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# Best Practices for Common Material Review Issues

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## Contents

# Introduction

Organic certifiers and material review organizations strive for consistency in evaluating material inputs for compliance with the National Organic Standards. However, material reviewers find that evaluation is a nuanced process and the language of the regulations does not always present clear direction. Guidance is sought from the National Organic Program (NOP) regarding known material disputes, and material reviewers work together to arrive at resolutions to common questions.

In 2017, a working group comprised of certifiers and material reviewers assembled to document common approaches for reviewing a number of materials. This information was presented at the 2018 ACA Annual Training in San Antonio, Texas. Later, the group re-assembled to develop similar training materials for the 2019 ACA Annual Training in Greenville, South Carolina. Some of the 2017 materials were revised at that time, having been noted as such in this updated document.

Group members have determined that it would be best to revisit and add to this document on an annual basis with input from as many certifiers and material reviewers as possible. Those interested in participating in ongoing working group efforts should contact the ACA.

*The ACA recommends all accredited certifiers adopt ACA Best Practices for the sake of consistent implementation of the USDA Organic Regulations. ACA Best Practices are reviewed periodically to ensure they are accurate and up to date. Concerns with this or any ACA Best Practice or guidance document should be submitted to the ACA Coordinator.*

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# Crop

Synthetic inputs are permitted for a specific use in organic crop production if listed at §205.601, and all non-synthetic inputs are permitted for use in organic crop production except for those listed as prohibited at §205.602. In addition, §205.203 states that "The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances…"

## 1. Newspaper or other recycled paper

*References: §205.601(b)(2)(ii); §205.601(c)*

**Sources:** In determining allowed sources of "other recycled paper", we generally support a liberal interpretation of what it means to be "recycled." An analysis of the full manufacturing process of the paper is not necessary. Rather, we just need to verify that it meets any definition of "recycled" and also that it does not contain glossy or colored inks.

Allowable sources of "recycled" paper include:

- Any paper (including virgin paper) that has been diverted from a waste stream
- Any paper (including virgin paper) that has been previously used in any manner
- Any paper that includes any amount of recycled content (e.g., paper with 5% recycled content)

Newspaper from any source is allowed and is not required to be verified as "recycled." Virgin newsprint-grade paper is allowed. The only prohibited source of paper that we could identify is 100% virgin non-newspaper paper which was not previously used and/or diverted from a waste stream.

**Additives:** Additives and processing aids that are used during the manufacturing of paper, as described in the technical reports, are allowed as part of the "standard of identity" of paper as it is listed on 205.601. For additives that are added after the paper has been manufactured (e.g. adhesives added to paper), there are 2 different approaches used by certifiers for evaluation (listed below). NOP guidance is pending to determine the appropriate approach for these "post-paper" additives.

- Approach #1: Additives added after the paper has been manufactured are reviewed individually in accordance with the National List (synthetics must be on 205.601). Under this approach, glue inherent in corrugated cardboard is allowed, but glue added to make paper pots is prohibited.

- Approach #2: Additives added after the paper has been manufactured are allowed if they are the same/similar to additives that would have been allowed in the manufacturing of paper. Under this approach, glue added to make paper pots is allowed.

**Uses:** Newspaper and other recycled paper are clearly allowed for use as mulch and as compost feedstocks. Certifiers are also allowing the use of these paper products to be planted directly in the ground (e.g., paper pots used to grow transplants), even though the National List does not directly provide for this use* (e.g. paper pots may not have an explicit weed control or compost feedstock function). The allowance of paper to be planted in the ground is based on common sense justification, such as: When paper is used as a mulch, it is in direct contact with soil and may be left in the field to decompose. Paper that is planted in soil is essentially having the same impact on organic integrity.

* During the Spring 2018 Meeting of the National Organic Standards Board (NOSB), the National Organic Program clarified that, while use of paper is allowed as mulch or compost feedstock, use of paper for the purpose of transplanting does not comply with the regulations. Certifiers noted this was a departure from common practice of certifiers, and NOP allowed an initial phase-out period to end after the 2018 growing season. They suggested that interested stakeholders should submit a petition for paper pots to be added to the National List for the use described. Since then, a petition has been submitted to the NOSB for consideration. At the request of many stakeholders, NOP has extended the phase-out period until further notice. These Best Practices may be amended depending upon the outcome of the petition process.

New paper pots should be reviewed for acceptable sources of paper and additives as stated above in approach #2. Any crop producer can use approved paper pots, including growers that were not previously using paper pots. The review and approval of paper pots is subject to change depending on the completion of the NOSB review.

## 2. Substrate used inside containers for container/hydroponic production (including transplants)

*References: §205.601(j)*

In this issue, we are using the term “substrate” to refer to soil or soil-substitute materials that hold plant roots and the matrix within which the roots grow. Examples of substrate are pictured below. The substrate is distinct from the container or tray (e.g. “devices”) that physically contains/holds the substrate materials.


Substrate ingredients must be disclosed and reviewed individually in accordance with the National List (synthetics must be on 205.601). Under this approach, synthetic foam cubes and plastic mesh pads are prohibited if the roots permeate the material and cannot be removed.

