>***Representative Commodities***<br>Cabbage<br>Pechay | Whole commodity after removal of obviously decomposed or withered leaves. For cauliflower and headed broccoli, analyze flower head and stems, discarding leaves. For sprouts, analyze "buttons" only. |
| **Group 5 - STEM VEGETABLES** | |
| Stem vegetables are foods derived from the edible stems or shoots of a variety of plants. | |
| ***Stem vegetables:***<br>Artichoke<br>Asparagus<br>Bamboo shoots<br>Banana Heart<br>Celery<br>Chicory (wit loof)<br>Gabi Stalk<br>Rhubarb | Whole commodity after removal of obviously decomposed or withered leaves.<br>Rhubarb and asparagus: stems only.<br>Celery and asparagus: remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity). |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 6 - LEGUME VEGETABLES** | |
| Legumes are derived from the dried or succulent seeds and immature pods of leguminous plants commonly known as beans and peas. Pods are fully exposed to pesticides during the growing season. Dried forms are fully exposed to post harvest treatments. Succulent forms may be consumed as whole pods or as shelled product. Legume fodder is in Group 18. | |
| ***Legume Vegetables:***<br>Beans, Asparagus (winged bean)<br>…Common (habichuela)<br>…Kidney<br>…Lablab<br>…Lima<br>…Mung<br>…Snap<br>…String (sitao)<br>Cowpea<br>Peas, Chick (garbanzo)<br>…Garden (chicharo)<br>…Sweet<br>Soybeans<br>***Representative Commodities***<br>Beans, Mung<br>…String (sitao)<br>Peas, Garden (chicharo)<br>Soybeans | Whole commodity. |
| **Group 7 - FRUITING VEGETABLES - EDIBLE PEEL** | |
| Fruiting vegetables - edible peel (except cucurbits) are derived from the immature or mature fruits of various plants, usually annual vines or bushes. These vegetables are fully exposed to pesticides during the growing season. The entire fruiting vegetables may be consumed. | |
| ***Fruiting Vegetables - edible peel:***<br>Bitter gourd<br>Eggplant<br>Okra<br>Pepper, Sweet and Chili<br>Tomato<br>Malunggay<br>***Representative Commodities***<br>Eggplant<br>Tomato | Whole commodity after removal of stems. |
| | |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 8 - FRUITING VEGETABLES - INEDIBLE PEEL** | |
| Cucurbit vegetables are derived from the immature or mature fruits of various plants, usually annual veins or bushes. Fruits are fully exposed to pesticides during the growing season. Edible portion is protected by skin, peel or husk which is removed or discarded before consumption. | |
| ***Fruiting vegetables - inedible peel:***<br>Cantaloupe — Kundol<br>Chayote — Melon, Musk<br>Cucumber — Pumpkin<br>Gherkins — Squash<br>Gourd, edible — Watermelon<br>***Representative Commodities***<br>Cantaloupe — Squash<br>Cucumber | Whole commodity after removal of stems. |
| **Group 9 - CITRUS FRUITS** | |
| Citrus fruits are produced by trees of the *Rutaceae* family and are characterized by the aromatic oily peel, globular form and interior segments of juice-filled vesicles. The fruit is fully exposed to pesticides during the growing season. The fruit pulp may be consumed in succulent form or as a beverage. The entire fruit may be used for preserving. | |
| ***Citrus fruit:***<br>Calamondin — Orange (cahel)<br>(calamansi) — Pomelo<br>Lemon — Grapefruit<br>Mandarin<br>Naranghita<br>***Representative Commodities***<br>Calamondin — Pomelo | Whole commodity. |

| CLASSIFICATION OF COMMODITIES | | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|---|
| **Group 10 - POME FRUITS** | | |
| Pome fruits are produced by trees related to the genus *Pyrus* of the family (*Rosaceae*). They are characterized by the fleshy tissue surrounding a core consisting of parchment-like carpels enclosing the seed. The entire fruit, except the core, may be consumed in the succulent form or after processing. | | |
| ***Pome fruits:*** | | Whole commodity after removal of stems. |
| Apple | Pear | |
| Chico | | |
| **Group 11 - STONE FRUITS** | | |
| Stone fruits are produced by trees related to the genus *Prunus* of the rose family (*Rosaceae*) characterized by the fleshy tissue surrounding a single hard-shelled seed. The fruit is fully exposed to pesticides applied during the growing season. The entire fruit except seed, may be consumed. | | |
| ***Stone fruits:*** | | Whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stem. |
| Apricot | Prunes | |
| Cherry | Nectarines | |
| Sour cherry | Peach | |
| Sweet cherry | Plums | |
| **Group 12 - SMALL FRUITS AND BERRIES** | | |
| Small fruits and berries are derived from a variety of plants whose fruit is characterized by a high surface-weight ratio. The fruits are fully exposed to pesticides applied during the growing season. The entire fruit, often including the seed, may be consumed in a succulent or processed form. | | |
| ***Small fruits and berries:*** | | Whole commodity after removal of caps and stems. Currants; fruit with stems. |
| Bignay | Grapes | |
| Blackberries | Mulberry | |
| Blueberries | Raspberries | |
| Currants | Strawberries | |
| Dewberries | | |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 13 - ASSORTED FRUITS - EDIBLE PEEL** | |
| Assorted fruits- edible peels are derived from the immature or mature fruits of a variety of plants, usually shrubs or trees from tropical or subtropical regions. The whole fruit may be consumed in a succulent or processed form. | |
| ***Assorted fruits - edible peel:***<br>Dates Olives<br>Figs Guava | Dates and olives: whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit.<br>Figs: Whole commodity. |
| **Group 14 - ASSORTED FRUITS - INEDIBLE PEEL** | |
| Assorted fruits - inedible peels are derived from the immature or mature fruits of different kinds of plants, usually shrubs or trees from tropical or subtropical regions. Edible portion is protected by skin, peel or husk. Fruit may be consumed in fresh or processed form. | |
| ***Assorted fruits- inedible peel:***<br>Avocado Mango<br>Banana Papaya<br>Guava Passion fruit<br>Jackfruit Pineapple<br>Kiwi fruit | Whole commodity unless qualified.<br>Pineapples: after removal of crown.<br>Avocados and mangoes: whole commodity after removal of stone but calculated on the whole fruit.<br>Bananas: after removal of crown tissue and stalks. |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 15 - CEREAL GRAINS** | |
| Cereal grains are derived from the clusters of starchy seeds produced by a variety of plants primarily of the grass family (Poaceae, formerly Graminae). The edible seeds are protected at varying degrees from applied pesticides during the growing season by the husk. Post-harvest treatments are common. Husks are removed before consumption. | |
| ***Cereal grains:*** | Whole commodity. |
| Corn Triticale<br>Rice Rye<br>Barley Sorghum<br>Maize Sweet corn<br>Oats Wheat<br>Pearl millet<br>***Representative Commodities***<br>Corn Rice | Fresh corn and sweet corn: kernels plus cob without husk. |
| **Group 16 - STALK AND STEM CROPS** | |
| Stalk and stem crops are various kinds of plants, mostly of the grass family (Poaceae, formerly Graminae) cultivated extensively for animal feed and for production of sugar. Stems and stalks used for animal feeds are consumed as succulent forage, silage, or as dry fodder or hay. Sugar crops are processed. | |
| ***Stalk and stem crops:*** | Whole commodity. |
| Corn forage, fodder and straw<br>Rice forage, fodder and straw<br>Barley fodder and straw<br>Grass fodders<br>Sorghum fodder<br>Sugarcane<br>***Representative Commodities***<br>Corn forage Rice forage | |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 17 – LEGUME OILSEEDS** | |
| Legume oilseeds are mature seeds from legumes cultivated for processing into edible vegetable oil or for direct use as human food. | |
| ***Legume oilseeds:***<br>Peanuts Soybean | Whole commodity after removal of shell. |
| **Group 18 – LEGUME ANIMAL FEEDS** | |
| Legume animal feeds are various species of legumes used for animal forage, grazing, fodder, hay or silage with or without seed. Legume animal feeds are consumed as succulent forage or as dried fodder or hay. | |
| ***Legume and Animal Feeds:***<br>Alfalfa fodder Mungbean pods<br>Bean fodder Pea fodder<br>Clover fodder Peanut fodder<br>Mungbean leaves Soybean leaves<br>***Representative Commodities***<br>Mungbean pods Soybeans | Whole commodity. |
| **Group 19 – TREE NUTS** | |
| Tree nuts are seeds of a variety of trees and shrubs which are characterized by a hard, inedible shell enclosing an oil seed. The seed is protected from pesticides that were applied during the growing season by other parts of the fruit and the shell. The edible portion of the nut is consumed in succulent, dried, or processed form. | |
| ***Tree nuts:***<br>Almonds Pecans<br>Cashew nuts Pili nuts<br>Chestnuts Walnuts<br>Macademia nuts<br>***Representative Commodities***<br>Cashew nuts Pili nuts | Whole commodity after removal of the shell.<br>Chestnuts: whole in skin. |

