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OFFICE OF THE PRESIDENT
FERTILIZER AND PESTICIDE AUTHORITY
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1 August 2016

NOTICE OF PUBLIC CONSULTATION

FOR : **ALL CONCERNED**

FROM : **The Executive Director**

DATE : **August 11, 2016**

SUBJECT : **STAKEHOLDER CONSULTATION ON THE PROPOSED GUIDELINES FOR THE REGISTRATION OF PLANT-INCORPORATED PROTECTANTS (PIPs) IN PEST-PROTECTED PLANTS (PPPs) DERIVED FROM MODERN BIOTECHNOLOGY**

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Pursuant to the provisions of Presidential Decree No. 1144 and in compliance with the DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, s. 2016, the Fertilizer and Pesticide Authority (FPA) is inviting all concerned stakeholders and interested parties to the forthcoming consultation on the Proposed Guidelines for the Registration of Plant-Incorporated Protectants (PIPs) in Pest-Protected Plants (PPPs) Derived from Modern Biotechnology on **August 11, 2016, 1:00 pm** at 4/F FPA Bldg., BAI Compound, Visayas Avenue, Diliman, Quezon City.

Kindly send your confirmation of attendance through our telefax number **(02) 920-8449** or email us at fpa.lsd@gmail.com. A copy of the proposed guidelines can be downloaded at the FPA website (http:// fpa.da.gov.ph) starting August 2, 2016.

NORLITO R. GICANA, CESO III
Executive Director
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01 August 2016

MEMORANDUM CIRCULAR NO. ____
Series of 2016

TO : ALL CONCERNED

SUBJECT : GUIDELINES FOR THE REGISTRATION OF PLANT-INCORPORATED PROTECTANTS (PIPs) IN PEST-PROTECTED PLANTS (PPPs) DERIVED FROM MODERN BIOTECHNOLOGY

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I. RATIONALE

The Fertilizer and Pesticide Authority (FPA) is mandated by Presidential Decree (PD) No. 1144 to regulate, control and develop the pesticide industry, including the licensing of all handlers and the registration of all 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 pesticidal substances and other genetically modified products 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
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FPA to regulate transformation event that has pesticidal action which serves as the Plant-Incorporated Protectant (PIP) in Pest-Protected Plant (PPP) produced through modern biotechnology.

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 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 for the registration of PIPs in PPPs derived from modern biotechnology.

The FPA proposed PIP guidelines had been subjected to multi-stakeholder consultations, evaluation of PPTAC members and expert scrutiny of FPA Board members. Several technical meetings and consultations had already been conducted by the FPA with relevant stakeholders from government, academe, and industry to identify the technical requirements for the registration of PIPs and the mechanisms for its implementation, which served as basis for this guideline on the registration of plant-incorporated protectants.

II. PURPOSE

The guidelines is for the registration of PIPs in PPPs derived from modern biotechnology in compliance with the mandate of FPA under PD. No. 1144 and the 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, nematicide, herbicide, molluscicide, avicide, rodenticide, plant regulator, defoliant, dessicant and the like.[1]

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

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]

Other Agricultural Chemicals – shall mean chemicals, chemical inputs and chemical compounds not herewith covered by the definition of fertilizer and pesticide but utilized by the agricultural sector.[3]

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 agricultural chemicals or substances that have pesticidal actions against particular pests and diseases that are 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 REGISTRATION OF PIPS

As a new category of biorational/biopesticides, PIPs shall be registered by FPA based on the general principles found in its *Pesticide Regulatory Policies and Implementing Guidelines* (2001 FPA Green Book) issued on December 2001, but with the following modifications specified below, due to the distinct and contained nature of PIPs.

A. Approach to Testing – The approach to testing of PIPs shall be conducted in accordance with Section 3.2.2 of the 2001 FPA Green Book.

B. Data on Product Specification for PIPs – Based on Section 3.3.2 of the 2001 FPA Green Book, the following are the data required for product analysis of PIPs:

    1. Product Identity – Each application for the registration of a PIP 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 shall contain a confidential statement of formula. This shall

[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.

[3] Presidential Decree No. 1144 (May, 1977). Creating the Fertilizer and Pesticide Authority and Abolishing the Fertilizer Industry Authority.

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 2001 FPA Green Book.

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

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 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 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

Toxicology data guidelines for PIPs shall be conducted in accordance with Section 3.4.4 of the 2001 FPA Green Book.

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 2001 FPA Green Book.

E. Non-Target Effect Testing for PIPs

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

Non-target effect testing for PIPs shall be conducted in accordance with Section 3.6.1 of the 2001 FPA Green Book.

F. Environmental Fate for PIPs

1. Scope and Approach – Environmental fate data confirm what is the expected fate of a PIP. It validates the anticipated persistence of the PIP 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 2001 FPA Green Book 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 2001 FPA Green Book.

G. Product Performance Data Requirements for PIPs

1. General Provisions

   a. Policy on the Waiver of Data Requirements – shall be followed in accordance with Section 3.8.1.A of the 2001 FPA Green Book.
   b. Efficacy Data – shall be required in accordance with Section 3.8.1.B of the 2001 FPA Green Book.
   c. Data on phytotoxicity is waived since the regulated substance is incorporated in the pest-protected plant itself. Other plants within and surrounding areas will not be unduly exposed to the regulated substance.

2. Specific Provisions – shall be followed in accordance with Section 3.8.2 of the 2001 FPA Green Book.

H. Experimental Use Permit and Field Testing Guidelines

1. General Provisions:
   a. Registration of PIPs in PPPs 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 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 only be one field trial that may

cover several trial sites. The field trial 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 shall cover the generation of local bioefficacy data only.
   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 PIP registration, FPA shall evaluate the application for registration and the Executive Director of FPA shall decide whether to approve or deny the registration of the PIP based on its technical evaluation. If approved, the registration of PIP shall be valid for a period of one (1) year for conditional registration or three (3) years for full registration.

J. Penalties/Sanctions
   1. Non-compliance to any provision on data requirements stated in this guideline shall serve as ground for denial of PIP registration.
   2. Whenever necessary to prevent or control serious injury to plant or animal life, public health and the environment, any PIP containing product that are not registered with FPA or a PIP product registered with FPA but there is either a scientific evidence that the product is unsafe to public and environment or there is 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 and/or suspend registration and the PIP products 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 – The conduct of public awareness on PIPs shall be in accordance with Section 3.10 of the 2001 FPA Green Book.

VI. PAYMENT OF FEES

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

VII. 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 guidelines.

VIII. EFFECTIVITY

This Memorandum Circular takes effect fifteen (15) days after publication in one (1) newspaper of general circulation and repeals or amends all other issuances relative thereto that are inconsistent thereof.

APPROVED BY:

NORLITO R. GICANA, CESO III
Executive Director

Annex 1. Relationships among the Different Pest Control Agents