PESTICIDE REGULATORY PROCESSES

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CHEMIST III

FERTILIZER AND PESTICIDE AUTHORITY

CREATION OF FPA

- On ***May 30, 1977***, the *Fertilizer and Pesticide Authority* was created and attached to the Department of Agriculture by virtue of ***Presidential Decree No. 1144***

- On ***May 05, 2014***, under Executive Order 165, the FPA was transferred to the ***Office of the President***

- Last ***September 17, 2018***, *under* ***Executive Order No. 62*** FPA was again transferred to the ***Department of Agriculture***

LEGAL BASIS

- Pursuant to Section 9 of PD 1144 and Section 1, Article II of FPA Rules and Regulation No. 1 Series of 1997, all pesticides must be registered with the Fertilizer and Pesticide Authority.

- “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”

PURPOSE OF THE REGISTRATION

- Ensure that the pesticide products meet the prescribed standards before they are imported, manufactured, formulated, distributed and sold in the Philippines

- Standards:
  - Quality and suitability of the active ingredient and of the formulated products
  - Bioefficacy
  - Safety to handlers
  - Safety to consumers and users
  - Safety to the environment
  - Handling, packaging, labeling and disposal

PESTICIDE REGISTRATION

- Controls over quality, use levels, claims, labeling, packaging and advertising.
- Involves evaluations of the benefits and risks of a pesticide under consideration based on the following data:
  - Chemical and physical properties
  - Biological efficacy
  - Toxicology
  - Residues and fate in the environment
- Requires approval of the pesticide product label

REGISTRATION PROCEDURES

- **COVERAGE:**

  FPA requirements for pesticide registration applied to all types of pesticides as defined under PD 1144 and which will be used in agriculture, structural and household purposes

- **WHO MAY REGISTER**

  Only local companies registered by Securities and Exchange commission to do business in the Philippines and duly licensed by FPA may apply for registration of pesticide products. In practice, the applicant or registrant should be a distributor or the local subsidiary of a foreign-based company.

APPLICATION FOR REGISTRATION

Documentation required

A complete application consists of:

- Properly accomplished registration forms for the active ingredient (P-012), pesticide product (P-022)
- Complete set of data requirements as specified in Table 2.2 of the Revised Pesticide Regulatory Policies and Implementing Guidelines and Procedures. Report of studies submitted are to be accompanied by a certification that they comply with GLP and internationally accepted protocol.

- Summary of data submitted with proper citation and an applicants assessment of how these data supports registration for the purpose and uses claimed.
- Proof of registration in other countries where relevant
- Review of data done by other countries and international organization especially US-EPA and European Union if available
- Third party authorizations, if applicable (any authorizations necessary to cite previously submitted data)

- Sample of material to be registered:
  - 1g analytical grade of active ingredient
  - 10 g technical grade material
  - 500mL or 0.500 kg of formulation

Certificate of analysis of formulated product and active ingredient

- Receipt of payment of filing fees
- Receipt of fee for confirmatory analysis

TYPES OF REQUIRED DATA

- Test Substance

Test protocols generally provide information on the test substance

- Identity of registrant, product manufacturing process

  A brief description of the manufacturing process supported with a simple flow chart plus a few paragraphs of description shall be submitted, to understand the basic steps to forecast where impurities or other undesirable constituents may enter into the product.

- Specifications

  To make sure that the registration data were produced using a chemical sufficiently similar to that being proposed for registration:

-Product Composition

-Chemical and Physical Properties

- Bioefficacy

  To ensure that the pesticide product will perform as indicated in the label against the intended pests.

- Toxicology

  -Acute Toxicity Studies

  -Short Term and Long Term Studies

  -Special studies (e.g. Pharmacokinetics, Mutagenicity, Breakdown products, Teratogenecity and Reproduction Studies)

- Human Exposure and Safety

  Required for new proprietary products under registration with strong toxicological concern.

- Environmental Effects

  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.

- ## Residues in Food

  Used to estimate the exposure of the general public to pesticide residues in food.

- ## Environmental Fate and Transport

  Used to assess the toxicity to man through exposure to pesticide residue remaining after application; the presence of widely distributed and persistent pesticide in the environment and to assess the potential environmental exposure of other non-target organisms.