| CLASSIFICATION OF COMMODITIES | | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|---|
| **GROUP 20 - OILSEED** | | |
| Oilseed consists of the seed from a variety of plants used in the production of edible vegetable oils. Some important vegetable oilseeds are by-products of fiber or fruit crops. | | |
| ***Oilseed:*** | | Whole commodity. |
| Cottonseed | Safflowerseed | |
| Linseed | Sunflowerseed | |
| Rapeseed | | |
| **GROUP 21 - TROPICAL SEEDS** | | |
| Tropical seeds consist of the seeds from several tropical and semitropical trees and shrubs mostly used in the production of beverages and confections. Tropical seeds are consumed after processing. | | |
| ***Tropical seeds:*** | | Whole commodity. |
| Cacao beans | Coffee beans | |
| **Group 22 - HERBS** | | |
| Herbs consist of leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavor other foods. They are consumed in succulent or dried form as components of other foods. | | |
| ***Herbs:*** | | Whole commodity. |
| Oregano | Pandan | |
| **Group 23 - SPICES** | | |
| Spices consist of aromatic seeds, roots, fruits and berries from a variety of plants used in relatively small amounts to flavor other foods. They are consumed primarily in the dried form as components of other foods. | | |
| ***Spices:*** | | Whole commodity. |
| Achuete | Black pepper | |

| CLASSIFICATION OF COMMODITIES | | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|---|
| **Group 24 - TEAS** | | |
| Teas are derived from the leaves of several plants, but principally *Camellia sinensis*. They are used in the preparation of infusions for consumption as stimulating beverages. They are consumed as extracts of the dried or processed product. | | |
| Teas: | | Whole commodity. |
| Tea, black | | |
| **Group 25 - MEATS** | | |
| Meats are the muscular tissue, including the adhering fatty tissue from animal carcasses prepared for wholesale distribution. The entire product may be consumed. | | |
| ***Meats:***<br>Carcass meat (and carcass fat)<br>Carcass meat of cattle<br>Carcass meat of goat<br>Carcass meat of horse<br>Carcass meat of pig<br>Carcass meat of dog<br>Carcass meat of sheep<br>Carcass meat of rabbit | | Whole commodity. (For fat-soluble pesticides a portion of carcass fat is analyzed and MRLs apply to carcass fat.)[3] |
| **Group 26 - ANIMAL FATS** | | |
| Animal fats are the rendered or extracted fatty tissue of animals. The entire product may be consumed. | | |
| ***Animal fats:***<br>Cattle fat<br>Pig fat | Sheep fat | Whole commodity. |

[3] For milk and milk products regarding the soluble pesticides see Section 1 of FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Establishment of MRL

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 27 - MEAT BY-PRODUCTS** | |
| Meat by-products are edible tissues and organs, other than meat and animal fat, from slaughtered animals as prepared for wholesale distribution. Examples: liver, kidney, tongue, heart. The entire product may be consumed. | |
| ***Meat byproducts (such as liver, kidney, etc.):***<br>Cattle meat by-products<br>Goat meat by-products<br>Pig meat by-products<br>Sheep meat by-products | Whole commodity. |
| **Group 28 - MILKS** | |
| Milks are the mammary secretions of various species of lactating herbivorous ruminant animals, usually domesticated. The entire product may be consumed. | |
| Milks | Whole commodity. For fat-soluble compounds, a portion of the fat is analyzed but the residue is expressed on a whole commodity basis on the assumption that milk contains 4% fat. |
| **Group 29 - MILK FATS** | |
| Milk fats are the fats rendered or extracted from milk. | |
| Milk fats | Whole commodity. |
| **Group 30 - POULTRY MEATS** | |
| Poultry meats are the muscular tissues, including adhering fats and skin, from poultry carcasses as prepared for wholesale distribution. The entire product may be consumed. | |
| ***Poultry meats:***<br>Poultry meats (carcass fats) | Whole commodity. (For fat soluble pesticides a portion of carcass fat is analyzed and MRLs apply to carcass fat). |

| CLASSIFICATION OF COMMODITIES | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|
| **Group 31 - POULTRY FATS** | |
| Poultry fats are the rendered or extracted fats from fatty tissues of poultry. The entire product may be consumed. | |
| Poultry fats | Whole commodity. |
| **Group 32 - POULTRY BY-PROUCTS** | |
| Poultry by-products are edible tissues and organs, other than poultry meat and poultry fat, from slaughtered poultry. | |
| Poultry by-products | Whole commodity. |
| **Group 33 - EGGS** | |
| Eggs are the fresh edible portions of the reproductive body of several avian species. The edible portion includes egg white and egg yolk after the removal of the shell. | |
| Eggs | Whole egg whites and yolks combined after removal of shells. |
| **Group 34 - GRASS FORAGE, FODDER AND HAY** | |
| Any grass, (*Poaceae, formerly Gramineae)* family, (either green or cured) except sugarcane and those included in the group cereal grains and legumes that will be fed to or grazed by livestock, all pasture and range grasses and grasses grown for hay or silage. | |
| ***Grass forage, fodder and hay:***<br>African stargrass — Guinea grass<br>Bagokbok — Napier grass<br>Cogon — Para grass | Whole commodity. |
| **Group 35 - NON-GRASS ANIMAL FEEDS (FORAGE, FODDER, STRAW AND HAY)** | |
| ***Non-grass animal feeds:***<br>Ipil-ipil — Stylo<br>Kudzu | Whole commodity. |

