

# BIOAGRICERT INSTRUCTION FOR MATERIAL REVIEW

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## 1. Purpose

Under the USDA organic regulations, each certified organic operation (producer or handler of a production or handling operation) must have an Organic System Plan (OSP) - § 205.201 Organic production and handling system plan.

According to § 205.201(a), the OSP must include:

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) **A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;**
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in §205.103;
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances;
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

Inputs manufacturers may request a material evaluation to verify the conformity to USDA organic regulations; in this case the materials review is based on point (2) § 205.201(a).

## 2. Scope

This Instruction is addressed to Bioagricert evaluators and inspector. The aim of this document is to provide the information to perform the evaluation of inputs and other materials used in the organic operation under the NOP certification and those produced by inputs manufacturers.

## 3. Terms defined (§ 205.2)

**Agricultural inputs.** All substances or materials used in the production or handling of organic agricultural products.

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**Allowed synthetic.** A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

National List. A list of allowed and prohibited substances as provided for in the Act.

**Certification or certified.** A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

**Certified operation.** A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

**Compost.** The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.

**Feed additive.** A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

**Feed supplement.** A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

**Fertilizer.** A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

**Inert ingredient.** Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

**Manure.** Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

**Materials.** Substances to be used as an input in organic production and handling. Materials include, but are not limited to: 1) fertilizers, soil amendments, potting soil, crop production aids, and pest control materials used in crop production; 2) feed supplements, feed additives, medications, and livestock production aids used in livestock production; and 3) ingredients, processing aids, post-harvest handling substances, sanitizers, and facility pest control materials used in processing and handling.

**Nonagricultural substance.** A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

**Nonsynthetic (natural).** A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

**Pesticide.** Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*)

**Sewage sludge.** A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge

incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

**Synthetic.** A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

#### 4. Material list

The Operator must submit to Bioagricert a list of each substance used as an input in organic production and handling (fertilizers, soil amendments, potting soil, crop production aids, pest control materials, feed supplements, feed additives, sanitizers, etc.); in particular must submit the Bioagricert Organic System Plan (OSP) and/or the **Annex to Master 080 (OSP) – INPUT MATERIAL APPLICATION RECORD CROP OPERATION**.

For each input the following information are required:

<b>Material</b>	Product Name (material or product name and formulation, if applicable), MSDS and SDS, manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).
<b>Source/Manufacturer</b>	It is necessary to correctly identify the manufacturer (the one that formulates, manufactures, and packages a product) in order to verify whether a product is allowed for use in organic production and handling. Be careful to note the manufacturer (distinct from the distributor – a business from which you purchase a product but that does not make it).
<b>Purpose/Reason for Use</b>	May include soil fertility and pest- or disease-management, etc. Some materials, for example, are allowed for pest management but not as a soil amendment.
<b>Organic Status Verification</b>	<p><b>OMRI or WSDA List, NOP Seal on label, or certifier review and approval.</b></p> <ul style="list-style-type: none"> <li>- <b>OMRI List:</b> Please visit <a href="http://www.omri.org/omri-lists/download">http://www.omri.org/omri-lists/download</a></li> <li>- <b>WSDA List:</b> Please visit <a href="https://cms.agr.wa.gov/getmedia/6322228c-c949-44a2-926c-2a86739269e3/WSDA_Organic_Input_Material_List">https://cms.agr.wa.gov/getmedia/6322228c-c949-44a2-926c-2a86739269e3/WSDA_Organic_Input_Material_List</a></li> <li>- NOP Seal on label, or certifier review and approval;</li> <li>- For <b>inert ingredients:</b> Please visit <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a></li> </ul> <p>Please consult <b>NOP Official documents:</b> NOP Standard (Organic Regulation), NOP Handbook (NOP Policies; Guidance) and NOSB Recommendation are available on NOP website: Please visit <a href="http://www.ams.usda.gov/AMSV1.0/nop">http://www.ams.usda.gov/AMSV1.0/nop</a></p>

**Documentation should be available for inspection to support the information recorded by producers and handlers (e.g. receipts for purchased inputs, labels, receiving/source records).**

#### 4.1 Evaluation of inputs

Bioagricert must review all materials used by organic producers and handlers for compliance with the USDA organic regulations. See 7 CFR § 205.201(a)(2). Bioagricert must verify that materials used by organic operations comply with the regulations, including the National List of Allowed and Prohibited Substances, and any annotations provided therein (see 7 CFR §§ 205.601-606).

