

**DEPARTMENT CIRCULAR** 

No. <u>05</u> Series of 2020

SUBJECT: GUIDELINES ON THE REGISTRATION OF ORGANIC BIO-CONTROL AGENTS (OBCA) PRODUCERS AND PRODUCTS

Pursuant to the 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), this Department Circular (DC) repeals the relevant provisions of the Administrative Order No. 14, Series of 2011 (Guidelines on the Registration of Organic Food and Organic Input Producers), particularly the coverage pertaining to plant protection, pest management products and bio-control agents (BCA).

#### ARTICLE I OBJECTIVES

The provisions under this Circular aim to:

- 1. Provide streamlined requirements and procedure for the registration of OBCA producers and products; and
- 2. Ensure that the certified organic bio-control agent products being marketed are compliant with the current Philippine National Standards (PNS).

### ARTICLE II SCOPE

This Circular covers the registration of OBCA producers and products with the Bureau of Agriculture and Fisheries Standards (BAFS).

### ARTICLE III DEFINITION OF TERMS

Section 1. As used in this Circular, the following terms and phrases shall be understood to have the meaning correspondingly provided below:

#### 1.1 Brand Name

a term, name or trademark, with logo, which may or may not be registered in the Intellectual Property Office (IPO) and used in connection with the OBCA product. BAFS reserves the right to approve and disapprove product brand





Page : 2 of 18

name based on the list of products registered with BAFS

#### 1.2 Certificate of Registration (COR)

a written approval granted by BAFS to registered OBCA producers

#### 1.3 Certificate of Product Registration (CPR)

a written approval granted by BAFS to registered OBCA products

#### 1.4 Certified Researcher for Organic Bio-Control Agent

an expert who has undergone assessment and evaluation by BAFS and is included in the list of authorized experts to conduct efficacy trials for OBCA products

#### 1.5 Conformity Assessment (Evaluation)

the process of gathering evidence about whether a product or process meets specified requirements

#### 1.6 Efficacy Trial

in the f

an experiment conducted following an approved efficacy trial protocol and conducted by BAFS certified researcher for OBCA, as attested by issued experimental use permit (EUP), to support claims on the effectiveness of OBCA product on plant protection and pest management.

#### 1.6.1. Efficacy trial protocol

research design specifying the introduction, objectives, materials and methods, cultural management practices, data to be gathered and statistical analysis tool

#### 1.6.2. Efficacy trial terminal report

document providing the results and analysis of data generated from an efficacy trial

#### 1.7 Evaluator

officially designated expert of BAFS tasked to review and provide recommendations on an applicant's submitted efficacy trial protocol and efficacy trial terminal report

#### 1.8 Label

written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations

#### 1.9 Labelling

display of any written, printed or graphic matter that is present on the label, accompanies the product, or is displayed near the product, including that for the purpose of promoting its sale or disposal

#### 1.10 Mislabeling

deliberate labeling or advertising that is misleading, where the labeling and/or advertising claims certain product properties that cannot be supported by reliable source, an organic certifying body or by scientific evidence





Page : 3 of 18

#### 1.11 Post-market surveillance

refers to validation activities conducted to verify continued compliance of the registered products with the recent version of applicable PNS relevant to organic agriculture and other regulatory requirements after release in the market

#### 1.12 Producer

1 1 The To 1

establishment that is responsible for ensuring that manufacture, distribution, exportation and importation of OBCA products meet, and continues to meet, the recent version of the applicable PNS relevant to OBCA and other regulatory requirements, on which the registration is based

#### 1.13 Organic

labeling claim with written or equivalent attestation that a product has beenproduced, prepared, processed, and handled in accordance to applicable PNS relevant to organic agriculture and other regulatory requirements

#### 1.14 Organic Certifying Body (OCB)

body responsible for verifying that a product sold or labeled as "organic" is produced, processed, prepared, handled and imported according to the recent version of an applicable PNS relevant to organic agriculture and other regulatory requirements, and whose operations/practices are aligned with the principles of ISO/IEC 17065

#### 1.15 OBCA Producer

includes those that are engaged in the manufacture, distribution, exportation and importation of OBCA products.