| CLASSIFICATION OF COMMODITIES | | PORTION OF COMMODITY TO WHICH THE CODEX MRL APPLIES (AND WHICH IS ANALYZED) |
|---|---|---|
| **Group 36 - FISH** | | |
| Fish are gilled, aquatic vertebrates and cartilaginous animals in various species, usually wild as prepared for wholesale distribution. Exposure to pesticides is through animal metabolism. The entire product may be consumed. | | |
| Fish | | Whole commodity. |
| **Group 37- SHELLFISH** | | |
| Shellfish are aquatic animals of various species, wild or cultivated, having an inedible inner or outer shell. Exposure to pesticides is through animal metabolism. The entire product exclusive of the shell may be consumed. | | |
| Shellfish | | Whole commodity after removal of shell. |
| **Group 38 - PRODUCTS NOT CLASSIFIED FOR GROUP TOLERANCES** | | |
| Carambola | Mangosteen | |
| Chesa | Pomegranate | |
| Coconut | Rambutan | |
| Durian | Rimas | |
| Kamias | Santol | |
| Kaong | Soursop (guyabano) | |
| Lanzones | Star apple | |
| Litchi | Sugar apple (atis) | |
| Mabolo | Tamarind | |
| Makopa | | |

# *Annex XI*

# *REPORTING OF HANDLERS*

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
**FERTILIZER AND PESTICIDE AUTHORITY**
4TH FLOOR, BUILDING B, NIA COMPLEX, EDSA, QUEZON CITY
Tel Nos. 929-6071 LOC 123, 922-3362, 922-3364, 922-3368, 922-3371
Tel/Fax Nos. 922-3355, 922-3368
P.O. Box 2582 QUEZON CITY

**FPA Form No. 200**

## MONTHLY PEST CONTROL OPERATION REPORT

For the month of _____

| List of Chemicals Used (Brand Names) | Source(s) of Chemicals | Purpose (Target Pest) | Quantity Used | Name and Address of Client | Remarks (Hazards Observed) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Certified true and correct:

_____
FPA Certified Pesticide Applicator
Control No.

Submitted by:

_____
Name & Address of Company

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
**FERTILIZER AND PESTICIDE AUTHORITY**
4TH FLOOR, BUILDING B, NIA COMPLEX, EDSA, QUEZON CITY
Tel Nos. 929-6071 LOC 123, 922-3362, 922-3364, 922-3368, 922-3371
Tel/Fax Nos. 922-3355, 922-3368
P.O. Box 2582 QUEZON CITY

# THE REPORT FORM
# ANNUAL KEY FARMER PESTICIDE REPORT FORM

**Year** _____ **Ref. No.** _____

**Farmer's Name** _____ **Address** _____
**Site of Farm** _____

| **Main Crop** | **Area** | **Average Yield** |
|---|---|---|
| | | |
| | | |

**Pesticides Purchased During The Year**

| Product Name | Month | Quantity |
|---|---|---|
| | | |
| | | |
| | | |

| Crop Sprayed | Dates | Dose Rates | Results |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

Sprayer Make _____ Comments: _____

General Comments _____

Any Poor Results, Health Problems, Crop Damage _____

## GENERAL COMMENTS ON PESTICIDE USED IN THE BARANGAY

1. **Estimated No. of farmers using spray** _____
2. **Estimated Area Sprayed**

| Crop | Area |
|---|---|
| | |
| | |
| | |

3. **State if pesticides are used safely and correctly**

Safety ☐ Yes ☐ No ☐ Ineffective

Correct Dose ☐ Yes ☐ No If no, lower or higher than recommended _____

4. **What literature, visual aids, advice, talks, radio are required to improve the safe use of pesticides.**

_____

_____

5. **Visits and Advice on pesticides during the year**

Agricultural Extension Staff _____ No. of visits _____
Chemical Company Staff _____ No. of visits _____
Others _____ No. of visits _____

*" Better harvest, health and environment through safe and judicious use of fertilizers and pesticides"*

**7. Total Value of Sales for Quarter**

- To farmers P_____
- To dealers P_____

**8. Publicity, Promotion Items Received and Distributed**

| Name of Company | Product | Type Material | Qty. Received | Qty. Distributed |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**9. Staff Training - Brief details of training courses attended. Number and type.**

Name of Staff _____ Training _____
Date _____ Result _____
Farmer meetings _____ Organized
Attended _____

Number and Type of Staff Employed - sales _____ Accounts
- drivers _____ Stocks

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF AGRICULTURE
**FERTILIZER AND PESTICIDE AUTHORITY**
4TH FLOOR, BUILDING B, NIA COMPLEX, EDSA, QUEZON CITY
Tel Nos. 929-6071 LOC 123, 922-3362, 922-3364, 922-3368, 922-3371
Tel/Fax Nos. 922-3355, 922-3368
P.O. Box 2582 QUEZON CITY

# THE LICENSED DEALER PESTICIDE QUARTERLY REPORT

This form replaces the pesticide data and routine comments previously contained in the FPA Coordinators monthly report.

## 1. OBJECTIVES

(i) To record reliable authenticated data within each province, on sales of pesticides to:

(a) farmers (users)
(b) sub dealers

(ii) To report on the condition of pesticides being sold with particular regard to labels (new registration), date of formulation, quality, etc. and hazard warnings.

(iii) To report on good dealer housekeeping - rotation of stocks (first in, first out), stock grouping and display (All those on categories I and II should be in one area).

(iv) To report on training needs and professional competence of staff.

(v) To report on extension needs, promotional materials, etc. at the "point of sale".

(vi) To recommend changes, improvements, training to achieve a minimum standard of competence as set out in the Dealer License requirements of FPA.

## 2. SALES AND STOCK RECORDS - MAIN LIST (Form D1)

The section numbered 5 on the form is a quarterly summary of the dealers own weekly or daily records.

The data recorded should be checked (authenticated) from time to time, product by product with the local representative of the National Distributor against copy delivery receipts/invoices.

Only those dealers purchasing pesticides direct from the National Distributor should be included on the main list.

## 3. SALES AND STOCK RECORD - SUB DEALER/OUTLETS (Form SD2)

This form should contain the same data as in D1 but uncorrelated information.

