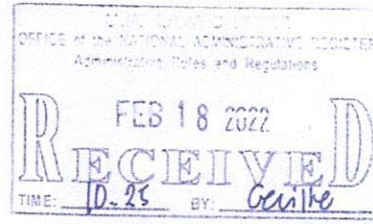




Republic of the Philippines
OFFICE OF THE SECRETARY
 Elliptical Road, Diliman
 1100 Quezon City



DEPARTMENT CIRCULAR
 No. 01
 Series of 2022

SUBJECT : GENERAL GUIDELINES ON THE REGISTRATION OF NEW FERTILIZER PRODUCTS WITH REQUIRED BIOEFFICACY TRIAL AND MANDATORY PUBLICATION OF THE BIOEFFICACY TRIAL TERMINAL REPORT

In the interest of the service, for the continuous improvement and effective implementation of the regulation for new fertilizer products with required bioefficacy trials to ensure the effectiveness and safety of the products, and in compliance with the rules and regulations stipulated in Presidential Decree 1144, and R.A. 10611 otherwise known as the Food Safety Act of 2013, titled "An act to strengthen the food safety regulatory system in the country to protect consumer health and facilitate market access of local foods and food products, and for other purposes", and their respective Implementing Rules and Regulations (IRR), this Department Circular is hereby issued with the following guidelines:

Section 1. Definition of Terms

Accredited Researcher. A technical expert authorized by FPA to conduct bioefficacy trials for the generation of test data for product registration and has attended the required seminar by FPA.

Efficacy of the trial terminal report. The Efficacy Trial Terminal Report shall be defined as the technical and scientific paper written by an active FPA accredited researcher based on the standards for Experimental Use Permit (EUP) stipulated in the Fertilizer Regulatory Policies and Implementing Guidelines. The terminal report must be approved by the FPA Technical Evaluator/s. The terminal report shall be based on the generated data of the approved efficacy experimental design of EUP.

Experimental Design. The framework that an experiment follows to observe, evaluate, describe, and explain the data as well as any variations in information that are to be gathered under conditions that are hypothesized and in accordance with the prescribed standard set by FPA as stipulated Fertilizer Regulatory Policies and Implementing Guidelines.

Experimental Use Permit. A permit issued to authorize conduct of a bio efficacy trial by an accredited researcher to generate data following the treatments and protocols specified in the existing Fertilizer Regulatory Policies and Implementing Guidelines

Fertilizer. Any substance that is applied to the soil or on the plant to provide one or more of the essential nutrients to improve plant nutrition, growth, yield or quality, or for promoting a chemical change that enhances plant nutrition and growth.

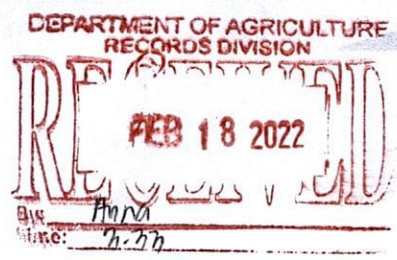
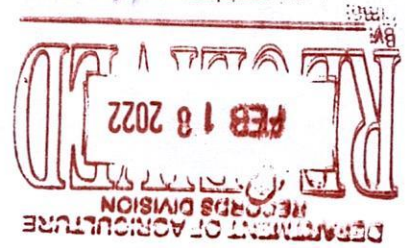
Technical evaluator. An officially designated external expert of FPA tasked to review and provide recommendations on applicant's submitted trial protocol and terminal report as a requirement for product registration.

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Certificate of Product Registration. A written approval indicating the company name, brand name, guaranteed analysis, manufacturer, country of origin, registration number and validity granted to registered products

Registered Product. A product approved by FPA covered by its corresponding certificate of product registration.

Section 2. **Products Requiring Bioefficacy Trial**

New Fertilizer Products with less than ten (10) years in the market required to undergo bioefficacy trials are:

Section 2.1. New grades of Micro Nutrients alone or combination thereof such as Co, Cu, Fe, and so on;

Section 2.2. Plant growth regulators;

Section 2.3. Biostimulants;

Section 2.4. Microbial inoculants or decomposers; and


Section 2.5. Those products that are not covered by FPA Memorandum Circular No. 5, Series of 2019 titled, "Amendment to Memorandum Circular No. 14, Series of 2017 "Exemptions from Bioefficacy Data Generation of Fertilizers Using Traditional Fertilizers as Raw Materials", with wet and dry season planting. FPA Memorandum Circular No. 5 in simple terms refer to N-P-K containing fertilizers whether in solid or in liquid form.

Section 3. **Products Exempted from Bioefficacy Trials.** New Product registration for inorganic fertilizers registered for ten (10) years or more are exempted from bioefficacy trial based on these criteria:

Section 3.1. Products containing Nitrogen, Phosphorus and Potassium as single component or as combination thereof whether in solid or liquid form, except for nano size. This is in line with FPA Memorandum Circular No. 5, Series of 2019 titled, "Amendment to Memorandum Circular No. 14, Series of 2017 "Exemptions from Bioefficacy Data Generation of Fertilizers Using Traditional Fertilizers as Raw Materials", with wet and dry season planting;

Section 3.2. Products that are fully registered with FPA for ten (10) years or more without any N-P-K component, such as micro nutrients, beneficial microorganisms, chemical biostimulants and plant growth regulators; and;

Section 3.3. Bulk blended fertilizers using inorganic fertilizers that are registered with FPA for ten (10) years or more such as: urea, ammonium sulphate, ammonium chloride, ammonia, potassium nitrate and calcium nitrate. Fertilizers with potassium include the following: potassium sulfate and potassium chloride; while fertilizers with phosphorus content include: di-ammonium chloride, ammonium phosphate sulfate (16-20-0), ordinary superphosphate, triple superphosphate, mono-ammonium phosphate phosphoric acid, rock phosphate and Triple 14. Other sources of plant nutrients may include but are not limited to sulfuric

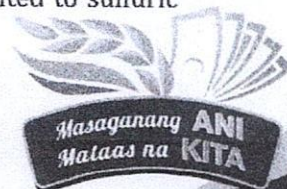

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acid, magnesium sulfate, zinc sulfate, ferrous sulphate, agricultural lime and dolomite.