#### 1.16 OBCA Product

includes organic botanicals, organic microbials, organic macrobials, organic semiochemicals, and others that may be covered under the PNS for Organic Bio-control Agents

#### 1.17 Raw Materials (Substrates)

naturally occurring materials used in the production of OBCA. Raw materials if mined or naturally extracted should comply with the Department of Environment and Natural Resources (DENR) regulations

#### 1.18 Registration

a process wherein BAFS records information about producers engaged in the manufacture, distribution, exportation, and importation of OBCA products in an official list or official system

#### 1.19 Third-Party Authorization (TPA)

an agreement or contract between two (2) companies, the registered producer and party recipient of the TPA, to allow the latter to distribute the product of the former and to which rebranding of the registered product of the registered producer is also allowed





Page : 4 of 18

### ARTICLE IV GENERAL PROVISION

- Section 1. All organic bio-control agent (OBCA) producers such as manufacturers, distributors, exporters, and importers shall register, including their OBCA products, with BAFS.
- Section 2. Only producers and products certified as organic by BAFS' officially accredited organic certifying body (OCB) are accepted for BAFS registration.
- Section 3. Registration with BAFS shall be secured prior the sale and distribution of any OBCA products.
- Section 4. Any OBCA product intended for registration shall be tested for efficacy under local conditions.
- Section 5. The approval of application for registration will be based on pertinent requirements of PNS for OBCA and presentation of documentary evidence to support claims on the safety and quality of the product and its effectiveness to target pests.
- Section 6. Any OBCA product being applied for registration shall be registered on a per producer basis regardless of country of origin. No products with the same brand name of different producers shall be registered unless they enter into a Third Party Authorization (TPA)<sup>1</sup>.
- Section 7. Only registered producers can import or export OBCA products. Likewise, only registered OBCA products can be imported or exported, and importation/exportation permit shall be applied with BAFS. The requirements specified under Article XII of this Circular shall be submitted.
- Section 8. For efficacy trial purposes, only applicants with BAFS' Experimental Use Permit (EUP) can import OBCA products. The volume of product to be imported for use in efficacy trial shall be computed based on the approved efficacy trial protocol. The contingency may be allowed up to four (4) times of the volume needed, depending on the volume of the product container.
- Section 9. The applicant shall notify BAFS of any changes that may affect their application for Experimental Use Permit (EUP), Certificate of Registration (COR), and Certificate of Product Registration (CPR).
- Section 10. The applicants must apply for EUP, COR, CPR and importation/exportation permit in accordance with the regulatory requirements of this Circular.
- Section 11. Registered OBCA producers shall establish a Product Stewardship Program (PSP) for their registered OBCA products. The product stewardship program should include meetings, trainings/seminars and/or caravans on safe and effective use of the product. Moreover, the program must also include the recall of the expired products from the market outlets/stalls and proper disposal of used packaging. Likewise, copy of the annual PSP report shall be submitted to BAFS during renewal application of registration.

0



<sup>&</sup>lt;sup>1</sup> See Article X

Page : 5 of 18

Section 12. The applicants for Certificate of Registration (COR), including Certificate of Product Registration (CPR), must apply electronically following the regulatory requirements of this Circular.

### ARTICLE V PREREQUISITES FOR THE REGISTRATION

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

- Section 1. Application for Experimental Use Permit (EUP) with BAFS. Only application with complete requirements and conforms to PNS relevant to OBCA shall be accepted. Section 3 of Article VI of this Circular shows the requirements for EUP application.
- Section 2. Application for Organic Certificate (OC) with the BAFS' Officially Accredited Organic Certifying Body (OCB). Applicants shall provide to OCB their scope of business and activities, including the details of their products and production process. Likewise, applicants must comply with the requirements of OCB.
- Section 3. Applicants may request BAFS for preliminary assessment of their OBCA products.