## 3. Molasses in crop production

*References: NOP 5033; NOP 5034-1*

**Additives:** To confirm non-synthetic status, certifiers should evaluate whether any synthetic additives are added and intended to remain in the final molasses product (synthetic additives include those listed in 5034-1 and any other prohibited additive or ingredient that remains in the final product). An analysis of the full manufacturing process of the molasses material is not necessary. This "sound and sensible" approach is supported by an understanding that processing aids used in the manufacture of molasses are expected to be removed from the final product during standard manufacturing procedures and considered to have no functional effect in the finished product. Synthetic preservatives, artificial colors, and artificial flavors are considered functional and prohibited additives.

Certified organic molasses should be allowed as a crop input without further review. This is another sound and sensible approach.

**Documentation:** Information to confirm non-synthetic status of molasses may be obtained from the final handler or distributor of the molasses product, provided that the party is knowledgeable. This documentation may include a label with a complete ingredient list, a spec sheet, or a statement from the molasses supplier about whether the molasses contains additives that are intended to remain in the final product. If not, then the certifier would need to trace back in the chain until such verification can be obtained.

## 4. Non-synthetic minerals in crop production

*References: NOP 5033; NOP 5034; NOP 5034-1*

Minerals which are permitted only in non-synthetic form vary in their risk of being processed or formulated in a manner that may be synthetic. The source of any non-synthetic mineral must be documented. An analysis of the full manufacturing process of the mineral is not necessary in every case, but additional information can always be requested as needed.

**High risk minerals:** The minerals listed below should be evaluated for certain high-risk aspects of their manufacturing process to ensure non-synthetic status. Information to confirm compliance should ideally come from the original manufacturer of the mineral product, and not as a self-declaration from a distributor or re-packager the product. This approach is based on an understanding that distributors/re-packager commonly are unaware of un-labeled additives (such as dust suppressants) or processing methods used in manufacturing and formulating the product.

- Gypsum/Calcium Sulfate: Risk of dust suppressant, recycled wallboard, or smoke stacks (FGD Gypsum).
- Lime/Calcium Carbonate: Must not be beet lime, precipitated lime, or quick lime (calcined from calcium carbonate), or water treatment lime.
- Potash/MOP/SOP/KCl: Must be from mined source. Must not contain prohibited dust suppressants.
- Calcium chloride: Must be from natural brine sources. We interpret the calcium chloride restriction at 205.602(c) to pertain to diseases on fruits such as bitter pit in apples and blossom end rot in tomatoes, peppers, and cucurbits. To our knowledge, there are no agronomic crops that suffer from calcium uptake disorders.
- Salt: Must not contain prohibited anti-caking agents or other additives
- Kaolin: Must not be calcined at a high temperature, resulting in synthetic metakaolin

**Low risk minerals: Although the source should be confirmed,** the minerals listed below do not require additional documentation or further review to confirm non-synthetic status, although additional information can be requested if any questions arise. This "sound and sensible" approach is based on an understanding that these minerals are rarely, if ever, formulated or processed in a manner that would render them synthetic. These materials will be periodically re-reviewed to determine continued "low risk status."

- Vermiculite
- Perlite
- Diatomaceous Earth (calcined forms are considered non-synthetic)
- Leonardite
- Oyster Shell
- Sand
- Greensand
- Basalt Grit

## 5. Conventional Manure

*References: §205.203, §205.601, §205.602, NOP 5034-1*

Manure is defined at §205.2 as feces, urine, other excrement, and bedding produced by livestock that has not been composted.

**Raw Manure:** Raw manure is permitted for use on organic operations, provided that it is:

> (i) Applied to land used for a crop not intended for human consumption;
>
> (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
>
> (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles

Raw conventional manure is allowed as long as it is verified that prohibited additives (e.g. pit additives, fly sprays, odor control) are not added after the manure is removed from the animal area. The attached Off-Farm Manure Verification can be used to verify compliance with this best practice.

The use of raw conventional manure must comply with §205.203(c):

> The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

Associated documents: Off-Farm Manure Verification

## 6. Compost, Vermicompost, and Processed Manure

*References: §205.203, §205.601, §205.602, NOP 5006, NOP 5021, NOP 5034, NOP 5034-1*

**Compost, Alternative Composting Methods, and Processed Manure**

Compost is defined at §205.2 as 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.

Alternative Composting Methods are clarified in NOP 5021. Compost is acceptable if (i) made from only allowed feedstock materials; (ii) the compost undergoes an increase in temperature to at least 131ºF (55ºC) and remains there for a minimum of 3 days; and (iii) the compost pile is mixed or managed to ensure that all of the feedstock heats to the minimum temperature for the minimum time.

Processed Manure / Heat Processed Manure guidelines are specified in NOP 5006. Processed manure may be used as a supplement to a soil building program without a specific interval between application and harvest. Processed manure must be treated so that all portions of the product, without causing combustion, reach a minimum temperature of either 150° F (66° C) for at least one hour or 165° F (74° C), and are dried to a maximum moisture level of 12%; or an equivalent heating and drying process could be used. Processed manure products must not contain more than $1x10^3$ (1,000) MPN fecal coliform per gram of processed manure sampled and must not contain more than 3 MPN Salmonella per 4 grams of processed manure sampled.

