

PHILIPPINE NATIONAL STANDARD

**PNS/BAFS 182:2023
ICS 65.080**

Organic Bio-Control Agents (OBCA) — Product Standard — Specifications



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Published by:

Bureau of Agriculture and Fisheries Standards
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(+632) 8928 8756 to 65 local 3301 – 3325

ISBN 978-621-455-524-6

www.bafs.da.gov.ph

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Foreword

In 2020, the DA-BAFS commenced the amendment of the PNS/BAFS 182:2016 (Organic biocontrol agents – Microbials and botanicals – Minimum data requirements) to accommodate the continuous development of the organic agriculture industry and harmonize it with relevant regional and international standards. Similarly, in 2021, the DA-BAFS-Organic Agriculture Division (OAD) submitted further request to review and update the minimum data requirements for the safety assessment of organic biocontrol agents. Specifically, they requested to include the allowable limit of heavy metals indicated in microbials and botanicals. In response, the DA-BAFS Standards Development Division (SDD) reconvened the Technical Working Group (TWG) to continue the amendment of the PNS on OBCA in 2023.

A TWG was established through the following Special Orders (SO):

1. SO No. 532, series of 2023 (Addendum to SO No. 146 series of 2023 entitled “Creation of TWG for the Development of PNS for Agricultural and Fishery Products, Machineries, and Infrastructures”); and
2. SO No. 1314, series of 2023 (Addendum to SO No. 146 series of 2023 entitled “Creation of TWG for the Development of PNS for Agricultural and Fishery Products, Machineries, and Infrastructures”).

The TWG was composed of relevant stakeholders from the government sector, academe/research institutions, and private sector organization. The draft PNS underwent a series of TWG meetings and stakeholder consultations conducted via an online platform before its endorsement to the DA Secretary for approval.

This Standard includes the following significant changes compared to its previous version:

- a) Inclusion of normative reference;
- b) Amendment of the Clause 3 Terms and Definitions;
- c) Inclusion of product description for microbial and botanical OBCA;
- d) Modification on the minimum requirements for safety assessment of microbial and botanical OBCA;
- e) Inclusion of minimum requirements for quality assurance and monitoring, environmental safety, packaging, labelling, and recordkeeping, traceability, and product recall; and
- f) Inclusion of Annex A (List of needed information for the properties of microbial OBCA) and Annex B (List of needed information for the properties of botanical OBCA).

This Standard cancel and replaces PNS/BAFS 182:2016, which has been technically amended. This document was drafted in accordance with the editorial rules of the DA-BAFS-Standards Development Division (SDD) Standardization Guide No. 1: Writing the PNS.

1 Scope

This Standard covers the minimum requirements for Organic Bio-Control Agents (OBCA) specifically microbial control agents (microbials) and botanical pesticides (botanicals) for organic crop production and postharvest management. This Standard is not applicable to Bio-Control Agents (BCA) under categories of macrobials, semiochemicals, and BCA for organic livestock and poultry production.

2 Normative reference

The following document is referred to in the text in such a way that some or all of its contents constitute the requirements of this document. The latest edition of the referenced documents (including any amendments) applies.

Department of Agriculture (DA). (2020). National list of permitted substances for organic agriculture (Department Circular [DC] No. 09, series of 2020).
https://bafs.da.gov.ph/bafs_admin/admin_page/laws_files/DC.No.09%20s%202020%20National%20List%20of%20Permitted%20Substances%20for%20OA.pdf

3 Terms and definitions

For the purposes of this Standard, the following terms and definitions apply:

3.1

active ingredient

part of the product that provides the pesticidal action (Food and Agriculture Organization of the United Nations [FAO] & World Health Organization [WHO], 2016). In the context of this Standard, it refers to either microbial or botanical pest control agents.

3.2

contaminant

any microorganism or substances it produces that are present in a product, other than the specified microorganism (or substances it produces) of the microbial pest control agent (MPCA) (WHO, 2017)

3.3

formulation

combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application (FAO & WHO, 2016). The product of formulation is called the formulated product.