Note: EUP and OC applications can be sequential or simultaneous (6-10 months to complete, if all the requirements are complied on-time).

### ARTICLE VI APPLICATION FOR EXPERIMENTAL USE PERMIT (EUP)

- Section 1. Experimental Use Permit (EUP) shall be applied for and issued by the Bureau of Agriculture and Fisheries Standards (BAFS) before any efficacy trial for OBCA product is conducted to generate the data required for registration. Only data generated from approved experiments conducted by BAFS-certified researchers 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 Ariculture 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. The applicants are required to accomplish the evaluation matrix provided by BAFS;
  - 3.3 Product profile, including the list of raw materials (substrates) used and the production process, with authorized name and signature; and





Page 6 of 18

- 3.4 Material Safety Data Sheet (MSDS) or any available product technical information, with authorized name and signature.
- Requirements 3.3 to 3.4. are not required for label expansion Note: application unless there were changes.
- Upon compliance with the above requirements, BAFS will grant Experimental Section 4. Use Permit (EUP) to applicant within fifteen (15) working days.
- Section 5. The following are required for the conduct of efficacy trials per OBCA product:
  - For Annual Crops:

e cit

- 5.1.1 As Insecticide/Fungicide/Rodenticide: Two (2) efficacy trials (2 locations; 1 cropping season); and conducted in season of prevalence
- 5.1.2 As Herbicide: Four (4) efficacy trials (2 cropping seasons; 2 locations per cropping season); and acceptance criteria: level of control based on recommended dose
- 5.2 For Perennial Crops/Plantation Crops:
  - 5.2.1 As Insecticide/Fungicide/Rodenticide: One (1) efficacy trial [1 location; 1 crop cycle (protocol-based)]; and conducted in cropping season of prevalence/incidence
- 5.3 There must be a maximum of five (5) target pests per efficacy trial.
- Section 6. Acceptable efficacy of the product shall be at least fifty percent (50%) based on the untreated control.
- BAFS should conduct field visits of approved efficacy trials for compliance and Section 7. conformity assessment within the period of validity of EUP.
- Validity of EUP. The EUP is valid only for one (1) location trial. The EUP's Section 8. validity period and location may be amended, provided that the following conditions are met:
  - The request for amendment is done through a formal request addressed to the BAFS Director, within the period of the issued EUP;
  - The on-going trial was affected by calamities;

  - 8.2 The on-going trial was affected by calculated as Expected pest prevalence did not occur; and 8.4 Other compelling reasons that are acceptable for BAFS.
- Requirements for label expansion. The required number of efficacy trials Section 9. specified in Section 5 of Article VI of this Circular shall be completed.
- Section 10. Approval of Efficacy Trial Terminal Reports (ETR). All ETR must be submitted to BAFS, within six (6) months after the trials, for evaluation and approval. The applicants are required to accomplish the evaluation matrix provided by BAFS. BAFS will issue a notice of approval of submitted ETR to applicants after complete evaluation within fifteen (15) working days.





Page : 7 of 18

#### ARTICLE VII

#### REGISTRATION OF ORGANIC BIO-CONTROL AGENT (OBCA) PRODUCERS

- Section 1. All producers engaged in the manufacture, distribution, exportation, and importation of OBCA products shall register with BAFS.
- Section 2. Procedure and processing time for the registration of OBCA producers is shown in *Annex B*.
- Section 3. **Requirements for COR.** Applicants for COR shall submit the following requirements to BAFS (Organic Agriculture Division):
  - 3.1 Duly accomplished application form, with authorized name and signature;
  - 3.2 Company Profile, with authorized name and signature;
  - 3.3 Copy of Organic Certificate from a BAFS Officially Accredited OCB; and
  - 3.4 Copy of Distributorship Agreement/TPA (when applicable).