Note: Only the data from Form D1 will be recorded on the computer and published as Annual Pesticide Sales at the Provincial/Regional level.

All data must be recorded in the relevant sales pack

| Sizes: | 1 liter | 1 Kg. |
|---|---|---|
| | 500 mL | 500 g |
| | 250 mL | 250 g |
| | etc. | etc. |

Sub totals for group of products is essential and where possible they should be grouped by company.

# *Annex XII*

# *FPA MANUAL ON OCCUPATIONAL SAFETY*

# FPA MANUAL ON OCCUPATIONAL AND TECHNICAL SAFETY OF PESTICIDE MANUFACTURING, FORMULATION, REPACKING PLANTS, WOOD TREATMENT PLANTS AND OTHER INSTITUTIONAL USERS

## I. Introduction

The Fertilizer and Pesticide Authority (FPA) was created on May 30, 1977 under Presidential Decree 1144. As mandated by law, FPA is charged with the power to regulate the importation, exportation, manufacture, formulation, distribution, sale, transport, storage, use and disposal of pesticides.

Pesticides are important chemical inputs in the country where they are extensively used both in agriculture and in public health programs. Their adverse effects on human health and environment are generally acknowledged.

On the basis of a mathematical model, WHO estimates that about 500,000 cases of pesticide poisoning, resulting in 5,000 deaths occur each year. Jeyaratnam, in his studies in Sri Lanka, extrapolated that about 2.9 million cases of acute pesticide poisoning requiring admission to hospitals with about 220,000 deaths are likely to occur annually in developing countries.

The FPA and the Department of Health (DOH) monitor, through public hospitals, the cases and causes of pesticide poisoning on a nationwide basis.

During the eight (8) year period from 1980 to 1987, a total of four thousand thirty one (4,031) cases were reported: 2,594 or 64.35% were suicidal; 714 or 17.71% were accidental; 558 or 13.84% were occupational; and 165 cases or 4.1% were not specified.

Of the total number of reported cases, 3,185 or 79% recovered; and 603 or 15% died. Sixty one (61) or 1.5% of the cases were transferred and 82 or 2.0% of the cases were not specified as to its disposition.

The male population had a higher number of incidents at 2,193 or 54.40% compared to female, which numbered at 1,838 or 45.60%.

A detailed summary of pesticide poisoning cases from 1980-1987 is appended to this Manual.

The FPA instituted the National Pesticide Safety Program in 1979 through the Agro-medical services unit with the primary objective of training medical and paramedical personnel on the recognition, treatment and management of pesticide poisoning cases. Through the Department of Health, monitoring of pesticide poisoning cases is done at the rural health units, emergency, provincial and regional hospital levels. Over the last three (3) years, about 2,263 doctors and paramedical personnel have attended these seminars. First-aid kits containing supplies for the initial management of pesticide poisoning cases were distributed to rural health units and hospitals. To date, 412 of these have been given to hospitals in identified pilot areas. Training modules have also been conducted for Agro-pesticide dealers, pesticide applicators and farm technicians.

## II. Hazards

The FPA has classified pesticides based on toxicity and hazard (see Table 1).

**Table 1. Classification of Pesticides Based on Toxicity and Hazard[1]**

| Category and Signal Words | Color Band Symbol[2] | Acute Oral, $LD_{50}$ (Rat) | | Acute Dermal, $LD_{50}$ (mg/Kg BW) | |
|---|---|---|---|---|---|
| | | Solid | Liquid[3] | Solid | Liquid |
| CATEGORY I<br>DANGER: POISON | RED | 50 or less | 200 or less | 100 or less | 400 or less |
| CATEGORY II<br>WARNING: HARMFUL | YELLOW | 51 to 500 | 201 to 2000 | 101 to 1000 | 401 to 4000 |
| CATEGORY III<br>CAUTION | BLUE | 501 to 2000 | 2001 to 3000 | Over 1000 | Over 4000 |
| CATEGORY IV<br>---------- | GREEN | Over 2000 | Over 3000 | N/A | N/A |

[1] Toxicity classification based on formulation.
The FPA Classification Table is adopted from the World Health Organization (WHO) Classification By Hazards, the only modification being in the Title and combination of Categories 1a and 1b of the WHO Table into Category I for FPA.

[2] The following shades must be used as norms: Pantone red 199-C, Pantone yellow-C, Pantone blue 293-C and Pantone green 347-C.

[3] The terms “solid” and “liquid” refer to the physical state of the product or formulation being classified.

Table 2 shows the WHO recommended classification of pesticides by hazard. The present WHO statement reclassifies pesticides not only according to their acute toxicities but also takes into consideration chronic toxicities and local irritation.

The hazard referred to is generally the acute risk to health (that is, the risk of single or multiple exposures over a relatively short period of time) that might be encountered accidentally by any person handling the product in accordance with the directions for handling by the manufacturer or in accordance with the rules laid down for storage and transportation by competent international bodies.

**Table 2. WHO Recommended Classification of Pesticides by Hazard**

| Class | | $LD_{50}$ for the rat (mg/kg body weight) | | | |
|---|---|---|---|---|---|
| | | Oral | | Dermal | |
| | | Solids | Liquids | Solids | Liquids |
| Ia | Extremely hazardous | 5 or < | 20 or < | 10 or < | 40 or < |
| 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 | Over 500 | Over 2000 | Over 1000 | Over 4000 |

The classification distinguishes between the more and the less hazardous forms of each pesticide in that it is based on the toxicity of the technical compound and on its formulations. In particular, allowance is made for the lesser hazards from solids as compared with liquids.

The classification is based primarily on the acute oral and dermal toxicity to the rat since these determinations are standard procedures in toxicology. Where the dermal $LD_{50}$ value of a compound is such that it would place it in a more restrictive class than the oral $LD_{50}$ value would indicate, the compound will always be classified in the more restrictive class. Provision is made for the classification of a particular compound to be adjusted if, for any reason, the acute hazard to man differs from that indicated by $LD_{50}$ assessments alone.

**Absorption of Pesticides**

Pesticides may be absorbed into the body by three specific routes – by ingestion, inhalation or through the skin.

1) Ingestion : usually accidental or suicidal

2) Inhalation : inhalation of mist or powder may cause absorption through the mucous membrane of the nose, mouth or respiratory passages.

3) Skin Absorption : most likely route by which occupational poisoning may occur.

## III. Organizational Aspects

A specific management person should be designated as responsible for safety. A functioning safety committee is needed with 50% management input and 50% worker and occupational health input. That means representatives will come from management, workers, engineering and medical profession. The task is to lay down policies, supervise the implementation of rules and monitor any accident and/or health problems.

Periodic interval audit of occupational health, industrial hygiene, safety and security, environmental and public protection should be undertaken on a monthly basis.

Specific safety training should be provided to each worker for his/her job before employment. Periodic general safety training should be provided for all workers with at least eight (8) hours per year or two (2) hours per quarter. Specific workplace hazards to human health must be communicated as part of this training to give workers reasons for following work rules.