**Feedstock:**

- Non-synthetic non-agricultural ingredients
    - Must not be prohibited at 205.602
    - Non-synthetic status may be verified according to NOP 5033-1
    - Compost containing manure must comply with the days-to-harvest restrictions if it does not meet one of the three criteria outlined below.
        - Manure feedstock must be verified according to best practice section 5.

- Non-synthetic agricultural compost feedstocks
    - Allowed unless prohibited at 205.602
    - Not required to be organic
    - Not verified to be free of pesticide residues
    - Processed ag ingredients and food waste are not considered non-synthetic agricultural ingredients
- Synthetic compost feedstocks
    - Must be listed as allowed at 205.601(c) or 205.601(j), in accordance with any restrictions.

**Compost (or alternative) manufacturing process verification:**

- No manure or animal feedstocks used:
    - Compost that contains only plant materials is permitted for use without restriction, even if it does not meet the composting requirements at §205.203(c)(2), NOP 5006 and NOP 5021.
- Containing manure:
    - To be allowed without restriction, must meet <u>one of the three</u> following criteria:
        - 1. Meets the NOP definition of compost at §205.2 and the composting standard at 203(c)(2).
        - 2. Meets the alternative composting methods in NOP 5021, Compost and Vermicompost in Organic Crop Production. The monitoring of the parameters in this NOP guidance must be documented in the OSP in accordance with § 205.203(c) and verified during the site visit. Certifiers reviewing compost inputs produced by commercial operators should similarly review the production methods and source materials, although onsite visits are not required (NOP 5021). Initial C:N ratio is not required.
        - 3. Meets the Processed Animal Manures Guidelines in NOP 5006

**Vermicompost:**

Not Containing Manure:

- Vermicompost that contains only plant material may be used without restriction, and does not need to meet additional vermicompost production requirements.

Containing Manure:

- Vermicompost containing manure that does not have the days-to-harvest restriction may be used without restriction, and does not need to meet additional vermicompost production requirements.
- Vermicompost containing manure that meets the vermicompost production requirements may be used without restriction.
    - Vermicomposting is an acceptable method of composting when:
        - 1. It is made from allowed feedstock materials (either non-synthetic substances not prohibited at § 205.602, or synthetics approved for use as plant or soil amendments);
        - 2. Aerobic conditions are maintained by regular additions of layers of organic matter, turning, or employing forced air pipes such that moisture is maintained at 70-90%; and
        - 3. The duration of vermicomposting is sufficient to produce a finished product that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Verification may include:
            - Type and duration of vermicomposting (duration of vermicomposting is at least 12 months for outdoor windrow, 4 months for indoor container systems, 4 months for angled wedge systems, or 60 days for continuous flow reactors).
                - For outdoor windrows, one indicator that the process is complete is when the worms move out of the compost, which would typically take 6 months in warm conditions, or up to 12 months in colder climates.
            - Testing for pathogens (Salmonella and fecal coliform organisms) and/or heavy metals.
            - Earthworms fragment the organic wastes into finely-divided materials with a low C:N ratio and high microbial activity.
            - Nitrogen is mostly found in the nitrate form, and potassium and phosphorus are in soluble forms.
            - For most organic wastes, no traces of the raw materials are visible. Processing is maintained at 70-90% moisture content with temperatures maintained in the range of 18-30 degrees C (65-86 degrees F) for good productivity.

- Vermicompost that contains manure that does not meet vermicompost production requirements must comply with the days-to-harvest restrictions.

## 7. Biodynamic Prep - Horn Manure

*References: §205.203, §205.601, §205.602, NOP 5034-1*

Horn manure spray is produced by filling a horn with raw animal manure, burying the horn in soil for a specified period of time, unburying the horn, and diluting the contents with water for application to crops or fields.

- Synthetic ingredients must be listed at §205.601(j) and non-synthetic ingredients must not be prohibited at §205.602. Restrictions and annotations, such as documentation for micronutrient deficiencies, must be followed.
- Preparations containing animal manure, including horn manure spray, must comply with raw manure days-to-harvest restrictions. The pre-harvest interval begins the date the horn is buried.
    - In general, this process does not satisfy the requirements for composted manure or processed manure that would exempt the use from the pre-harvest interval requirements that apply to raw manure under section 205.203(c)(1) of the USDA organic regulations or NOP Guidance 5006. Certifying agents may need to review the manufacturing process on a case-by-case basis to determine whether the raw manure restriction applies; however, for purposes of the guidance, we have not amended the listing. The only manufacturing process that would not require the raw manure days-to-harvest restriction would be using composted or processed manure.

Note: FSMA regulations, state, and local regulations were not evaluated or addressed in this best practice.