Section 4. **Required Seasons of Planting for Bioefficacy Trials.** The bioefficacy trials must be conducted in two (2) different seasons, the wet and dry seasons.

Section 5. **Registration requirements for New fertilizer Product with Efficacy Trial:**

Section 5.1. **Experimental Use Permit.** Approved Experimental Use Permit (EUP) based on the Fertilizer Regulatory Policies and Implementing Guidelines with two different seasons of planting, and representing the wet and dry seasons.

Section 5.2. **Conduct of Product Efficacy Trial.** The product efficacy trial shall only be conducted and evaluated based on the approved experimental use permit (EUP) to ensure that the approved protocols and treatments are followed. Only active FPA accredited researcher shall be authorized to conduct the trial and must be monitored by the FPA officer covering the experimental site.


The data for showing the effectiveness of the new products should be statistically significant over the control. The terminal report shall be submitted within one (1) year after conclusion of the trial.

Section 5.3. **Publication of Bioefficacy Trial Terminal Reports.** For transparency and to allow the public and interested parties access to information on the efficacy and performance of the New fertilizer product, publication of the Efficacy Trial Terminal Report shall be required. The technical report shall be published either in technical bulletins, or technical journals published by the government or private institutions or academes.


Section 5.4. **Certificate of Product Registration for New Fertilizer Product with Bioefficacy Trial Terminal Report.** The applicant can only apply for the certificate of product registration for the new fertilizer product upon compliance of the publication of the efficacy trial terminal report as prescribed in Section 5.3 of this Circular. The requirements for the application and issuance of the certificate of product registration shall follow the existing Fertilizer Regulatory Policies, and Implementing Guidelines for registration of New Product required with efficacy trial.

Section 6. **Validity of the Certificate of Product Registration for New Fertilizer Products with Bioefficacy Trial.** All approved product registration shall be valid for three (3) years, and shall be cancelled, revoked, or suspended for cause stipulated in PD 1144 and its Implementing Rules and Regulations and the existing Fertilizer Regulatory Policies and Implementing Guidelines.

Section 7. **Label Expansion.** Label expansion can be filed by registrants who wish to add other crop groupings to the target crop/s. Prior to filing, one approved efficacy test must be conducted on a representative crop of the desired crop grouping such that other crops belonging to the same grouping no longer need any additional trial based on the existing Fertilizer Regulatory Policies and Implementing Guidelines. Multiple efficacy tests on representative crops from different groupings may be filed simultaneously and will be charged per crop.


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Section 8. **Exclusivity in The Use of Data.** Data submitted to support the first full registration of a particular product will be granted protection for a period of five (5) years from the date of first issuance of full product registration. During this period, subsequent registrants may rely on these data only with first party authorization. Otherwise, they should submit their own data. After five (5) years from the date of first issuance of registration or data reporting, other applicants may use the data of the primary registrant provided they share the cost in the data generation expenses incurred by the latter. The applicants should agree on the cost and/or otherwise, government mediates on the amount of their share of expenses. Moreover, the applicants must submit convincing proof that the product being registered is of the same raw materials and follows the same production process.

Section 9. **Renewal of Product Registration.** The product registration may be renewed on or three (3) months before the expiry date. The confirmatory analysis shall be required with passed or acceptable remarks for all the required parameters on the official test result and evaluation summary (TRES) valid for one (1) year from date of analysis.

Section 10. **Fees.** Filing and registration fees shall be collected for new application and upon renewal, only a registration fee shall be collected depending on the type of fertilizer product applied.

Section 11. **Transitory Provision.** Application for Experimental Use Permit and product registration received by FPA prior to the effectivity of this Circular, shall continue to be governed by the provisions of the 2019 Fertilizer Regulatory Policies and Implementing Rules and Regulations.

Application for product registration with EUP, approved prior to the effectivity of this Circular, shall not be required to publish their efficacy trial terminal reports provided that:

Section 11.1. The efficacy trial is ongoing;

Section 11.2. The efficacy trial terminal reports are for completion;


Section 11.3. The efficacy trial terminal reports are already submitted to FPA for evaluation.

The products registered with provisional certificate of product registration shall continue to be valid until its expiration date unless sooner terminated, cancelled, or revoked.


This implies that provisional certificate of product registration shall no longer be awarded, instead only Full Product registration subject to Fertilizer Regulatory Policies and Implementing Guidelines.

Section 12. **Repealing Clause.** All issuances, orders, rules, and regulations or parts thereof which are inconsistent with the provisions of this circular are hereby repealed, amended, or modified accordingly.

Section 13. **Separability Clause.** If any provision of this Circular be declared invalid or unconstitutional, the other provisions not affected thereby shall remain valid and subsisting.


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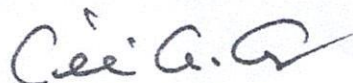
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Section 14. **Effectivity.** This Circular shall take effect after fifteen (15) days following the complete publication in the Official Gazette or a newspaper of general circulation and its filing with the National Administrative Register of the University of the Philippines Law Center.

Done this 16th day of February 2022.


APPROVED BY:



WILLIAM D. DAR, PhD
Secretary

DEPARTMENT OF AGRICULTURE

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