## IV. Occupational Health

### A. Staffing and Training

Occupational health staffing and training of occupational health staff must be in accord with section 1963.02 of DOLE regulations for first-aiders, nurses, and physicians.

*Safety/First Aid training should be conducted:*

a. Occupational health personnel: Physicians and nurses working in establishments where pesticides are used must have been accredited by the Department of Labor and Employment (DOLE). The company should submit certification to the FPA. Other paramedical staff should be trained and accredited by the Philippine National Red Cross (PNRC) or by the Safety Organization of the Philippines (SOPI).

b. Workers: all workers (regular, contractual, permanent, casuals) handling pesticides must undergo pre-placement and periodic training on the proper and safe handling of pesticides, proper use of personal protective clothing and equipment, basic knowledge of the chemicals they are handling and first aid procedures in cases of poisoning. Periodic general safety training should be conducted for a minimum of eight (8) hours per year or two (2) hours per quarter. Specific workplace hazards must be communicated to the workers to ensure compliance.

## B. Health Examinations

Pre-placement, periodic and exit health examinations are required for all permanent, contractual and casual personnel working with pesticides.

Health examinations will consist of the following minimum requirements which **will be provided by the employer free of charge**:

1. Complete and thorough physical examination which will be properly recorded and kept in the clinic.

2. Laboratory tests which shall include:

    a. Hematology – hemoglobin, hematocrit, leucocyte count, and differential, reticulocyte and platelet count.

    b. Chest X-ray

    c. Urinalysis

    d. Fecalysis

    e. Biochemical monitoring – BUN, creatinine, uric acid, total protein, alkaline phosphatase, total cholesterol, SGOT and SGPT.

3. Special examinations, whenever applicable and necessary are the following:

    a. ***For organophosphate and carbamate compounds*** - nerve conduction test.

    b. ***For organochlorine compounds such as lindane and heptachlor*** - EKG, FBS, OGTT, Triglycerides, LDL and HDL quarterly.

    c. ***For arsenic and pentachlorophenol*** - monthly pulmonary function tests.

    d. ***For paraquat*** – monthly pulmonary function tests.

4. Biologic monitoring will be as follows:

    a. ***For organophosphate and carbamates*** - red cell cholinesterase activity determinations; if red cell testing is not available, do serum or white blood cholinesterase determinations.

b. ***For organochlorine, in particular, lindane*** - mutagenicity test is recommended.

c. ***For inorganic arsenicals and pentachlorophenols*** - urinary level determinations of the chemicals are required.

d. ***For paraquat*** - urinary paraquat level determinations are done.

Workers exposed to Category I-II pesticides should have semi-annual examination (twice a year) consisting of a complete medical examination, hematologic, liver, and kidney function tests. Workers exposed to Category III-IV should have annual medical and laboratory examinations.

To ensure the safety of workers, only regular personnel shall be allowed to work in formulating/manufacturing plants and institutions handling Category I-II pesticides. Casuals should not be allowed to handle AI or technical materials.

## C. Biological Monitoring

1. General Guidelines:

   a. Testing to be done as recommended.

   b. All workers manifesting signs and symptoms of toxicity should have biological monitoring.

   c. Only results from laboratories recognized and accredited by the FPA and/or Bureau of Research and Laboratory-DOH will be acceptable.

   d. Return to work orders can only be issued by the company doctors.

2. Cholinesterase testing for permanent, contractual and casual personnel exposed to cholinesterase-inhibiting compounds should be done.

   Baseline Cholinesterase is determined as follows:

   a. No exposure to organophosphorus and carbamate compounds for at least 30 and 14 days, respectively prior to extraction.

   b. No alcohol intake for at least 2 days.

   c. Mean of two (2) determinations with 24-hour interval but not to exceed three (3) days between the 2 testings with blood extraction done at the same time of day or at most +/- 30 minutes of the first extraction. If the result of the two (2) determinations varies within 15%, the mean of the two (2) determinations shall be the baseline level. If the results show variability greater than 15%, a third determination should be done, ensuring that factors that can affect the RBC cholinesterase levels are eliminated (such as acute alcoholic intoxication, exposure to organophosphates and carbamates).

Regular cholinesterase determination, the frequency of which would vary depending on the toxicity category of the pesticide and the type of work done (see Table 3).

**Table 3. Frequency of Cholinesterase Determinations ***

| Type of work | Hours of exposure/day | |
|---|---|---|
| | 3-4 hrs/day | >4 hrs/day |
| When exposed to Category I-II pesticides (AI): | | |
| Mixer/loader/blender | Every 2 weeks | Weekly |
| Sprayman/packager | Every 3 weeks | Every 2 weeks |
| Flagman/capper/filler | Every 3 weeks | Every 2 weeks |
| When exposed to Category III-IV pesticides: | | |
| Mixer/loader | Every 4 weeks | Every 3 weeks |
| Sprayman/packager | Every 8 weeks | Every 6 weeks |
| Flagman/capper/filler | Every 8 weeks | Every 6 weeks |

*this is applicable to work schedule of 5 days/week

Levels of cholinesterase (ChE) activity should be interpreted by the occupational health physician with the following guidelines:

a. Asymptomatic, with 20-25% depression from pre-exposure value of RBC and whole blood ChE, respectively must be investigated and repeat RBC or whole blood ChE done.

b. Asymptomatic, with 30-50% or greater depression from pre-exposure value of RBC and whole blood ChE, respectively, the worker must be removed from further exposure to anti-ChE pesticides.

c. Symptomatic, with 20-25% or greater depression from pre-exposure value of RBC and whole blood ChE, respectively must be evaluated by the physician and treated appropriately and removed from further exposure to anti-ChE pesticides.

d. Workers must not be exposed again to ChE-inhibiting compounds until further tests show they are fully recovered from signs/symptoms of cholinergic excess (if symptomatic) and/or cholinesterase activity of the red cell or whole blood ChE is within 20% of the pre-exposure value.

e. Return to work certification can only be issued by the company physician.

Cholinesterase levels and action taken for low levels must be properly recorded for every worker. The suggested format is shown in Figure 1.

***Figure 1. Personal ChE Record***

| Name: | | | | |
|---|---|---|---|---|
| Date | Product Handled | Nature of Work | ChE | Action taken |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

3. Urinary Arsenic and Pentachlorophenol (PCP)

Baseline levels are determined from samples collected after 7 days of no exposure.

Periodic follow-up sampling of workers' urine is to be collected after at least 4 days of work, or equivalent to 36 hours of exposure, on a monthly basis.

Any worker with signs and symptoms should have a urinary testing.

For methods, see Appendix II.

4. Urinary Paraquat

Baseline monitoring to be determined from sample collected after 7 days of no exposure.

Periodic monitoring to be determined from sample collected at least 4 hours and not greater than 8 hours after ceasing Paraquat exposure, on a monthly basis.

Any worker with signs and symptoms should have a urinary testing.