## 8. Plastic Mulch and Covers

*References: §205.2, §205.206(c)(6), §205.601(b)(2)(ii), NOP Policy Memo 15-1, NOP 5034-1*

*Mulch. Any non-synthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.*

**Non-biodegradable:**

- Plastic and other synthetic mulches and covers (petroleum-based other than polyvinyl chloride (PVC)) are allowed for weed control, provided that they are removed from the field at the end of the growing or harvest season. Current commercial product used (at least in USA) do not contain PVC, so PVC free is not verified for synthetic mulches and covers. Recycled products (billboard covers) should be reviewed for PVC content.
- Plastic mulch should be verified to be non-biodegradable.
- Plastic covers alone are not considered an acceptable buffer or barrier from prohibited substances.
- For perennial crops harvested over more than one season, synthetic plastic mulch may be used provided it is removed before it breaks down or degrades. The operator must provide a description of the estimated life span of the material and plans for removal at the appropriate time in the Organic System Plan.

**Biodegradable Biobased Mulch Film**

*Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:*

*(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);*

*(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and*

*(3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).*

- Biodegradable biobased mulch films as defined in §205.2 are allowed for weed control, provided that they are produced without organisms or feedstock derived from excluded methods.
- It is unlikely that any brand name products currently in the marketplace will comply with the NOP regulations. Most and possibly all, of the currently marketed biobased mulch films contain some petrochemical feedstocks, and the feedstocks are typically less than 50% biobased.

## 9. Agricultural products

*References: §205.2, §205.203, §205.602, NOP 5033-2, NOP 5034, NOP 5034-1*

Raw, single ingredient agricultural inputs, such as straw, are non-synthetic and therefore allowed in crop production unless prohibited at §205.602. Processed agricultural products such as fortified milk products are not considered raw, single ingredient agricultural inputs.

Best Practice: Composted or uncomposted raw, single ingredient agricultural inputs, such as straw, are allowed for use in organic crop production without verification of additives or GMO status. Inputs may be verified to be agricultural according to NOP 5033-2

*Some certifiers may choose to verify non-GMO status of at-risk non-organic single ingredient agricultural inputs, such as corn and cotton.*

## 10. Green waste

*References: §205.2, §205.203, §205.601-602, NOP 5034, NOP 5034-1*

Green waste composed of grass clippings or leaves is non-synthetic and not prohibited at §206.602. Therefore, it is permitted in organic crop production, provided that it does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

Best Practice: Composted and un-composted green waste composed of grass clippings or leaves is allowed in organic crop production, provided that it is verified that the manufacturer or certified operation removes any prohibited contaminants, such as trash or plastic or biodegradable bags prior to composting or prior to use as a non-composted input material.

## 11. Multi-ingredient processed food products and food processing by-products

*References: §205.2, §205.203, §205.601-602, NOP 5034, NOP 5034-1*

Requests to approve multi-ingredient processed food products and by-products as a crop input are occasionally submitted. They are considered non synthetic inputs unless they undergo a chemical change (NOP 5033-1). Certifiers have different approaches to reviewing processing aids in these cases, but agree that, when composted, multi-ingredient food products and by-products pose little threat to organic integrity.

**Best practice:** When composted according to NOP requirements at §205.203 or alternative approved composting methods (NOP 5021), or when meeting the Processed Animal Manures Guidelines (NOP 5006), multi-ingredient food products, such as beer, whey waste, and bread, and food processing by-

products, such as cannery waste, pomaces (peels, stems and cores), vegetable and fruit waste, and distillers grain, are permitted in organic crop production.

Note: The group has not yet developed a best practice on uncomposted multi-ingredient processed food products and food processing by-products.

## 12. Post-consumer food waste

*References: §205.2, §205.203, §205.601-602, NOP 5034, NOP 5034-1*

Post-consumer food waste, composed from scraps from a cafeteria, restaurant, or kitchen, is often requested for use as a compost feedstock in organic crop production. Post-consumer food waste is at risk of containing trash, plastic, or biodegradable plastics, such as plastic silverware, plates, cups and trash bags.

Best practice: When composted according to NOP requirements at §205.203 or alternative approved composting methods (NOP 5021), or when meeting the Processed Animal Manures Guidelines (NOP 5006), post-consumer food waste is permitted in organic crop production, provided that trash, plastic, or biodegradable plastic is confirmed to be removed by the supplier or the certified operator prior to composting.

Note: The group has not yet developed a best practice for uncomposted post-consumer food waste.

13. Verification of management of animal materials to prevent contamination of crops, soil or water by pathogenic organisms

References: §205.2, §205.203, NOP 5006, NOP 5021, NOP 5034-1

§205.203(c) states that "The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include: (1) Raw animal manure,… (2) Composted plant and animal materials… (3) Uncomposted plant materials." According to NOP 5034-1, animal materials include, but are not limited to, manure, slaughter renderings, tankage, blood meal, etc.

§205.203(c) states:

> "The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:
>
> (1) Raw animal manure, which must be composted unless it is:

(i) Applied to land used for a crop not intended for human consumption;

(ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or

(iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

(2) Composted plant and animal materials produced through a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

(3) Uncomposted plant materials."

§205.203(c) lists three types of plant and animal materials: (1) raw animal manure, (2) composted plant and animal materials, and (3) uncomposted plant materials. §205.203 does not clarify which animal materials, if any, need to be composted or otherwise processed unless they meet the requirements at §205.203(c)(1)(i), (ii), and (iii).

Best practice: In order to verify that an operator is managing animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances, certifiers may consider whether or not the animal material applied to crops for human consumption has been processed by the manufacturer or producer in a way that reduces pathogen contamination concerns.