  - Degradation studies
  - Metabolism studies
  - Mobility studies
  - Accumulation studies

DOCUMENTS FOUND IN THE DATA PACKAGE

- SPECIFICATION
  - Application letter
  - Application forms
  - Certification/Authorization from the Supplier
  - Label
  - Product Stewardship Program
  - Specification summary/data
- BIOEFFICACY
  - Application letter
  - Application forms
  - Label
  - Specification summary
  - Bioefficacy summary data
  - Approved EUP
  - Assessment of how these data support registration purpose/uses claimed

- Toxicology
  - Application letter
  - Application forms
  - Label
  - Specification summary
  - Toxicology summary/data
- Residue and Fate in the Environment/Environmental Effects
  - Application letter
  - Application forms
  - Label
  - Specification summary
  - Residue and Fate summary/data

STEPS IN PROCESSING APPLICATION FOR REGISTRATION

- Initial review

- Technical evaluation of the data packages

-Pesticide Policy and Technical Advisory Committee (PPTAC)

-Pesticide Registration Consultants (Evaluators)

- Advice to applicants

TYPES OF REGISTRATION GRANTED

- FULL-granted for products which fully meet all the requirements on the specification, bioefficacy, toxicology, residue and fate in the environment and proper labeling.
- CONDITIONAL-granted to a product meet almost all requirements for full registration except for some data which requires companies to submit within an agreed period of six (6) months/or one (1) year. Products with this type of registration may be marketed subjected to agreed conditions.

Conversion to full registration-when conditions and requirements have been met satisfactorily

- PENDING/DENIED-application does not meet the requirements for registration

PERIOD OF VALIDITY AND RENEWAL OF REGISTRATION:

- Each registration shall be valid for a period of 3 years, unless earlier revoked or cancelled.
- Renewal of registration shall be filed at least 3 months before its expiry date by paying the appropriate fees, notarized application forms, MSDS and label.
- Application for renewal filed within 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

New Application-Filing Fee	
Active Ingredient	4,500
Product	3,000
Conditional Registration	
Renewal (Annually)	
Product Category I and II Category III and IV	 5,000 3,000
Active Ingredient Category I and II Category III and IV	 7,000 5,0000
Full Registration/Renewal (3 years validity)	
Product Category I and II Category III and IV	 15,000 7,000
Active Ingredient Category I and II Category III and IV	 20,000 15,000
Submission of Additional Data	4,000
Label/Expansion/Crop	3,000

EXPERIMENTAL USE PERMIT (EUP)

- All pesticides to be tested in the Philippines, either to generate local data to support registration or to conduct preliminary screening tests in the products must be covered by an appropriate EUP.

The experiment shall be conducted by researchers accredited by FPA following the standard protocols for biological efficacy testing.

SPECIAL TYPES OF EUP

- EUP IA-covers coded compounds in the initial stages of development to be listed only within the company research station.

  IB-covers coded compounds to be tested outside the company research station but on limited areas.

  II-covers pesticides, in pre market, development stage and the bioefficacy data generated may be used for registration purposes.

  III-covers registered pesticides to be tested for additional uses or for label expansion.

SUPPORTING REGULATORY PROCESSES

- LICENSING OF HANDLERS
  - Persons involved in production, application and sale of pesticides have the appropriate license issued by the Authority.

- IMPORT CONTROL
  - No importation of any pesticide is allowed without the appropriate Certificate Authorizing Importation of Pesticides (CAIP)

PESTICIDE LICENSING PROCEDURES

- Pursuant to Section 9 of PD1144 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 with 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."

License-is a written authority issued by FPA to a Handler for a particular activity as a business enterprise.