For methods, see Appendix II.

5. Blood chromosomal tests for Organochlorine (specifically Lindane and Heptachlor)

Baseline monitoring:

Periodic monitoring to be undertaken at least on a semi-annual basis.

For methods, see Appendix II.

## D. First Aid

An emergency clinic should be provided for all hazardous workplaces regardless of the number of workers.

The minimum personnel requirement for plants/plantations/pest control establishments handling Category I-II pesticides is shown in Table 3.

Table 4 shows the emergency medicines and medical supplies and equipment for pesticide formulating plants, plantations, and pest control establishments handling Category I-II pesticides.

**Table 3. Professional Services Schedule for Workers Exposed to Category I-II Pesticides***

| *Number of Workers* | *Personnel* |
|---|---|
| 1 - 10 | 1 First Aider<br>Part-time Nurse<br>Occupational Health Consultant |
| 11 - 50 | 2 First Aiders<br>Full-time Nurse<br>Part-time Physician 2 hrs 3x/week |
| 51 - 100 | 3 First Aiders<br>Full-time Nurse<br>Part-time Physician 2 hrs 3x/week<br>Full-time Dentist 2 hrs 3x/week |
| 101 - 300 | 3 First Aiders<br>Full-time Nurse<br>Full-time Physician 4 hrs 5x/week<br>Full-time Dentist 4 hrs 5x/week |
| 301 - 600 | 3 First Aiders<br>Full-time Nurse<br>Full-time Physician 4 hrs 5x/week<br>Part-time Physician 2 hrs 3x/week<br>Full-time Dentist 4 hrs 5x/week |
| 601 and above | 1 First Aider for every 30 workers<br>1 Nurse for every 300 workers<br>1 Dentist for every 600 workers<br>1 Physician for every 600 workers |

***** Based on amendment to Labor Code of the Philippines 1986.

**Table 4. List of Emergency Medicines and Medical Supplies and Equipment for Pesticide Formulating Plants, Plantations, and Pest Control Establishments Handling Category I-II Pesticides.**

## A. Medicines

1. Systemic-Acting
   a. Atropine Sulfate - ampule (1 mg/mL)
      tablet (0.6 mg/mL)
   b. Diazepam - ampule (5 mg/mL)
      tablet (5 mg/mL)
   c. Phenytoin - ampule (100 mg/mL)
      capsule (100 mg/mL)
   d. Glucose 5% in distilled water (500 mL for venoclysis)
   e. Dopamine - ampule (40 mg/mL)
   f. Tetanus Toxoid ampule
   g. Phytonadione - (Vitamin K1) ampule (10 mg/mL)
   h. Sodium bicarbonate 7.5% - 50 ml ampule
   i. Any antihistaminic ampule and tablet
   j. Any coronary vasodilator ampule or sublingual tablet or capsule
   k. Anti-hypersensitive ampule and tablet

2. Locally-acting
   a. Topically antiseptic (Providone-Iodine)
   b. 70% ethyl alcohol
   c. Hydrogen peroxide 3%
   d. Silver-sulfadiazine ointment/cream for burns
   e. Local anesthetic ointment and 1-2% ampule/vial for local infiltration anesthesia
   f. Activated charcoal (Merck – 90% adsorbent, fine)
   g. Eye-wash solution

## B. SUPPLIES AND EQUIPMENT

1. Sterile gauze pads
2. Gauze bandage, roll
3. Triangular bandage
4. Adhesive tape, roll
5. Absorbent cotton (sterile)
6. Bandage scissors
7. Tongue depressors
8. Splinter forceps
9. Hot water bag
10. Ice bag
11. Disposable needle and syringes
12. Venoclysis with butterfly needles (gauge 20, 21, 23) and “Soluset”
13. Stethoscope
14. Sphygmomanometer
15. Mouth tube (for adult)
16. Otoscope
17. Flash light
18. Examining table
19. Portable stretcher with flatboard (at least 5 feet)
20. Rubber tourniquet
21. Suctioning bulb

*Continuation of Supplies and Materials*

22. Nasogastric tube (Adult)
23. Medicine cabinets
24. Thermometer
25. Ophthalmoscope
26. Linens
27. Waste sanitary pail (with cover, foot-operated)
28. Hospital bed for observation
29. Ambu bag
30. Oxygen tank with regulator and humidifier
31. Oxygen mask (half-mask)
32. Nasal catheter for oxygen
33. Surgical instruments for suturing (forceps, iris, scissors, 4-0 cotton suture, surgical knife)
34. Splint
35. Tourniquets
36. Suction apparatus

## V. Industrial Hygiene

### A. Personal Protective Clothing and Equipment (PPE)

1. Recommendations for **OPs** and **carbamates**:

Protective clothing and equipment must be provided by the employer free of charge. The following table shows the recommended personal protective clothing and equipment (PPE).

**Table 5. Recommended Protective Clothing and Equipment**

---

***I. For Category I-II Pesticides:***

A. Handling of technical materials and formulated products with open equipment (loading, mixing, spraying):
   1. Chemical resistant gloves with reverse gauntlets
   2. Protective head covering of chemical-resistant material
   3. Face shield
   4. Chemical-resistant apron
   5. Full body cover-alls (siliconized cotton) without cuffs
   6. Respirator, half mask with replaceable activated charcoal cartridge whenever liquid formulation is volatile, solvent is xylene or formulation is malodorous
   7. Chemical-resistant footwear (boots)

(cont'n of Table 5)

B. Handling of sealed, non-leaking containers:
   1. Full body cover-alls (siliconized cotton or chemical-resistant materials)
   2. Chemical-resistant gloves

C. Handling and Laundering of contaminated clothes:
   1. Chemical-resistant gloves
   2. Chemical-resistant footwear
   3. Chemical-resistant apron

---

***II. For Category III-IV Pesticides:***

A. Liquid Formulation

   1. Handling of technical material with open equipment (mixing, repacking and spraying)
      a. Chemical resistant gloves (seamless)
      b. Full body cover-alls (cotton)
      c. Rubber boots
      d. Half masks with activated charcoal replaceable cartridge

   2. Handling of close containers
      a. Chemical-resistant gloves (seamless)
      b. Chemical-resistant apron
      c. Cotton cover-alls

B. Granular, powder or dust formulation

   1. Handling of technical material (mixing and spraying)
      e. Full body cover-alls (cotton)
      f. Chemical-resistant gloves (seamless)
      g. Rubber boots
      h. Half face masks or dust mask
      i. Face shield

   2. Handling of close containers
      a. Chemical resistant gloves (seamless)
      b. Chemical-resistant apron
      c. Cover-alls

---

2. Recommendations for **Arsenicals** and **PCP**:
   a. lightweight cover-all
   b. knee high boots (chemical-resistant)
   c. gauntlet gloves (chemical-resistant)
   d. face masks, shields or goggles
   e. below knee length apron (chemical-resistant)
   f. carbon filter respirators
   g. in case of spillage, workers involved in clean-up must wear same PPE.