3.4**Genetically Modified Organisms (GMO)**

refers to organisms that possess a novel combination of genetic materials obtained through the use of modern biotechnology (Organic Agriculture Act of 2010, 2010)

3.5**pathogenicity**

ability of an organism to cause disease and/or inflict damage on the host (WHO, 2017, *modified*)

3.6**toxicity**

quality of being poisonous or harmful to animals, plants, or microorganisms (British Columbia Ministry of Agriculture, Food, and Fisheries, 2022, *modified*)

3.7**Organic Bio-Control Agents (OBCA)**

organic biological control agents

organisms and their associated metabolites as well as naturally occurring substances that control pests and diseases. These are classified as botanicals, macrobials, microbials, and semiochemicals (An act amending Republic Act No. 10068 or the Organic Agriculture Act of 2010, 2020)

4 Product Description

The following shall be the specified OBCA in this Standard:

4.1 Microbial products

active substance that are microorganisms such as protozoan, fungus, bacterium, viruses, nematodes, rickettsias, mycoplasmas or mycoplasma or mycoplasma-like organisms, rickettsiae/rickettsia-like organisms or other microscopic self-replicating biotic entity and any associated metabolites, to which the effects of pest control are attributed (FAO & WHO, 2017, *modified*)

4.2 Botanical products

consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species that demonstrate toxicity to pests and diseases (FAO & WHO, 2017, *modified*)

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5 Minimum Requirements

5.1 Manufacturing process

5.1.1 Complete details on the procedure of the manufacturing of the OBCA product shall be properly documented.

5.1.2 Details should include starting and intermediate materials and steps taken both chemical and biological.

5.1.3 The procedures used in establishing the identity and purity of the product, quality control methods, and the presence of toxic sensitizing substances should be specified for microbial products.

5.2 Biological and chemical characteristics

5.2.1 The information regarding the biological and chemical characteristics of the OBCA product shall be properly documented.

5.2.2 Microbial and botanical OBCA shall include the following information specified in Annex A (List of needed information for the properties of microbial OBCA) and Annex B (List of needed information for the properties of botanical OBCA), respectively.

5.3 Composition of the product

5.3.1 GMO or any of its derivatives shall not be used in the production and processing of OBCA products as raw materials or ingredients.

5.3.2 The ingredients and/or raw materials used shall be listed in the Department Circular (DC) No. 9, series of 2020 (National List of Permitted Substances for Organic Agriculture).

5.4 Product performance

5.4.1 OBCA products shall meet the claims in terms of efficacy stated by the applicant. The claims shall be subjected to the guidelines for the registration of an OBCA product established by the competent authority.

5.4.2 The advantages of the use of OBCA products such as the reduction of hazards to human or the environment and other positive effects shall be specified and properly accompanied by scientific data or rationale.

5.5 Toxicology

5.5.1 Results of analyses on the potential human health hazards from the exposure and use of the OBCA product shall be provided to establish its safe use.

5.5.2 Data package to be submitted are as follows whenever applicable but not limited to:

- a) oral toxicity;
- b) dermal toxicity;
- c) inhalation;
- d) ocular irritation test;
- e) dermal irritation test; and
- f) allergy/sensitization test (for botanicals).

5.5.3 Scientific evidence or rationale shall be submitted as justification if a particular toxicology test(s) is/are unimportant and not applicable to the OBCA product.

6 Quality Assurance and Monitoring

6.1 The quality of the OBCA shall be ensured in all parts of the production process. A protocol to monitor the quality of the OBCA should be in place and documented.

6.2 The OBCA shall be practically free from any physical contaminant. Other contaminants shall not exceed the maximum allowable levels specified in Tables 1 and 2.