Some animal materials are processed in a manner that reduces pathogens. The following uncomposted animal materials may be considered to be processed by the manufacturer to reduce pathogen contamination concerns:

- Blood meal
- Feather meal
- Bone meal
- Fish meal
- Egg shell, egg shell meal

Even these processed animal materials could be a source of pathogen contamination if they are not stored and applied in a way that would prevent such contamination from developing.

The following uncomposted, unprocessed animal materials may raise pathogen contamination concerns when applied to crops for human consumption:

- Food processing by-product, such as raw eggs, raw milk, meat trimmings, fat waste, slaughter renderings, fish scraps
- Animal mortalities
- Blood

These materials may contribute to unsafe levels of Salmonella or fecal coliform.

If an uncomposted animal material raises pathogen contamination concerns, the following actions taken by the organic producer will reduce pathogen contamination concerns:

- Composting according to §205.2, §205.203(c), or NOP 5021, or processing according to NOP 5006. Pathogen testing may be used to confirm pathogen levels. Please see the best practice on Compost, Vermicompost, and Processed Manure for more information.
- Using according to §205.203(c)(1):
    - (i) Applied to land used for a crop not intended for human consumption;
    - (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
    - (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles

If a review of any animal material and/or its use raises concerns for pathogen contamination, certifiers may require additional information, such as a full description of the processing or pathogen testing verifying pathogen levels to verify that use of the material does not violate §205.203(c).

Note: FSMA regulations, state, and local regulations were not evaluated or addressed in this best practice.

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# Livestock

## 1. Bedding treatments in livestock production

*References: §205.603, §205.239(a)(3)*

**Ingredients:** Ingredients in bedding treatments must be reviewed individually in accordance with the National List (synthetics must be on 205.603).

- Synthetic vitamins and minerals that are listed at 205.603(d) are prohibited.
- Agricultural ingredients must be certified organic. (Note: OMRI does not currently require agricultural ingredients to be organic but will revisit this policy in the future.)

**Other considerations**

- Alternative label claims or intended uses could result in different review criteria (e.g., treatments for the purpose of controlling pests may contain synthetic EPA List 4 inerts; treatments intended for health care purposes may have synthetic excipients permitted via 205.603(f), non-organic agricultural ingredients, and/or other synthetic ingredients on 205.60(a)).
- Use of treated bedding in other areas of production (e.g., removing spent bedding from barn and spreading on organic fields) may involve additional considerations by certifiers.

## 2. Excipients in livestock health care products

*References: §205.603(f)*

*Excipients are Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents (§205.2). Synthetic excipients are allowed if identified at §205.603(f). Non-synthetic excipients are allowed if not prohibited for this use at §205.604. When reviewing excipients in formulated products, the specific section of the applicable regulations should be documented to demonstrate that the excipient complies with § 205.603(f).*

**Resources for identifying allowed excipients:** The following website and databases may be used to identify specific materials that are allowed under §205.603(f):

*Quick List:*

- *Meta-database, including GRAS Notices, Indirect Additives used in Food Contact Substances, and Substances Added to Food (formerly EAFUS)*
    - https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?cat=foodingredpkg&type=basic&search
- *GRAS*
    - GRAS Listings in 21 CFR: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=786bafc6f6343634fbf79fcdca7061e1&rgn=div5&view=text&node=21:3.0.1.1.13&idno=21
    - 21 CFR GRAS Search
    - https://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=21a99a763c56f94f771057eccd64105f&mc=true&tpl=/ecfrbrowse/Title21/21CIsubchapB.tpl
- *Approved by FDA as Food Additive:*
    - Food Additives (Direct and Indirect) Listings in 21 CFR: ● https://www.fda.gov/food/food-additives-petitions/food-additive-status-list
    - Substances Added to Food (Formerly EAFUS):

      https://www.accessdata.fda.gov/scripts/fdcc/?set=FoodSubstances
    - Color Additives Status List: https://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm
    - Indirect Additives used in Food Contact Substances: https://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- *Included in FDA review and approval of NADA or NDA:*
    - To verify FDA approval of NADA (New Animal Drug Applications)*:* https://animaldrugsatfda.fda.gov/adafda/views/#/search
    - To verify FDA approval of NDA (New Drug applications), use the Inactive Ingredients in FDA Approved Drugs database: https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm .
    - To verify APHIS approval, use the Current Veterinary Biologics Product Catalog: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/ct_vb_licensed_products

Materials that are allowed under 205.603(f) must meet one or more of the following criteria:

1. *Identified by the FDA as GRAS:*
    - GRAS Listings in 21 CFR

- 21 CFR GRAS Search

2. *Approved by the FDA as a food additive:*

   The FDA definition of a food additive includes food contact substances, indirect food additives, and color additives. The definition excludes GRAS substances, but GRAS substances are explicitly allowed in the rule.