Note: Requirement 3.2 is not required for renewal application unless there were changes.

- Section 4. Upon compliance with all the regulatory requirements of this Circular, BAFS will grant Certificate of Registration (COR) to applicant within three (3) working days.
- Section 5. **Validity of COR**. The COR is valid for five (5) years, and is renewable, subject to BAFS annual conformity assessment.
- Section 6. The COR shall contain at least the following information:
  - 6.1 Name of Producer;
  - 6.2 Complete Address of the Head Office;
  - 6.3 Nature of Business;
  - 6.4 Product

. . . . .

- 6.5 Registration Number;
- 6.6 Date of Issue and Validity;
- 6.7 QR Code; and
- 6.8 Terms and Conditions (these are the conditions that must be met during the validity of COR).

#### ARTICLE VIII

#### REGISTRATION OF ORGANIC BIO-CONTROL AGENT (OBCA) PRODUCTS

- Section 1. All OBCA products, which are produced locally or imported, must be registered with BAFS.
- Section 2. Registration of OBCA products can be categorized into:
  - 2.1 **Full Product Registration**, when all regulatory requirements of this Circular are satisfactorily complied with, which includes complete efficacy trials as required under Section 5 of Article VI of this Circular with significant and acceptable results; or

0



- 2.2 **Provisional Product Registration,** when the required number of efficacy trials under Section 5 of Article VI of this Circular are incomplete. Provided however, that the submitted product efficacy has significant and acceptable result.
- Section 3. Procedure and processing time for the registration of OBCA products is shown in *Annex B*.
- Section 4. **Requirements for CPR.** Applicants for CPR shall submit the following requirements to BAFS (Organic Agriculture Division):
  - 4.1 Duly accomplished application form, original copy with authorized name and signature;
  - 4.2 Copy of Organic Certificate from a BAFS Officially Accredited OCB;
  - 4.3 Copy of the recent laboratory analysis for heavy metals of the product (only for botanicals) from a BAFS Officially Accredited OCB;
  - 4.4 Copy of BAFS' Notice of Approved Product Efficacy (NAPE);
  - 4.5 Toxicity Data, with authorized name and signature;
  - 4.6 Product brochure/pamphlet; and
  - 4.7 Proposed packaging and labeling.

Note: Requirements 4.4 to 4.7 are not required for renewal application unless there were changes.

- Section 5. Upon compliance with all the regulatory requirements of this Circular, BAFS will grant Certificate of Product Registration (CPR) to applicant within three (3) working days.
- Section 6. **Validity of CPR**. The CPR with full status is valid for five (5) years, and is renewable, subject to BAFS annual conformity assessment. The CPR with provisional status is valid for one (1) year and not renewable. The validity period of CPR with provisional status may be extended upon request provided the reasons are acceptable (see Section 5 of Article XIII of this Circular).
- Section 7. The CPR shall contain at least the following information:
  - 7.1 Brand Name;

i, i.

- 7.2 Product Type;
- 7.3 Name of Producer or Producers in case of recognized TPAs;
- 7.4 COR Number/s;
- 7.5 Product Registration Number;
- 7.6 Nature of Registration (Provisional or Full Registration)
- 7.7 Date of Issue and Validity;
- 7.8 Recommended Use;
- 7.9 QR Code; and
- 7.10 Terms and Conditions (these are the conditions that must be met during the validity of CPR).

### ARTICLE IX POST-MARKET SURVEILLANCE

Section 1. BAFS shall conduct post-market surveillance in market outlets to ensure that labeling and display of organic products are compliant with the requirements





Page : 9 of 18

of this Circular, and the Republic Act No. 10068 (Organic Agriculture Act of 2010) and its amendments hereon.