Bioagricert have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:

- Evaluator can verify that the material complies with the regulations by evaluating the product, all of the ingredients within the product, and, if applicable, the manufacturing processes, source materials, and processing aids used to produce the ingredients or final product (e.g., contacting the supplier/ formulator/ manufacturer to obtain full disclosure of the ingredients in the product and manufacturing processes, including processing aids).
- Evaluator may consult with another certifier who has already evaluated the product and accept that certifier's determination of the product's compliance with the regulations. The Washington State Department of Agriculture, as an accredited certifying agent, has a publicly available list of approved

products available at <http://agr.wa.gov/FoodAnimal/Organic/MaterialsLists.aspx>.

- Evaluator may accept pesticides that have been determined by the U.S. Environmental Protection Agency (EPA) to comply with the USDA organic regulations.
- Evaluator may consult with material review organizations accredited to ISO Guide 17065 (formerly ISO Guide 65). These material review organizations must abide by USDA Agricultural Marketing Service (AMS) guidance and policies on materials. The California Department of Food and Agriculture (CDFA) Organic Input Material (OIM) program may be consulted for their review of organic crop materials. The Organic Materials Review Institute (OMRI) may be consulted for crop and livestock materials, as well as for materials used in organic handling.

Evaluation result must be recorded on the **Annex to Master 080 (OSP) – INPUT MATERIAL APPLICATION RECORD CROP OPERATION** and on the Bioagricert software and communicate to the applicant and inspector.

### Liquid fertilizers with a nitrogen analysis greater than 3 percent

Liquid fertilizers with a nitrogen analysis greater than 3 percent must follow the specific NOP guidance that foressen a complete an onsite audit by a material evaluation program.

### Criteria for pesticides evaluation

The allowed pesticides on the National List are called active ingredients when they are formulated into a commercial product. Even if the active ingredient in a pesticide is allowed, if an inert ingredient is not allowed, the pesticide may not be used in organic crop production. The U.S. Environmental Protection Agency provides four classifications of inert ingredients: List 1, List 2, List 3, and List 4. At this time, only a small fraction of the inert ingredients on these lists is allowed in organic production (please visit <https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>

The active ingredient is listed on the product label, but the inert ingredients often are not listed, and companies may choose not to reveal that information. Determining whether a commercial pesticide is allowed for organic production is a daunting task.

### Products with Multiple Reviews

When Bioagricert concludes that a product may not comply with the regulations, and that product is allowed by another certifying agent or material evaluation program, Bioagricert notifies the NOP at [NOP.Guidance@ams.usda.gov](http://NOP.Guidance@ams.usda.gov).

The NOP will review information from both parties and determine whether the regulations have been properly applied.

## 4.2 On-site inspection

During the on-site inspection of an organic operation the inspector must verify:

1. The organic operation's compliance or capability to comply with NOP regulations .
2. That the information, including the Organic Production or Handling System Plan (OSP), accurately reflects the practices used or to be used by the applicant for certification or by the organic operation;
3. That prohibited substances have not been and are not being applied to the organic operation through means which (at the discretion of Bioagricert, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples).
4. Exit interview.

### Specific control points

The inputs checks must be recorded on inspection report and on **Annex to Bioagricert inspection report – NOP CROP OPERATION**.

In case of Non compliances (NC), the Inspector send to Bioagricert Non compliance reports (Non compliances shall be confirmed to the Operator by Bioagricert head office). All the documentation regarding the inspection and the documents obtained during the visit are sent to Bioagricert Head office.

### 4.3 Obligation for Operator

#### - Organic System Plan – Inputs update

If there is a need to apply a pest control or other material that was not originally listed in the Organic System Plan (OSP) and approved by Bioagricert, the organic operation prior to using any new input, must complete and send to Bioagricert the **Annex to Master 080 (OSP) – INPUT MATERIAL APPLICATION RECORD CROP OPERATION** or **Handling OSP**.

Application of a material without approval from Bioagricert, may be considered an application of a prohibited substance, which would remove the operation's land from certification for three years from the last application of the prohibited material

#### - Organic System Plan – Annual update inputs

Each year, the Operator must complete the **Annex to Master 080 (OSP) – INPUT MATERIAL APPLICATION RECORD CROP OPERATION** or in case of changes submit the **Handling OSP** and send it to Bioagricert evaluator for evaluation and approval.

