Republic of the Philippines
OFFICE OF THE SECRETARY
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DEPARTMENT CIRCULAR
No. 01
Series of 2021

SUBJECT: AMENDING RELEVANT PROVISIONS OF THE DEPARTMENT CIRCULAR NO. 05 SERIES OF 2020 ENTITLED "GUIDELINES ON THE REGISTRATION OF ORGANIC BIO-CONTROL AGENTS (OBCA) PRODUCERS AND PRODUCTS"

In the interest and exigency of service, for effective implementation of Section 16 (Registration of Organic Food and Organic Input Producers) and Section 17 (Labeling of Organic Produce) of Republic Act No. 10068 otherwise known as the "Organic Agriculture Act of 2010" and its Implementing Rules and Regulations (IRR), and to protect our farmers and consumers, specific provisions of the Department Circular No. 05, Series of 2020 are hereby amended, as follows:

Section 1. The definition of the term "Evaluator" under Article III, Definition of Terms, is hereby amended, to read as follows:

"**1.7 Evaluator**
Officially designated expert of BAFS tasked to review and provide recommendations on an applicant's submitted efficacy trial protocol."

Section 2. All provisions of Article V, Prerequisites for the Registration, are hereby amended, to read as follows:

"Prior to the application for registration (Articles VII and VIII of this Circular), the following shall be secured by applicants:

Section 1. **Conduct of Product Efficacy Trials.** Experimental Use Permit (EUP) shall be issued by the BAFS prior to the conduct of any efficacy trial for OBCA product to generate data required for registration. The applicant shall conduct the required number of trials prior to the application for registration. Section 3, Article VI of this Circular provides for the requirements for EUP application.

Section 2. **Publication of Efficacy Trial Terminal Reports.** Generated product efficacy terminal reports from the required local trials conducted by BAFS-certified researchers shall be published either in a technical bulletins or technical journals published by the government or private institutions (e.g. academe) prior to acceptance of OBCA products for registration. This will allow the public and other interested parties to assess the performance of the product.

Section 3. **Organic Certificate from BAFS Officially-Accredited Organic Certifying Body (OCB).** Applicants shall secure the required Organic Certificate from BAFS Officially-Accredited OCB. Applicants must comply with the requirements of OCB.

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Section 4. Applicants may request BAFS to conduct a preliminary assessment of their OBCA products' information."

Section 3. All provisions of Article VI, Application for Experimental Use Permit (EUP), are hereby amended, to read as follows:

"Section 1. Only EUP applications with complete requirements shall be accepted.

Section 2. Application for EUP must be submitted at least one (1) month before conducting the actual trial. Procedure and processing time for EUP application is shown in Annex A.

Section 3. **Requirements for EUP.** Applicants for EUP shall submit the following requirements to BAFS-Organic Agriculture Division:

3.1 Duly accomplished application form, with authorized name and signature;
3.2 Efficacy trial protocol (ETP) prepared and signed by a BAFS certified researcher for OBCA;
3.3 Product profile, including the list of raw materials (substrates) used and the production process, with authorized name and signature; and
3.4 Material Safety Data Sheet (MSDS) or any available product technical information, with authorized name and signature.

Note: Requirements 3.3 to 3.4. are not required for label expansion application unless there were changes.

Section 4. All ETPs and the conduct of efficacy trials per OBCA product must be in accordance with the requirements specified in the *BAFS Evaluators and Researchers Manual: Requirements for the Conduct of Efficacy Trials for Organic Bio-control Agents (OBCA) Products.*

Section 5. Upon compliance with the above requirements, BAFS will grant EUP to applicant within fifteen (15) working days.

Section 6. BAFS shall conduct field visits of approved efficacy trials within the period of validity of EUP for compliance assessment.

Section 7. **Validity of EUP.** The EUP is valid only for one (1) location trial. The EUP's validity period and location may be amended, provided that the following conditions are met:

7.1 The request for amendment is done through a formal request addressed to the BAFS Director, within the period of the issued EUP;
7.2 The on-going trial was affected by calamities;
7.3 Expected pest prevalence did not occur; and

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7.4 Other compelling reasons that are acceptable for BAFS.

Section 8. **Requirements for label expansion.** The required number of efficacy trials specified in the *BAFS Evaluators and Researchers Manual: Requirements for the Conduct of Efficacy Trials for Organic Bio-control Agents (OBCA) Products* per Section 4 of Article VI of this Circular shall be completed."

Section 4. All provisions of Article VIII, Registration of Organic Bio-control Agent (OBCA) Products, are hereby amended, to read as follows:

"Section 1. OBCA products, which are produced locally or imported, must be registered with BAFS.