### ARTICLE X THIRD PARTY AUTHORIZATION

- Section 1. The BAFS shall recognize the existence of a Third-Party Authorization (TPA) and its terms and conditions between the original registrant and the TPA recipient, subject to applicable laws, rules, and regulations. The minimum terms and conditions of the TPA are as follows:
  - 1.1 Validity of Agreement;
  - 1.2 Obligations of the parties to ensure that the organic integrity of the product is maintained;
  - 1.3 Exclusive use of product efficacy data between parties;
  - 1.4 Non-transferability of TPA to another party; and
  - 1.5 In case of product rebranding, the TPA recipient shall secure an organic certificate for the new brand.
- Section 2. The TPA is accepted provided that the OBCA product being applied is fully registered with BAFS.
- Section 3. Only the original registrant shall be allowed to enter into a TPA with at most three (3) parties. The TPA is non-transferable and the recipient/s is/are not allowed to issue the same to another company.
- Section 4. The TPA recipient shall follow the registration guidelines specified under Articles VII and VIII of this Circular.
- Section 5. In case of a recognized TPA without product rebranding (same brand name), the CPR issued to the original registrant shall be amended to reflect the name of registered TPA recipient/s. Otherwise, a separate CPR shall be issued to the registered TPA recipient/s.

### ARTICLE XI TRANSFER OF REGISTRATION

- Section 1. The registered producer may transfer its registration to another producer, subject to the applicable requirements and procedure as specified under Articles VII and VIII of this Circular.
- Section 2. Producers with product registration with the Fertilizer and Pesticide Authority (FPA), and were able to secured organic certification from the BAFS' Officially Accredited OCB shall register their products to BAFS. The applicable requirements specified under Articles VII and VIII of this Circular and a certified true copy of FPA CPR shall be submitted to BAFS.





Page : 10 of 18

### ARTICLE XII IMPORTATION AND EXPORTATION REQUIREMENTS

- Section 1. Applicants for the importation/exportation permit shall submit as applicable the following requirements at least two (2) days prior the arrival/departure of OBCA products to be imported/exported:
  - 1.1 Duly accomplished application form, with authorized name and signature;
  - 1.2 Copy of Bill of Lading, with authorized name and signature;
  - 1.3 Copy of Invoice, with authorized name and signature;
  - 1.4 Copy of Packing List, with authorized name and signature; and
  - 1.5 Copy of Quarantine Certificate from the country of origin (when applicable), with authorized name and signature. This is not a requirement for OBCA products with the following considerations: (a) organic compounds directly extracted from plants; and (b) not considered as microorganisms.
- Section 2. Application for importation/exportation permit shall be applied per shipment with BAFS. Procedure and processing time for such permit is shown in *Annex C.*
- Section 3. The importation/exportation permit is valid per shipment only and that such permit is valid for sixty (60) days from the date of approval.
- Section 4. Exportation of any OBCA product shall further be subjected to the rules and regulations promulgated by other agencies governing all exports. Exporting of products for countries where the Philippines has no trade relations has to be cleared by the exporter with other appropriate agencies, before BAFS issues an exportation permit.

### ARTICLE XIII RENEWAL, RETENTION AND CONDITIONS FOR EXTENSION 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 5. The validity period of CPR with provisional status may be extended up to twelve (12) months from its expiry date provided that the following conditions are met:



- 5.1 The request for extension is done through a formal request addressed to the BAFS Director at least five (5) working days prior the expiration of CPR:
- 5.2 The request for extension is on the ground that there is an on-going efficacy trial for  $2^{nd}$  location; and
- 5.3 The request is accompanied by a copy of an approved EUP for 2<sup>nd</sup> location.