3. Recommendations for ***Paraquat***:
   a. coveralls, (double-weave)
   b. knee high boots (chemical –resistant)
   c. gauntlet gloves (chemical-resistant)
   d. cloth mask with activated charcoal filter
   e. below knee length apron (chemical-resistant)
   f. in case of spillage, workers involved in clean-up must wear respirators and goggles.

4. Recommendations for ***Lindane***:
   a. coveralls (double weave)
   b. boots knee high (chemical-resistant)
   c. face shield and carbon filter respirator.

5. General Guidelines for Maintenance:

   a. Decontamination and Laundering of Protective Clothing

      Provision must be made for the frequent and regular decontamination and washing of dirty clothing, either by the company's own facilities or by those of an approved contract service. The decontamination agent may be 5% sodium carbonate solution. The clothing must be soaked for at least one (1) hour prior to laundering. Machine laundering is necessary for arsenic, PCP, paraquat, heptachlor, lindane and category I-II OPs and carbamates. Care must be made that these clothings are not taken home for laundering or for other purposes.

   b. Maintenance of Protective Clothing and Equipment

      Protective clothing and equipment must be regularly checked and maintained to ensure that its condition is satisfactory. Gloves and boots must be checked for leaks before use and after cleaning. Gloves must be decontaminated prior to cleaning.

### B. Personal Hygiene

Changing and washing facilities must be provided with personal lockers for personal and work clothes. A clean area must be provided separate from the “dirty” area where workers enter after work.

A separate clean area should be provided where workers can eat, drink, and smoke. Eating, drinking and smoking must not be allowed in the work area.

## VI. Safety and Security

Machinery should be maintained and shielded as necessary to reduce hazards. A closed system (automatic or semi-automatic) is required for Category I-II materials.

Emergency equipment to meet accidents must be provided such as emergency showers and eyewash facilities. In plantations or in the field, provision of water at work area of 25 gallons/person or minimum of 100 gallons per area, whichever is greater.

A safety committee should be established (see Organizational Aspects).

Maintain healthful work environment by requiring health personnel to conduct regular appraisal of workplace including all the facilities therein in order to detect occupational health hazards. The physician must be informed of the exact time, place and the type of pesticide to be used including the number of workers exposed.

Fire-fighting equipment must be provided and strategically located. Signs indicating smoking restrictions, access restrictions, the location of emergency equipment, re-entry time, and all escape routes must be prominently displayed.

Each team of workers must have at least one (1) person trained on first-aid treatment of poisoning.

All emergency and safety-related equipment must be frequently and regularly checked and maintained. Records should be kept of all inspection checks and maintenance carried out on the equipment.

Secure arrangements must be made to prevent undesired access to site.

Storage of chemicals and treated wood (i.e. in wood treatment plants) should be adequate so as to prevent contamination.

## REFERENCES


1. Jeyaratnam, O. Health problems of pesticide usage in the third world. British Journal of Industrial Medicine, 1985; 42:505-506.

2. Occupational Safety and Health Standards, Department of Labor, 1984.

3. WHO Document, VBC 178.692, Spectrophotometric kit for measuring cholinesterase activity.

4. WHO Document, VBC 84.889, Field methods for measuring blood cholinesterase activity.

5. WHO Document, VBC 84.2, The WHO recommended classification of pesticides by hazard.

6. Manual for Seminar on Occupational Safety and Health, The Safety Organization of the Philippines, Inc.

7. Biological Monitoring in Organophosphate Exposure, Department of Health, New Zealand, 1982.

# A P P E N D I X  I

## *SAFE HANDLING OF PESTICIDES*

### *1. Read the Label:*

The label provides useful information regarding pesticide use, dangerous properties, precautions and emergency procedures in cases of poisoning.

### *2. Use the Recommended Personal Protective Clothing and Equipment (PPE) (See Table 1):*

After pesticide application, the worker must shower and change his clothing. The work clothes must be decontaminated and laundered separately from general laundry everyday. Street clothes should not be worn under protective clothing.

### *3. Store Safely:*

Store pesticides only in original containers; never in food, beverages, feed and seed storage.

Store pesticides in cabinets, room or storage area that can be locked, secured from children, irresponsible persons and animals.

Store pesticides away from food, feed and seed storage.

### *4. Mix Safely:*

When mixing, utmost care should be taken. A stick should be used to dilute or mix the solution or mixture. Because of the danger of skin absorption, mixing must never be done with bare hands.

### *5. Avoid Spray Drift:*

This is essential to prevent contamination of the worker through skin absorption or by inhalation.

### *6. Clean-up Spillages:*

This can effectively be done with soil, sawdust, sand, etc. to absorb the material. The contaminated soil can be shoveled into open drums for safe disposal. The area should be washed down into copious amounts of water. Washings should be effectively contained and disposed of safely.

***7. Wash Carefully:***

Wash hands and face before smoking or eating. After working with pesticide, take a shower and change to clean clothing.

***8. Dispose Used Containers in a Safe Manner:***

Bottles should be broken and drums punctured before disposal. Bury container at least 50 centimeters deep in an isolated area away from water supplies.

***9. Be Prepared for Emergencies:***

In spite of all precautions, instances of pesticide poisoning sometimes occur, so know the symptoms or signs of poisoning. Follow label directions for immediate aid. Call physician.

***10. General Rules:***

a) In all cases, call a physician at once.
b) In cases of skin contact, wash thoroughly with soap and running water for at least 15 minutes and remove contaminated clothing.
c) If pesticide was splashed into the eyes, flush with gentle stream of running water for at least 15 minutes.
d) If pesticide was swallowed, follow label directions.

# A P P E N D I X  I I

## METHODS OF CHOLINESTERASE DETERMINATION

### A. Michel Method

This method is based upon measurement of the acid produced by the action of cholinesterase upon acetylcholine. The acid production is measured in terms of the pH produced by enzymatic activity in a standard buffer solution over a definite period of time. The pH is measured with a glass electrode.

### B. Ellman (Spectrophotometric) Method

The enzyme activity is measured by determining the rate of thiocholine formation due to enzyme hydrolysis of acetylthiocholine used as substrate. Thiocholine reacts with a reagent dithiobisnitrobenzoic acid forming a yellow complex, the intensity of which is measured spectrophotometrically. The more yellow complex formed in a unit of time, the higher the enzyme activity. Since the original method requires laboratory facilities, WHO has promoted the development of a kit which enables measurement of blood cholinesterase activity spectrophotometrically in the field. Unpublished Document WHO/VBC/84.888 available from Pesticide Development and Safe Use Unit, Vector Biology Control Division, WHO, Geneva.