PESTICIDE LICENSES ISSUED BY FPA

- Dealer
- Importer
- Extruder
- Exporter
- Repacker
- Distributor
- Area Distributor
- Indentor/Trader
- Importer End-User
- Pest Control Operator
- Manufacturer/Formulator
- Supplier's Local Subsidiary/Representative

POLICY GUIDELINES ON BIORATIONAL PESTICIDES

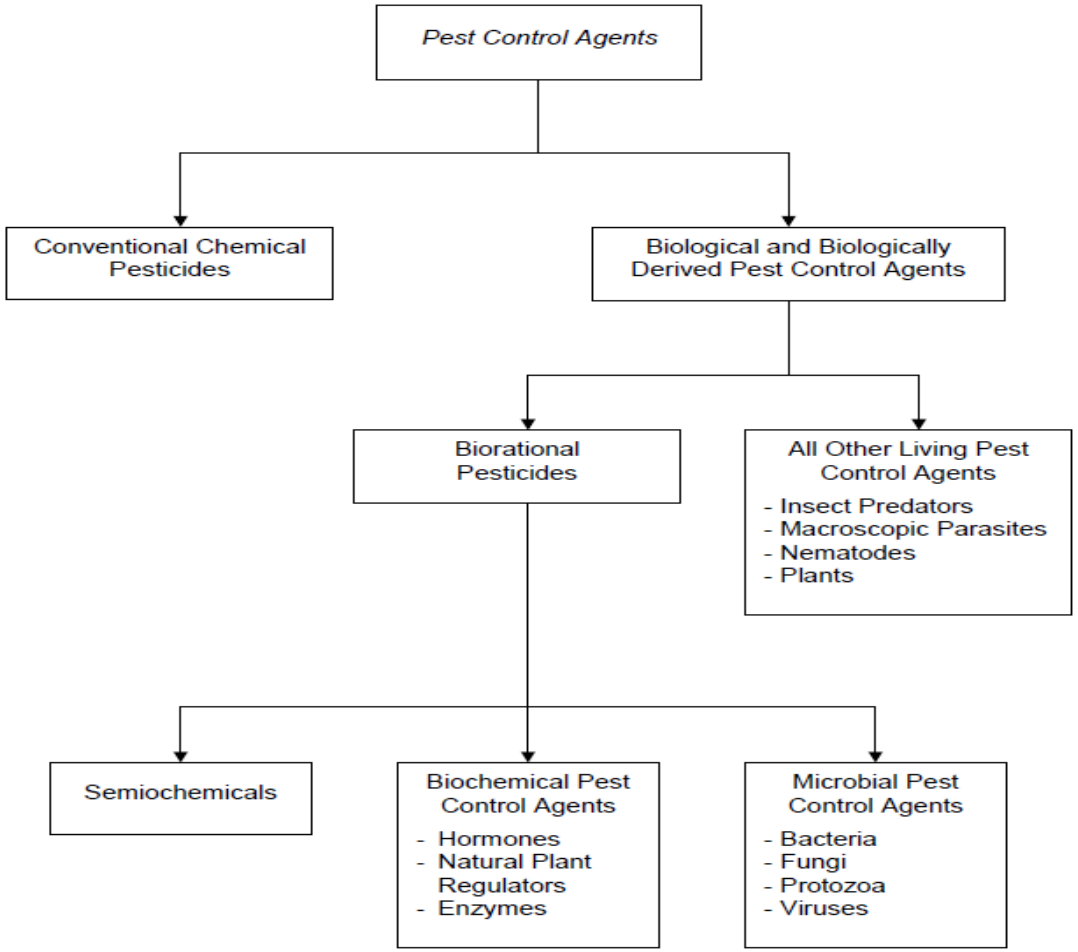
Biorational Pesticides - *any pesticide material that relatively causes no harm to humans or animals, and does little or no damage to the environment.*

POLICY STATEMENT

All applications should have:

- *clearance from National Committee on Biosafety of the Philippines (NCBP)*
- *inherently different and pose lower potential risks than conventional pesticides*
- *target species specificity, generally non-toxic mode of action, and natural occurrence of the biorational agents*

RELATIONSHIPS AMONG CONVENTIONAL PESTICIDES, BIOLOGICAL CONTROL AGENTS AND BIORATIONAL PESTICIDES



PIP (PLANT INCORPORATED PROTECTANTS)

- MEMORANDUM CIRCULAR NO. 10 SERIES OF 2017

- GUIDELINES FOR THE REGISTRATION OF PIP's IN PEST – PROTECTED PLANTS (PPPs) AND OTHER AGRICULTURAL PESTICIDAL SUBSTANCES DERIVED FROM MODERN BIOTECHNOLOGY.