### ARTICLE XIV SUSPENSION OF REGISTRATION

- Section 1. The COR or CPR shall be suspended based on any of the following grounds:
  - 1.1 Non-submission of new organic certificate within one (1) month after its expiration in accordance with the Section 4 of Article XIII of this Circular; and
  - 1.2 Non-conformance to current version of PNS relevant to organic agriculture and other regulatory requirements per post-market surveillance report.
- Section 2. Upon the decision of BAFS to move forward with suspension, the BAFS shall notify the registered producer of the suspension of its COR or CPR. The notice will generally contain the following elements:
  - 2.1 Statement of reason/s for such decision;

, . . . · ·

- 2.2 The period within which the COR or CPR is suspended; and
- 2.3 Notification that the suspended registered producer has the right to pursue an appeal for reconsideration following the procedures as stated in Clause 1.2 of Section 1 of Article XVI of this Circular.
- Section 3. The BAFS shall remove the producer and product names from all the official list or official system of registered OBCA producers and OBCA products.
- Section 4. The order of suspension shall be effective and executory immediately upon proof of receipt of the notification issued by BAFS to the registered producer. The suspension shall be for a maximum period of two (2) months.
- Section 5. The BAFS shall notify interested parties and the public of the suspension and its status through suitable media.
- Section 6. OBCA producers under the period of suspension are prohibited from selling their registered products.
- Section 7. Mislabels during the period of suspension shall, upon conviction, be punished pursuant to the provisions of Section 26 (Penal Provision) (c) of the RA 10068.
- Section 8. The BAFS shall lift the suspension upon the implementation of corrective actions by the producer to comply with the requirements of the PNS and this Circular subject to verification for effectiveness by BAFS.





Page : 12 of 18

### ARTICLE XV REVOCATION OF REGISTRATION

- Section 1. The COR or CPR shall be revoked based on any of the following grounds:
  - Revocation of organic certificate issued by an officially accredited OCB;
     and
  - 1.2 Failure of the registered producer to implement corrective actions within the suspension period.
- Section 2. Upon the decision of BAFS to move forward with revocation, the BAFS shall notify the registered producer of the revocation of its COR and CPR. The notice will generally contain the following elements:
  - 2.1 Statement of reason/s for such decision; and
  - 2.2 Notification that the revoked registered producer has the right to pursue an appeal for reconsideration following the procedures as stated in Clause 1.2 of Section 1 of Article XVI of this Circular.
- Section 3. The BAFS shall remove the producer and product names from all the official list or official system of registered OBCA producers and OBCA products.
- Section 4. The order of revocation shall be effective and executory immediately upon proof of receipt of the notification issued by BAFS to the registered producer.
- Section 5. The BAFS shall notify interested parties and the public of the revocation and its status through suitable media.
- Section 6. OBCA producers with revoked registration are prohibited to claim, label and sell their products as "organic".
- Section 7. Only products belonging to the same batch and lot with revoked registration shall be recalled in the markets by their producers.
- Section 8. Mislabels during the period of revocation shall, upon conviction, be punished pursuant to the provisions of Section 26 (Penal Provision) (c) of the RA 10068.

#### ARTICLE XVI APPEAL

Section 1. The appeal procedures shall apply in the following situations:

#### 1.1 Denial of Issuance of Registration

- 1.1.1 The applicant may file an appeal with BAFS (Organic Agriculture Division) to reconsider such decision attaching substantial documentation or the strategies to address the cause of such decision within fifteen (15) calendar days from receipt of notification for denied application.
- 1.1.2 The BAFS (Organic Agriculture Division) shall review, evaluate, and recommend decision to the BAFS Director. The BAFS Director shall decide on the filed appeal based on the assessment





report within twenty (20) calendar days from receipt of the appeal.

1.1.3 If the BAFS decides that reconsideration is not warranted, the appeal will be denied stating the reasons.

1.1.4 If the BAFS decides that the appeal is meritorious, the BAFS may reverse the denial decision and proceed with the granting of registration.