Table 1. Maximum allowable level of microbiological contaminants

Microbial contaminants	Maximum Allowable Level
Fecal streptococci	<100 CFU/g or mL ¹
Total coliforms	<1,000 MPN/g ²
<i>Salmonella</i>	Absent in 25 g ³
<i>Shigella</i>	Absent ⁴
<i>Vibrio</i>	Absent ⁴
Other microbiological contaminants	1x10 ⁴ CFU/mL or g ⁴
¹ Organization For Economic Cooperation and Development (OECD). (2011). OECD issue paper on microbial contaminant limits for microbial pest control products. https://www.oecd-ilibrary.org/docserver/9789264221642-en.pdf?expires=1701670249&id=id&accname=quest&checksum=1895B8B939CCE723F1173A5640B9D7A0	
² United States (US) Environmental Protection Agency (EPA). (1993). Part 503 — standards for the use or disposal of sewage sludge. Electronic Code of Federal Regulations (eCFR). https://www.ecfr.gov/current/title-40/chapter-I/subchapter-O/part-503	

³European Parliament and Council. (2019). Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1009>

⁴Food and Agriculture Organization (FAO). (2012). Guidance for Harmonizing pesticide regulatory management in southeast asia. <https://www.fao.org/3/i2806e/i2806e00.pdf>

Table 2. Maximum allowable level of heavy metals

Heavy Metals	Maximum Allowable Level (mg/kg dry wt.)
Arsenic (As)	40 ¹ (inorganic arsenic)
Lead (Pb)	100 ²
Chromium (Cr)	50 ²
Mercury (Hg)	1 ¹
Cadmium (Cd)	5 ²
Copper (Cu)	300 ^{1,2}
¹ European Parliament and Council. (2019). Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1009	
² Food and Agriculture Organization (FAO). (2023). NSP – Fertilizer Specifications. https://www.fao.org/agriculture/crops/thematic-sitemap/theme/spi/plantnutrition/fertspeccs/en/	

- 6.3** The OBCA shall be consistent with its claims in terms of the specifications of the product in relation to 5.4 Product performance.

7 Environmental Safety

7.1 Non-target and beneficial organisms

- 7.1.1** Information on the effect of the OBCA product on non-target and beneficial organisms shall be provided.
- 7.1.2** An evaluation shall be done to determine the potential effects of OBCA on its non-target and beneficial organisms such as but not limited to mammals, birds, pollinators, insects, arthropods, and earthworms.

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7.1.3 Tests and analyses regarding the infectivity, toxicity, pathogenicity, or hypersensitivity of the OBCA to its non-target organisms shall be done depending on the possible routes and pattern of exposure.

7.1.4 Other scientific studies, evidence, or rationale relevant to determining the safety of OBCA to non-target and beneficial organisms may be presented.

7.2 Environmental fate

7.2.1 The behavior and the persistence of OBCA in the environment particularly in the soil, water, and air should be evaluated if there is any indication of potential risks to human health and environment. The ability of the OBCA or its derivatives to survive, grow, and the potential longer exposure period to the environment shall be tested and analyzed.

7.2.2 The residue data of the OBCA shall be presented, if applicable.

7.2.3 Other scientific studies, evidence, or rationale relevant to determining the safety of OBCA to the environment may be presented.

8 Packaging

8.1 Packaging shall ensure the organic integrity of the OBCA product. It shall protect the OBCA product from contamination, and any physical and chemical change that may occur during transport and storage.

8.2 The primary package of the OBCA shall be specified.

8.3 If a secondary package is used to contain the OBCA, the packaging material should be specified.

8.4 The bulk package used for botanicals during transport shall be specified.

8.5 Microbials shall be packed in sterile materials.

8.6 Additionally, OBCA products shall be packed in accordance with Clause 9.4.4 Packaging of the PNS/BAFS 337:2022 (Philippine National Standard [PNS] on Organic Crop Production, Postharvest, and Processing — Code of Practice).

8.7 Proper disposal of empty OBCA packaging materials shall be in accordance with the relevant country regulations.

9 Labelling

9.1 The following information shall be indicated on the label of the OBCA product:

- a) name of product;
- b) chemical name/common name;
- c) category of use;
- d) formulation/contents of the product;
- e) identity of microbe (for microbial only);
- f) specific strain and count (for microbial only);
- g) net weight/net content;
- h) name of manufacturer and/or distributor;
- i) address and contact number of distributor/manufacturers;
- j) batch number;
- k) manufacturing date;
- l) shelf-life or expiry date;
- m) safety precautions/warning phrases/ pictograms;
- n) directions for use;
- o) storage conditions and disposal;
- p) recommended crop/commodity and target pests;
- q) dosage rate;
- r) restrictions (if applicable); and
- s) product registration number and validity.