Section 2. Procedure and processing time for the registration of OBCA products is shown in *Annex B.*

Section 3. **Requirements for Certificate of Product Registration (CPR).** Applicants for CPR shall submit the following requirements to BAFS-Organic Agriculture Division:

3.1 Duly accomplished application form, original copy with authorized name and signature;
3.2 Copy of Organic Certificate from a BAFS Officially-Accredited OCB;
3.3 Copy of the recent laboratory analysis for heavy metals of the product (only for botanicals) from a BAFS Officially Accredited OCB;
3.4 Copy of published efficacy trial terminal reports;
3.5 Toxicity Data, with authorized name and signature;
3.6 Product brochure/pamphlet; and
3.7 Proposed packaging and labeling.

Note: Requirements 3.4 to 3.7. are not required for renewal application unless there were changes.

Section 4. Upon compliance with all the regulatory requirements of this Circular, BAFS will grant CPR to applicants within three (3) working days.

Section 5. **Validity of CPR.** The CPR is valid for five (5) years, and is renewable, subject to BAFS annual conformity assessment.

Section 6. The CPR shall contain at least the following information:

6.1 Brand Name;
6.2 Product Type;
6.3 Name of Producer or Producers in case of recognized TPAs;
6.4 COR Number/s;
6.5 Product Registration Number;
6.6 Date of Issue and Validity;

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6.7 Recommended Use;
6.8 QR Code; and
6.9 Terms and Conditions (these are the conditions that must be met during the validity of CPR)."

Section 5. Article XIII, Renewal, Retention and Conditions for Extension of Registration, are hereby amended, to read as follows:

"ARTICLE XIII
RENEWAL AND RETENTION OF REGISTRATION

Section 1. The registered producer must apply for renewal of its COR and CPR within three (3) months prior to their expiration.

Section 2. Applicants for renewal of COR and CPR shall submit the applicable requirements as specified under Articles VII and VIII of this Circular.

Section 3. The BAFS shall notify its clients to apply for renewal of their organic certificate with OCB, COR and CPR, at least four (4) months prior to their expiration.

Section 4. The registered OBCA producers shall submit a copy of their new organic certificate to BAFS within one (1) month after expiration of their previous organic certificate."

Section 6. Annex A, Procedure and Processing Time for Experimental Use Permit (EUP) and Approval of Product Efficacy, is hereby amended, to read as follows:

"Annex A
PROCEDURE AND PROCESSING TIME FOR EXPERIMENTAL USE PERMIT (EUP)"

Step	Activity	By	To	Processing Time	Remarks
1	**Submit Application for EUP**	Applicant	BAFS (Organic Agriculture Division)	Within 60 minutes	Only applications with complete documentary and regulatory requirements shall be accepted. The applicants are required to accomplish the evaluation matrix provided by BAFS.

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2	**Evaluate Efficacy Trial Protocol (ETP)**	BAFS (Organic Agriculture Division)	N/A	Within 15 working days upon receipt	BAFS will issue EUP to applicant after approval of submitted ETP.
3	**Issue EUP**	BAFS (Organic Agriculture Division)	Applicant	Within 10 minutes	
4	**Conduct Efficacy Trials**	BAFS Certified Researcher (hired by the Applicant)	N/A	N/A	BAFS will conduct field visits of approved efficacy trials for compliance assessment.
5	**Publish Efficacy Trial Reports**	Applicant	Publisher	N/A	The publication may be done either in a technical bulletin or technical journal published by the government or private institutions (e.g., academe).

Section 7. **Transitory Provision.** Application for EUP and registration received by BAFS prior to the effectivity of this Circular, shall continue to be governed by the provisions of DC No. 05, Series of 2020.

Application for registration with EUP, approved prior to the effectivity of this Circular, shall not be required to publish their Efficacy Trial Terminal Reports provided that:

1. Their efficacy trials are on-going;
2. Their efficacy trial terminal reports are for completion; or
3. Their efficacy trial terminal reports are already submitted to the BAFS for evaluation.

Provisional Certificates of Product Registration shall continue to be valid until its expiration unless sooner terminated or revoked.

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Section 8. **Repealing Clause.** This Circular amends Articles III, V, VI, VIII, XIII and Annex A of DC No. 05, Series of 2020. 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 9. **Separability Clause.** If any provision of this Circular be declared invalid or unconstitutional, the other provisions not affected thereby shall remain valid and subsisting.

Section 10. **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 24th day of January 2021.

APPROVED BY:

WILLIAM D. DAR, Ph.D.
Secretary

DEPARTMENT OF AGRICULTURE
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