#### 1.2 Suspension/Revocation of Registration

- 1.2.1 The registered producer may file an appeal with BAFS (Organic Agriculture Division) through formal written request within fifteen (15) calendar days from receipt of notice of suspension/revocation.
- 1.2.2 The appeal must be accompanied by a report specifying the major documented errors of facts and how such errors contributed to the suspension/revocation decision, together with other relevant substantiating documentation.
- 1.2.3 If the revocation decision is due to the revoked status of the organic certificate from an officially accredited OCB, this shall disqualify the registered producer to appeal, unless otherwise the revocation of organic certificate is reinstated.
- 1.2.4 The BAFS (Organic Agriculture Division) shall review, evaluate and recommend decision to the BAFS Director. The BAFS Director shall decide on the filed appeal based on the statement of reason/s and submitted documented facts within twenty (20) calendar days from receipt of the appeal. The action will be based solely on the report and the supporting documentation submitted by the registered producer in accordance with the nature of the non-compliance that led to the suspension/revocation decision.
- 1.2.5 If the BAFS decides that the appeal is not meritorious, the appeal will be denied with a statement of reasons and such decision shall be final and executory.
- 1.2.6 In case the appeal on the suspension/revocation decision is meritorious, the BAFS shall lift the suspension or reverse the revocation decision, and reinstate the registration.

### ARTICLE XVII COMPLAINTS

- Section 1. Any person can file a complaint with BAFS against its registered producers or applicants (EUP, COR and CPR) due to their mislabeled products or deceptive acts or services pursuant to RA 10068.
- Section 2. The BAFS shall act on the received complaints, and apply the following procedures:
  - 2.1 Upon receipt of the complaint, either through the mail, personal delivery or electronic data messages/electronic documents, the BAFS shall act on it within fifteen (15) calendar days.
  - 2.2 Where the BAFS considers the complaint to be sufficiently substantiated, it shall notify the producer/applicant concerned and shall require a written explanation within fifteen (15) calendar days.





- 2.3 The BAFS shall discuss the lodged complaint and written explanation provided by the concerned registered producer or a producer with an on-going application, conduct investigation, and come up with the decision.
- 2.4 The complaint shall be decided within fifteen (15) working days from the time the investigation was terminated.

#### ARTICLE XVIII

#### LABELING OF REGISTERED ORGANIC BIO-CONTROL AGENT PRODUCTS

- Section 1. Pursuant to Section 17 (Labeling of Organic Produce) of RA 10068 and in addition to the labeling requirements of the recent version of applicable PNS for OBCA, the following information shall appear on the label of registered OBCA products:
  - 1.1 Name, logo or seal of the BAFS' officially accredited organic certifying body (OCB);
  - 1.2 "Organic" mark together with the OCB's official accreditation number provided by the BAFS' officially accredited OCB; and
  - 1.3 Product registration number and validity period provided by BAFS.
- Section 2. The rules and procedures for using of "organic" mark are provided in a separate Circular.
- Section 3. Only the recommendations for pest per crop approved by BAFS in which the product has been found to be effective must be indicated on the product label.

### ARTICLE XIX CONFIDENTIALITY AND IMPARTIALITY

- Section 1. All personnel involved in the registration of OBCA producers and products shall adhere to the principles of confidentiality and impartiality.
- Section 2. Information on production practices, product composition and formulation, ingredients, etc., submitted to BAFS shall not be released in any form to any party or to the public in general without written permission from the applicants/registrants.
- Section 3. However, the following general information may be made accessible to the public:
  - 3.1 Name, address and contact details of the producers;
  - 3.2 Effectivity date and validity of the registration;
  - 3.3 Product efficacy data;
  - 3.4 Any information to comply with a court order; and
  - 3.5 Any information to comply with a request from an office, investigating an alleged complaint.

### ARTICLE XX TRANSITORY PROVISION

Section 1. BAFS shall reissue a new COR and CPR to those OBCA producers that are registered prior the approval of this Circular. Provided, however, that these registered producers have valid organic certificates.





15 of 18 Page

Packaging materials and labels of OBCA products with valid organic certificates adversely affected by this Circular shall continue to be used until their supplies last.

#### ARTICLE XXI ADMINISTRATIVE PENALTIES

Administrative sanctions such as suspension or revocation of the issued COR and CPR, and delisting of the company name from BAFS official list or official system for registered OBCA producers and OBCA products shall be imposed against all persons or entities that violate or refuse to abide by the provisions of this Circular.