### C. Tintometric Method

The principle of the method is the measurement of the change of pH in a reaction mixture. The blood cholinesterase hydrolyzes acetylcholine, liberating acetic acid. The rate of this reaction (and thus the enzyme activity of the known amount of blood) is measured by the range of color change of an indicator (bromothymol blue) present in the solution. A mixture of blood, indicator and acetylcholine perchlorate is prepared and allowed to stand for a fixed time depending on the temperature. The change in colors produced by change in pH is matched against the colors on a comparator disc.

## A P P E N D I X  I I I

## WHO LIST OF CATEGORY I PESTICIDES

***List of Technical Products Classified in Category I***

| Name | Chemical Type | $LD_{50}$ (mg/Kg) |
|---|---|---|
| aldicarb | C | 0.93 |
| arsenous oxide | | 180 |
| calcium cyanide | | 39 |
| chlorfenviphos | OP | 10 |
| chlormephos | OP | 7 |
| chlorthiophos | OP | 7.1 |
| coumaphos | OP | 16 |
| crimidine | | 1.25 |
| CVP | | |
| cyanthoate | OP | 3.2 |
| cycloheximide | | 2 |
| DBCP | | |
| demephion-0 and –S | OP | 15 |
| demeton-0 and -S | OP | 1.7 |
| dibromochloropropane | | 170 |
| dieldrin | OC | 10 |
| dimefox | OP | 1 |
| disulfoton | OP | 2.6 |
| EPN | OP | 14 |
| ethoprophos | OP | 26 |
| ethoprop | | |
| ethylthiometon | | |
| fenamiphos | OP | 15 |
| fensulfothion | OP | 3.5 |
| fonofos | OP | 8 |
| fosthietan | OP | 5.7 |
| hexachlorobenzene | | 10 000 |
| leptophos | OP | 50 |
| M74 | | |
| MBCP | | |
| mephosfolan | OP | 9 |
| mercuric chloride | | 1 |
| metaphos | | |
| mevinphos | OP | 4 |
| parathion | OP | 13 |
| parathion-methyl | OP | 14 |
| phenylmercury acetate | | 30 |
| phorate | OP | 2 |
| phosfolan | OP | 9 |
| phosphamidon | OP | 17 |

***Continuation of List of Technical Products Classified in Category I***

| | | |
|---|---|---|
| prothoate | OP | 8 |
| red quill | | |
| schradan | OP | 9 |
| scilloriside | | c0.5 |
| sodium fluoroacetate | | 0.2 |
| sulfotep | OP | 5 |
| fluoroacetamide | | 13 |
| formetanate | C | 21 |
| heptenophos | OP | 96 |
| IPSP | OP | 84 |
| isazofos | OP | 60 |
| isofenphos | OP | 28 |
| isothionate | OP | 150 |
| isoxathion | OP | 112 |
| lead arsenate | | 10 |
| mercarbam | C | 36 |
| medinoterb acetage | NCP | 42 |
| methamidophos | OP | 30 |
| methidathion | OP | 25 |
| methacarbate | C | 19 |
| methomyl | C | 17 |
| 2-methoxymethyl-mercury chloride | OM | 30 |
| methyl-merkapto-phosteolovy | | |
| methylmercury dicyandiamide | OM | 32 |
| metilmarkapto-phosoksid | | |
| metriltriazotion | | |
| monocrotophos | OP | 14 |
| MPP | | |
| nicotine | | 50 |
| nitrilacarb | C | 9 |
| omethoate | OP | 50 |
| oxamyl | C | 6 |
| oxydemeton-methyl | OP | 65 |
| paris green | | 22 |
| pentachlorophenol | NCP | 80 |
| phenylmercury nitrate | OM | |
| pirimiphos-ethyl | OP | 140 |
| propaphos | OP | 70 |
| propetamphos | OP | 75 |
| salithion | OP | 180 |
| sodium arsenite | | 10 |
| sodium cyanide | | 6 |
| strychnine | | 16 |
| TBT | | |
| thiofanox | C | 8 |

***Continuation of List of Technical Products Classified in Category I***

| | | |
|---|---|---|
| thiometon | OP | 120 |
| thioxamyl | | |
| triamiphos | | 20 |
| triazophos | OP | 82 |
| triazotion | | |
| vamidothion | OP | 103 |
| zinc phosphide | | 45 |
| TEPP | OP | 1.1 |
| terbufos | OP | c2 |
| thionazin | OP | 11 |
| thiofos | | |
| timet | | |
| trichloronat | OP | 15 |
| acrolein | | 46 |
| aldoxycarb | C | 27 |
| aldrin | OC | 98 |
| allyl alcohol | | 64 |
| aminocarb | C | 50 |
| antu | | 8 |
| azinphos-ethyl | OP | 12 |
| azinphos-methyl | OP | 16 |
| azocyclotin | OT | 80 |
| bis (tributyltin) oxide | | 194 |
| blasticidin-S | | 16 |
| bromophos-ethyl | OP | 71 |
| butocarboxim | C | 158 |
| butoxycarboxim | C | 288 |
| calcium arsenate | | 20 |
| carbofuran | C | 8 |
| carbophenothion | OP | 32 |
| carbophenothio methyl | OP | 157 |
| chlordecone | OC | 114 |
| crotoxyphos | OP | 74 |
| DDVF | | |
| DDVP | | |
| delnav | | |
| demeton-S-methyl | OP | 40 |
| demeton-S-methylsulfan | OP | 37 |
| diamidafos | OP | 190 |
| diclorvos | OP | 56 |
| dicrotophos | OP | 22 |
| dimetilan | C | 47 |
| dinoseb | NCP | 58 |
| dinoseb acetate | NCP | 60 |
| dinoterb | NCP | 25 |

***Continuation of List of Technical Products Classified in Category I***

| | | |
|---|---|---|
| dioxathion | OP | 23 |
| DMTP | | |
| DNBP | | |
| DNBPA | | |
| DNOC | NCP | 25 |
| EDDP | | |
| medifenphos | OP | 150 |
| endothion | OP | 30 |
| endrin | OC | 7 |
| ESP | OP | 105 |
| fenthion | OP | 330 |
| flucythrinate | PY | 67 |

# APPENDIX IV

## DUTIES OF THE OCCUPATIONAL HEALTH PHYSICIAN

1. To assess the incidence and prevalence of ill-health in relation to work conditions and to recognize work conditions that contribute to subclinical and overt ill health and its short-term and long-term consequences. He needs special knowledge and experience in: toxicology, physiology, biostatistics, psychology, technological hazards, and internal medicine.

2. To identify occupational health problems in the light of the general health of the working population.

3. To manage adequately accidents and other emergencies (e.g. cardiovascular incidents, cases of intoxication); involves diagnosis, first-aid treatment and organization of a first-aid service and a disaster programme.

4. To prepare and evaluate statistical records of sickness, absences, to use such records to identify causes, and to propose measures to eliminate causes.

**FERTILIZER AND PESTICIDE AUTHORITY**
FPA Bldg. BAI Compound, Visayas Ave., Diliman, Quezon City

**Website: http://fpa.da.gov.ph**
**Email: fpacentral77@gmail.com**