   There is an FDA "Search Food Ingredient and Packaging Inventories" tool that simultaneously returns results from GRAS Notices, Substances Added to Food (formerly EAFUS), and Indirect Additives Used in Food Contact Substances, **along with other datasets that are not relevant to the NOP standards**. It is important to verify sure that search results come from a database that is covered under the standards. The "Search Food Ingredient and Packing Inventories" database covers all datasets that would satisfy the first two criteria in 205.603(f)

   Occasionally, CAS #'s or alternate names of substances do not match the listings in the searchable datasets. If this is the case, it may be worth asking the manufacturer if they know of a 21 CFR citation for the material that would meet the criteria for an FDA approved food additive. The 21 CFR description can referenced if the description substantially matches the material in question, and the material is listed in a section that meets the definition of a food additive:

3. *Included in FDA review and approval of NADA or NDA:* Excipients in APHIS-approved biologics or NADA/NDA-approved products are allowed without further review.

   a. NADA (New Animal Drug Applications)

   b. NDA (New Drug applications), verified using the Inactive Ingredients in FDA Approved Drugs database

   c. APHIS approval, verified using the Current Veterinary Biologics Product Catalog:

Note from 2015 technical evaluation report on excipients: "Although synthetic excipients did not appear at §205.603 until 2007, they have been used in livestock drugs and health care products with various interpretations by certification agencies and Material Review Organizations (MROs) as to their allowance (NOSB 2009). Since their listing on §205.603, there has still been some confusion among certification agencies about direct vs. indirect food additives, how those may be used, and their compliance with the excipient annotation (since the annotation does not stipulate 'direct' food additives and only says "approved by the FDA as a food additive") (emphasis added). Some certification agencies permit the use of indirect food additives only in health care products that are intended for external application (e.g., teat dips) while others do not permit them at all. Others permit indirect food additives in all types of health care products, including oral and injectable formulas."

**Excipients in Iodine products:** Ingredients that are identified as "complexing agents" in an iodine formulation are allowed as part of the "standard of identity" of iodine. Most complexing agents are identified in the Technical Report on Iodine. Ingredients that are not identified as the complexing agents for the iodine must be reviewed individually and be permitted under one of the resources listed above.

**NPEs:** If not being reviewed as iodine complexing agent, NPEs and APEs must be reviewed individually and be permitted under one of the resources listed above. The Technical Report on NPEs lists a few compounds that are permitted as livestock excipients.

## 3. GMO Vitamins in livestock feed

*References: §205.237, §205.603(d); NOP 5030*

The GMO status of AAFCO-listed vitamins used in certified organic livestock feed does not need to be verified. This position is supported by NOP 5030, which called out only a few specific items as needing to be additionally verified, but not vitamins. The draft version of this guidance was originally published with the following statement: "Minerals and vitamins cannot be sourced from slaughter byproducts from poultry or mammalian sources (if being fed to poultry or mammals) or sourced from products produced by excluded methods." This language was removed and not included in NOP 5030. Some vitamins are exclusively from GMO sources, and NOP 5030-1 Response to Comments recognizes that there is a lack of NOP/NOSB guidance regarding sources of livestock minerals and vitamins; it also suggests that vitamins "should" be reviewed for excluded methods and noted NOP may provide more information in the future, but it does not say that vitamins "must" be reviewed for excluded methods. (Note: OMRI and WSDA public lists will not include GMO vitamins.)

*AAFCO and FDA listed vitamins and minerals, as listed at 205.603(d), are allowed for use in livestock feed and feed additives without additional verification of GMO status, with the exception of proteinated minerals, which require some additional verification, and minerals sourced from bone such as bone charcoal, bone meal, and bone phosphate, which are prohibited.*

## 4. Non-synthetic feed additives and supplements

*The materials working group has removed the best practice on non-synthetic food additives based on feedback from the NOP that non-synthetic feed additives and supplements must be verified as legal to feed to livestock per §205.237(b)(6). This feedback contradicts the best practice, and verifying this requirement would be a significant change for many certifiers that would affect hundreds of products and even more certified operators. Therefore, the working group has removed this best practice, and we will retain our notes for the possibility of revisiting this topic in the future.*

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# Handling

## 1. Non-synthetic gases for organic processing

*References: §205.605(a)*

Non-synthetic oxygen and nitrogen are permitted at §205.605(a) as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)),"  provided that they are "oil-free" grades.

Best Practice: Oxygen or nitrogen for use in or on a processed "organic" or "made with organic (specified ingredients or food group(s))" product is considered to meet the annotation "oil free grades" if one of the following criteria is met:

- the gas is medical or food grade
- the SDS lists the ingredients as greater than or equal to 99% oxygen or nitrogen, respectively
- the manufacturer supplies a statement that the gas is oil free

## 2. Multi-ingredient packaged products for human consumption with less than 70 percent organically produced ingredients

References: §205.2, §205.101(a)(3)&(4), §205.301(d), §205.305, §205.310(b), 2016 NOSB Ancillary Substances Procedure Proposal

**Definitions:**

- Ingredient: Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.§205.2

- Processing Aid: (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at

insignificant levels and does not have any technical or functional effect in that food. §205.2

- Ancillary ingredient: Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for "incidental additives," which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3 i to iii4). To illustrate: Enzymes are listed on 205.605(a). The enzymes might contain the following additives, which are considered by the organic industry as "ancillary ingredients": calcium silicate (anticaking agent), calcium phosphate (carrier and/or filler), stearic acid (preservative), sorbitol (stabilizer), sodium citrate (pH control, buffer). 2016 NOSB Ancillary Substances Procedure Proposal.