#### ARTICLE XXII ANNEXES

All annexes, or any part thereof, referred to in this Circular are deemed integral part of this Circular.

#### ARTICLE XXIII SEPARABILITY CLAUSE

If any portion of this Circular is declared unconstitutional or invalid, the other portions thereof which are not affected thereby shall continue to be in full force and effect.

#### ARTICLE XXIV REPEALING CLAUSE

Applicable provisions, particularly the coverage pertaining to plant protection, pest management products and bio-control agents (BCA), of the Administrative Order No. 14, Series of 2011 (Guidelines on the Registration of Organic Food and Organic Input Producers), the Department Circular No. 02, Series of 2015 (Guidelines for the Conduct of Validation Process for the Registation of Organic Primary and Postharvest Food, Non-food and Input Producers), and all existing rules and regulations or parts thereof, which are inconsistent with the provisions of this Circular are hereby repealed accordingly.

#### ARTICLE XXV **EFFECTIVITY**

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

Done this 23rd day of MARCH

APPROVED BY:

100

Secretary

in replying pls cite this code : For Signature: S-03-20-0449

Received: 03/23/2020 03:54 PM



Page

16 of 18

# ANNEX A PROCEDURE AND PROCESSING TIME FOR EXPERIMENTAL USE PERMIT (EUP) AND APPROVAL OF PRODUCT EFFICACY

Step	Activity	Ву	То	Processing Time	Remarks
1	Submit Application for Experimental Use Permit (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.
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 Trial	BAFS Certified Researcher (hired by the Applicant)	N/A	N/A	BAFS will conduct field visits of approved efficacy trials for compliance and conformity assessment.
5	Submit Efficacy Terminal Report (ETR)	Applicant	BAFS (Organic Agriculture Division)	N/A	ETR must be submitted within 6 months after the trial. The applicants are required to accomplish the evaluation matrix provided by BAFS.
6	Evaluate ETR	BAFS (Organic Agriculture Division)	N/A	Within 15 working days upon receipt	BAFS will issue the Notice of Approved Product Efficacy to applicant after approval of submitted ETR. Thereafter, the applicant shall apply for registration.
7	Issue Notice of Approved Product Efficacy (NAPE)	BAFS (Organic Agriculture Division)	Applicant	Within 10 minutes	





Page : 17 of 18

## ANNEX B PROCEDURE AND PROCESSING TIME FOR REGISTRATION

Step	Activity	Ву	То	Processing Time	Remarks
1	Submit Applications for Certificate of Registration (COR); and Certificate of Product Registration (CPR)	Applicant	BAFS (Organic Agriculture Division)	Within 60 minutes	Only applications with complete documentary and regulatory requirements shall be accepted.
2	Review Application	BAFS (Organic Agriculture Division)	N/A	Within 3 working days upon receipt	Review includes validation of each submitted requirement. BAFS shall issue the COR together with the CPR after compliance with the registration requirements.
3	Issue COR and CPR	BAFS (Organic Agriculture Division)	Applicant	Within 15 minutes	Registered organic producers and their products shall be subjected for annual monitoring and post- market surveillance.





Page

18 of 18

### ANNEX C

### PROCEDURE AND PROCESSING TIME FOR THE APPLICATION FOR IMPORTATION/EXPORTATION OF OBCA PRODUCTS

Step	Activity	Ву	То	Processing Time	Remarks
1	Submit Application for Importation/ Exportation Permit	Applicant	BAFS (Organic Agriculture Division)	Within 15 minutes	Only application with complete requirements shall be accepted.
2	Review Application	BAFS (Organic Agriculture Division)	N/A	Within 2 working days upon receipt	Review includes verification of each submitted requirement.
3	Issue Permit	BAFS (Organic Agriculture Division)	Applicant	Within 10 minutes	The permit is valid within 60 days after approval.