## 5. NOP Regulatory References, Guidance, Instructions

**§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.**

**§ 205.201 Organic production and handling system plan.**

**§ 205.203 Soil fertility and crop nutrient management practice standard.**

**§§ 205.600-607 The National List of Allowed and Prohibited Substances.**

### 5.1 NOP National List

**§ 205.601 Synthetic substances allowed for use in organic crop production.**

The National List of synthetic substances includes materials that are specifically allowed in organic crop production.

The list includes algaecides, disinfectants, sanitizers, irrigation system cleaners, herbicides, animal repellents, insecticides, miticides, pheromones, rodenticides, slug baits, plant disease controls, soil amendments, and plant growth regulators; in short, many of the materials needed for crop production.

Any synthetic substance that is not on the National List is not allowed. For example, herbicides containing the synthetic material glyphosate are prohibited. Herbicides containing only natural substances, such as vinegar and clove oils, are allowed.

**§ 205.602 Non-synthetic substances prohibited for use in organic crop production.**

This is the National List of natural, or nonsynthetic, materials that are specifically prohibited in organic crop production. This list includes natural – but highly toxic – materials, such as arsenic.

**§ 205.603 Synthetic substances allowed for use in organic livestock production.**

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production.

**§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.**

The nonsynthetic substances in this section may not be used in organic livestock production.

**§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”**

The nonagricultural substances in this section may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

**§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”**

Only the nonorganically produced agricultural products in this section may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

## 5.2 NOP Handbook

Section A. Standards	Document	Date
<a href="#">Processed Animal Manure in Organic Crop Production</a>	NOP 5006	7/22/2011
<a href="#">Reassessed Inert Ingredients   Notice to Petitioners</a>	NOP 5008	7/22/2011
<a href="#">Approval of Liquid Fertilizers for Use in Organic Production</a>	NOP 5012	7/22/2011
<a href="#">Certification of Organic Yeast</a>	NOP 5014	7/22/2011
<a href="#">Compost and Vermicompost in Organic Crop Production   Response to Comments</a>	NOP 5021	7/22/2011
<a href="#">Guidance: Substances Used in Post-Harvest Handling of Organic Products   Response to Comments</a>	NOP 5023	1/15/2016
<a href="#">The Use of Chlorine Materials in Organic Production &amp; Handling   Response to Comments</a>	NOP 5026	7/22/2011
<a href="#">The Use of Kelp in Organic Livestock Feed   Response to Comments</a>	NOP 5027, NOP 5027-1	2/28/2013
<a href="#">Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed   Response to Comments</a>	NOP 5030, NOP 5030-1	2/28/2013
<a href="#">Classification of Materials   Decision Tree for Classification of Materials as Synthetic or Non-Synthetic   Decision Tree for Classification of Agricultural and Non-Agricultural Materials for Organic Livestock Production or Handling   Response to Comments</a>	NOP 5033, NOP 5033-1, NOP 5033-2 NOP 5033-3	12/2/2016
<a href="#">Materials for Organic Crop Production   Materials for Organic Crop Production   Appendix of Prohibited Materials for Organic Crop Production   Response to Comments</a>	NOP 5034, NOP 5034-1, NOP 5034-2 NOP 5034-3	12/2/2016
Section C. Accreditation	Document	Date
<a href="#">Material Review – Interim Instruction</a>	NOP 3012	8/30/2016
Section G. Policy Memos	Document	Date
<a href="#">Humic Acid Extraction</a>	PM 13-2	12/16/2013
<a href="#">Synthetic Algicides, Disinfectants, and Sanitizers Allowed in Organic Crop Production</a>	PM 13-3	6/6/2014

<a href="#">Aquatic Plant Extracts</a>	PM 14-1	3/12/2014
<a href="#">Chlorine Use in Egg Breaking Facilities</a>	PM 14-2	8/5/2014
<a href="#">Nanotechnology</a>	PM 15-2	3/24/2015
<a href="#">Electrolyzed Water</a>	PM 15-4	9/11/2015

<b>Section H. Notices to Certifying Agents</b>	<b>Document</b>	<b>Date</b>
<a href="#">Sodium Nitrate Use in Organic Crop Production</a>	Notice 12-1	9/11/2012