**Background:**

A handling operation or portion of a handling operation that only handles multi-ingredient packaged products for human consumption with less than 70 percent organically produced ingredients, as detailed at 205.301(d) and 205.305, is exempt from organic certification (§205.101(a)(3)). When these types of products are organically produced or handled on exempt operations, they must not be identified or represented as "organic" in a product processed by others (§205.310(b)).

In practice, products containing <70% organic agricultural ingredients are often requested to be used as ingredients or processing aids in or on certified organic products. According to §205.310(b), an agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation.

However, when a request is made to use an exempt product as an ingredient in a product processed by others, §205.310(b) states that the agricultural ingredients in the exempt product must not be identified or represented as "organic". The solution, then, is for these ingredients to be certified.

However, operations that produce products containing <70% organic agricultural ingredients may not be able to opt into organic certification for these products, as some certification agencies do not offer this type of certification.

In addition, inconsistencies and concerns have emerged when these materials have been approved by Material Review Organizations as inputs, but are not certified under an NOP certificate. In these cases, each ingredient is confirmed to comply with the organic requirements, but the production of the material in whole is not covered under an accredited certification agency.

**Best practice:**

All of the following scenarios involve a product containing <70% organic agricultural ingredients produced on an exempt operation, which is requested to be used as an ingredient or processing aid in a product processed by others.

I. Agricultural component is an ingredient or processing aid: A "<70% organic" product containing a non-ancillary organic component may not be used as an ingredient or processing aid in or on a certified product, unless the "<70% organic" product is processed and handled on an organic operation certified by an accredited certifier and covered under the handler's organic certification. The certifier's verification can be confirmed by a listing on an organic certificate in a "<70% organic" category or by a certifier letter. The remaining non-organic ingredients in the "<70% organic" product must be verified for compliance by the certifier of the processor that wants to use this product as an ingredient in their "organic" or "made with organic" product. This certifier must verify that the remaining non-organic ingredients in the "<70% organic" product are

    - Allowed at §205.105, §205.605 and §205.606, including annotation verification
    - Produced and handled without excluded methods, ionizing radiation, and sewage sludge
    - Allowed according to other certifier specific requirements (i.e., ancillary ingredient review policies)

II. Agricultural component is an ancillary ingredient: A "<70% organic" product may not be used as an ingredient or processing aid in or on a certified organic product, unless the organic component is an ancillary ingredient. If so, the "<70% organic" product does not need to be processed and handled on an organic operation or verified by a certifier. The remaining ingredients in the "<70% organic" product must be verified for compliance with the National List by the certifier of the processor that wants to use this product as an ingredient in their "organic" or "made with organic" product. This certifier must verify that the remaining non-organic ingredients in the <70% organic product are:

- Allowed at §205.605 and §205.606, including annotation verification
- Produced and handled without genetic modification, ionizing radiation, and sewage sludge
- Allowed according to other certifier specific requirements (i.e. ancillary ingredient review policies)

If a product contains greater than or equal to 70% organic agricultural ingredients, the product must be certified to be used as an ingredient or processing aid in or on an organic or "made with organic…" product. Please note that waxes and coatings are considered ingredients.

Note: Material Review Organizations (MROs) do not currently follow this best practice for "<70% organic" products used as an ingredient or processing aid in or on a certified product. MROs currently review and approve "<70% organic" products for use as ingredients or processing aids in or on a certified product, without requirements for certifier verification.

OMRI now applies a caution statement to all uncertified processing ingredients and processing aids that formulate with organic agricultural ingredients. Processing ingredients and processing aids that are certified organic will not be cautioned. The caution statement appears on an OMRI certificate and is also published on OMRI's website and reads:

"This ingredient or processing aid is not certified organic. The operation supplying this input material may be exempt from certification under §205.101. Agricultural ingredients in this product shall not be labeled as organic when used in further processed products unless the ingredient or processing aid is certified by a USDA accredited certifier."

MROs are currently in communication with NOP about policy revisions. Certifiers may or may not accept MRO reviews/approvals for such materials, and may instead independently review the materials in line with this best practice.

| | Certified Organic Ingredient in the "<70% Product" | |
|---|---|---|
| | Agricultural component is a ingredient or processing aid in the final product | Agricultural component is an ancillary ingredient in the final product |
| Product containing <70% certified | Example: Batch pack contains 30% certified organic wheat flour, salt, guar gum, citric acid, enzymes. This batch pack is used as an ingredient in an | Example: Non-Organic Flavor material with organic maltodextrin included as a carrier. This flavor is used as an *ingredient* in an organic final product. |

