



REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
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>

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MEMORANDUM CIRCULAR NO. 10
Series of 2017

TO : ALL CONCERNED

**SUBJECT : GUIDELINES FOR THE REGISTRATION OF PLANT- INCORPORATED
PROTECTANTS (PIPs) IN PEST- PROTECTED PLANTS (PPPs)
AND OTHER AGRICULTURAL PESTICIDAL SUBSTANCES DERIVED
FROM MODERN BIOTECHNOLOGY**

I. RATIONALE

The Fertilizer and Pesticide Authority (FPA) is mandated by Presidential Decree (PD) No. 1144 to regulate, control and develop the agricultural pesticide industry, including the licensing of all handlers and the registration of all agricultural pesticide products that are intended to be imported, exported, manufactured, formulated, stored, distributed, sold or offered for sale, transported, delivered for transportation or used in the country.

Science innovation produces agricultural inputs that are used for crop protection and nutrient management through modern biotechnology techniques, hence, there is a need to update the existing FPA regulatory policies and issuances to include the registration of biotechnology based PIP and other agricultural pesticidal substances that fall under the regulatory scope of FPA.

The Department of Agriculture (DA) and other government agencies created a Technical Working Group (TWG) that drafted the new rules and regulations for biotechnology, entitled DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2016 (JDC No.1, s. 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*. The aforesaid promulgated rules and regulations was subjected to extensive multi-stakeholders consultations in Luzon, Visayas and Mindanao.

On April 14, 2016 the aforesaid JDC No.1, s. 2016 became effective after fifteen (15) days in national publication since March 30, 2016 which tasked FPA to regulate transformation event that has agricultural pesticidal action which serves as the Plant-Incorporated Protectant (PIP) in Pest-Protected Plant (PPP) produced through modern biotechnology.

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Under Rule No. 4, Section 15 of Article VI states that *no regulated article shall be released for commercial propagation unless if the regulated article is a pest-protected plant, its transformation event that serves as Plant-incorporated protectant (PIP), has been duly registered with the Fertilizer and Pesticide Authority (FPA).*

Under Rule C.3., Section 16 of Article VI provides that if the regulated article is a pest-protected plant, the FPA determines if the applicant is duly licensed as agricultural pesticide handler in accordance with PD No. 1144 and if tolerance levels and good agricultural practices have been established for registration of the transformation event.

In compliance with JDC No.1, s. 2016 and pursuant to the provisions of Section 9 of P.D. No. 1144 and its Implementing Rules and Regulations, the FPA promulgated these guidelines as addendum to FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001) for the registration of PIPs in PPPs and other pesticidal substances derived from modern biotechnology.

The FPA PIP guidelines had been subjected to multi-stakeholder consultations, evaluation of Pesticide Policy and Technical Advisory Committee (PPTAC) members and expert scrutiny of FPA Board members. Several technical meetings and consultations has been conducted by the FPA with relevant stakeholders from government, academe, non-government organizations (NGO's) and industry to identify the technical requirements for the registration of PIPs and the mechanisms for its implementation, which served as basis for this guidelines on the registration of PIPs in PPPs and other pesticidal substances derived from modern biotechnology.

II. PURPOSE

The guidelines is for the registration of PIPs in PPPs and other agricultural pesticidal substances derived from modern biotechnology in compliance with the mandate of FPA under PD. No. 1144 and JDC No.1, s. 2016.

III. DEFINITION OF TERMS

Pesticide – 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, nematocide, herbicide, molluscicide, avicide, rodenticide, plant regulator, defoliant, dessicant and the like.¹

Pest-protected Plant (PPP) – refers to any plant that is made pest resistant through the use of any of the techniques of modern biotechnology.²

Plant-incorporated Protectant (PIP) – refers to pesticidal substance produced by plants and the genetic material necessary for the plant to produce the substance.²

¹ Fertilizer and Pesticide Authority (2001). Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition).

¹ Fertilizer and Pesticide Authority (2001). Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition).

² Section 2 (Definition of Terms) Article I (General Provisions). DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2016. April 14, 2016.

Other Agricultural Pesticidal Substances – refers to substances or products that are derived from modern biotechnology and the effects or intended use should be the same as pesticide as defined in accordance with the 2001 FPA Green Book.¹

Transformation Event – refers to 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.²

IV. COVERAGE

This memorandum circular shall apply to all PIPs of PPPs as well as other substances that have agricultural pesticidal action against particular pests and diseases produced using modern biotechnology techniques, for registration, either new or renewal and conditional or full registration status and for quality monitoring of the agency.

V. REQUIREMENTS FOR THE LICENSING OF HANDLERS OF PIPs AND OTHER AGRICULTURAL PESTICIDAL SUBSTANCES DERIVED FROM MODERN BIOTECHNOLOGY

Pursuant to Section 9 of the PD 1144, Section 1, and 2 of Article III of the FPA Rules and Regulations No. 1, series of 1977, all agricultural pesticide handlers must obtain a license from the Fertilizer and Pesticide Authority. All technology developer, dealers, importer 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 Section 4.2 and 4.3 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

VI. REQUIREMENTS FOR THE REGISTRATION OF PIPs AND OTHER PESTICIDAL SUBSTANCES DERIVED FROM MODERN BIOTECHNOLOGY

As a new category of biorational/biopesticides, PIPs and other agricultural pesticidal substances shall be registered by FPA based on the general principles found in its *Pesticide Regulatory Policies and Implementing Guidelines* (2nd Edition, 2001), but with the following modifications specified below, due to the distinct and contained nature of PIPs and other agricultural pesticidal substances derived from modern biotechnology.

- 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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).
- B. Data on Product Specification for PIPs and other agricultural pesticidal substances – Based on Section 3.3.2 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001), the following are the data required for product analysis of PIPs 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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).
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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

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 3.5.1.B of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001) for the diagram that outlines the Environmental Fate Testing Scheme.
2. Tier Testing – shall be followed in accordance with Section 3.7.1.B of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).

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 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).
 - b. Efficacy Data – shall be required in accordance with Section 3.8.1.B of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001).
 - 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.1, 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.1, 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.

2. 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.1, 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.
3. 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 3.10 of the FPA Pesticide Regulatory Policies and Implementing Guidelines (2nd Edition, 2001). 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.

VII. 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*".

VIII. REVOCATION CLAUSE

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.

IX. EFFECTIVITY

This Memorandum Circular takes effect fifteen (15) days after its publication in a newspaper of general circulation and repeals or amends all other issuances relative thereto that are inconsistent thereof.

APPROVED BY:


WILFREDO C. ROLDAN
Executive Director

Annex 1. Relationships among the Different Pest Control Agents