9.2 Label shall be of such design and material that does not deteriorate easily, become illegible, or get separated from the container under the rigors of transport, storage, and use. It should withstand extreme weather conditions.

9.3 Colors, font style, size, and other visual information presented on the label shall be identifiable and understandable.

9.4 The label of organic produce shall contain the name, logo, or seal of the Organic Certifying Body (OCB) and the accreditation number issued by the competent authority. The organic label/mark shall also include the trade name, as defined by pertinent domestic property rights laws, and the address of origin of the produce (An act amending Republic Act No. 10068 or the Organic Agriculture Act of 2010, 2020).

10 Recordkeeping, Traceability, and Product Recall

Each OBCA product shall be traceable to the source/manufacturer. The minimum documentation/records include but are not limited to the following:

- a) production and/or warehouse site map;
- b) purchases and inventory of OBCA products and/or raw materials including its source (for local manufacturers);
- c) production and distribution records;

- d) results of laboratory analysis;
- e) importation records of OBCA products;
- f) warehousing records;
- g) licenses/authorization records; and
- h) certification records.

Annex A
(Normative)**List of needed information for the properties of microbial OBCA**

- a) Common name;
- b) Scientific name;
- c) Strain/Serotype/Biotype depending on the organism;
- d) Taxonomic characteristics (if applicable);
 - 1. Morphological (cultural and cellular) characteristics
 - 2. Biochemical properties
 - 3. Molecular identification (rRNA gene sequence, if applicable)
- e) Natural occurrence of an organism (host/substrates, and habitat) and relation to other related species (mode of nutrition);
- f) Biological properties; and
 - 1. Biological properties of an active agent (target pest, microbial agent host range, life cycle, and mode of action) for technical grade active ingredient;
 - 2. Description of any unusual morphological, biochemical, or resistance characteristics of the organism that are different from the classic description of an organism for technical grade active ingredient;
 - 3. Toxic content and potency for microbials with pesticidal and antimicrobial properties.
- g) Composition for formulated product.
 - 1. Ingredients (percent composition)
 - 2. Microbial count (by weight or CFU, spores per unit of weight or volume, etc.)
 - 3. Other ingredients included in the formulation (e.g., stickers, spreaders);
 - 4. Analysis of contaminants, if any
 - 5. Specification together with methods of analysis
 - 6. Analytical test report
 - 7. Shelf life, storage requirement, and viability data

Annex B
(Normative)**List of needed information for the properties of botanical OBCA**

- a) Common name;
- b) Chemical name;
- c) Formula (Empirical and Structural, including molecular weight) (if applicable);
- d) Method of analysis (ownership per product);
- e) Physico-chemical properties;
 - 1. Plant species (common/ scientific name) from which the active ingredient extracted including tissue type
 - 2. Appearance (physical state, color, and odor)
 - 3. Minimum and maximum active ingredient (AI) content
 - 4. Outline of extraction process of AI of botanicals
 - 5. Specifications together with the methods of analysis (and physicochemical properties)
 - 6. Shelf-life/Storage stability for formulated product (in respect to composition and physical properties related to use)
 - i. Wettability for dispersible powders
 - ii. Persistent foam for formulations applied in water
 - iii. Suspensibility for dispersible powders, suspension concentrates
 - iv. Wet sieve test for dispersible powders, suspension concentrates
 - v. Dry sieve test for granules or dusts
- f) Composition of finished product; and
 - 1. AI content
 - 2. Other components included in the formulation (e.g., adjuvants and inert components) (% composition)
- g) Sample for verification of content.
 - 1. Active Ingredients
 - 2. Contaminants - Heavy Metal determination (such as but not limited to As, Pb, Cr, Hg, and Cd)

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