| | | |
|---|---|---|
| organic ingredient | organic final product. No ingredients in this batch pack are considered ancillary *ingredients* in the final product.<br><br>To allow as an ingredient, this batch pack product must be processed and handled by a certified organic operation and must have certifier oversight, confirmed with either a listing on a certificate or a letter from that certifier for the specific product.<br><br>Certifiers approving the use of this ingredient must still verify that the remaining ingredients are compliant with regs.<br><br>Example: Defoamer contains 50% sodium hydroxide, 50% certified organic canola oil. This defoamer is considered a processing aid in the final product.<br><br>To allow as a processing aid, this product must be processed and handled by a certified organic operation and must have certifier oversight, confirmed with either a listing on a certificate or a letter from that certifier.<br><br>Certifiers approving the use of this ingredient must still verify that the remaining ingredients are compliant with regs. | The maltodextrin is considered an ancillary *ingredient* in the final *product*, as it serves a function in the flavor but not in the final *product*.<br><br>*Because the agricultural component of this non-organic flavor is ancillary to the final product, the flavor is* NOT required to be processed and handled on an organic operation and certifier oversight is NOT required.<br><br>Additional verification of ancillary ingredients depends on individual ancillary ingredient policies. |

## 3. Applicability of the Commercial Availability Requirement

References: §205.2, §205.301(c), §205.605, §205.606, Federal Register Notices for Flavors and Yeast, NOP [NOTICE] on collagen gel commercial availability

**Summary:** organic commercial availability requirements do not apply to any permitted non-organic ingredients or processing aids used in or on products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))".

Non-organic materials listed at §205.606 of the National List of Allowed and Prohibited Substances are permitted as ingredients in or on processed products labeled as "organic" when the product is not commercially available in organic form. In addition, yeast is permitted at §205.605 with the following annotation:

> "When used as food or a fermentation agent in products labeled as "organic," yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available" (emphasis added)

Non-organic materials listed at §205.605 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.

Collagen gel, flavors and silicon dioxide are permitted at §205.605, with the respective annotations:

> "Collagen gel - as casing, may be used only when organic collagen gel is not commercially available."
>
> "Flavors - nonsynthetic flavors may be used when organic flavors are not commercially available..."
>
> "Silicon dioxide - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available."

Unlike for the substances at 606 and yeast, the listings for collagen gel, flavors, and silicon dioxide seem to indicate that the requirement to use an organic form of the product when commercially available applies to both products labeled as "organic" and "made with organic (specified ingredients or food group(s))"

However, §205.301(c) states:

> "Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s)). Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of § 205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of § 205.301..."

§205.301(f)(6) states:

> "All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not: ...
>
> (6) Be produced using nonorganic ingredients when organic ingredients are available.."

Therefore, the requirement to use organic ingredients when commercially available does not apply to collagen gel, flavors, silicon dioxide, and other non-organic ingredients when they are used as ingredients in products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."

# 4. Risk-based Assessment of 205.605(a) Substances

**Purpose**

This ACA Guidance Document details a practical risk-based approach for assessing the compliance of 205.605(a) inputs* with National Organic Program requirements, specifically with regards to classification verification and the prohibition on the use of excluded methods, ionizing radiation, and sewage sludge in the production of "Organic" and "Made with Organic (specified ingredients or food groups(s))" ("MWO") products.

*This best practice does not address the assessment of natural flavors, which are detailed in the ACA Best Practice for Review of Non-Organic Flavors

**Background**

The Organic Foods Production Act of 1990 (OFPA) and National Organic Program Final Rule established the National List of Allowed and Prohibited Substances and also detailed allowed and prohibited substances, methods, and ingredients in organic production and handling. Specifically, §205.605(a) lists nonagricultural, nonsynthetic substances allowed as ingredients in or on processed products labeled as "Organic" or "MWO", and §205.105 indicates that such products must be produced and handled without the use of excluded methods, ionizing radiation, and sewage sludge (the Big 3).

The terms "nonsynthetic", "excluded methods", and "sewage sludge" are defined at §205.2 Terms Defined as follows:

> 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.
>
> Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.
>
> 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.

Though "ionizing radiation" is not included at §205.2 Terms defined, §205.105(f) refers to ionizing radiation, "as described in Food and Drug Administration regulation, 21 CFR 179.26", which details the FDA permitted uses of ionizing radiation for the treatment of food.

Explicit verification that each §205.605(a) input used by a certified organic operation is nonsynthetic and complies with the Big 3 prohibitions is ideal. Certifiers have accordingly developed comprehensive forms that aim to collect the information needed to assess compliance. Ingredient manufacturers and suppliers often opt to complete these forms. However, manufacturers and suppliers typically market ingredients to entities certified by various certifiers, and understandably may submit their own attestations detailing ingredient compliance rather than completing the various and nuanced forms from multiple certifiers.

These attestations sometimes do not include all the information needed to verify a nonsynthetic status or production and handling without the Big 3.

Is it necessary to engage in the administrative burden of requesting, waiting for, and reviewing the complete manufacturing process for microorganisms to verify their nonsynthetic status, or is it reasonable and prudent to simply assume a nonsynthetic status for microorganisms? Similarly, should a sodium bicarbonate ingredient be prohibited if documentation is not available to affirm it was produced and handled without the use of excluded methods, or is this verification unnecessary considering the source and manufacture of sodium bicarbonate and that excluded methods only pertain to organisms?

This best practice takes the position that depending on the substance in question, certain compliance criteria may not require verification based on the inherent nature of the substance or based on commercially relevant production methods. Additionally, it establishes a risk-based approach for certifiers to implement in assessing §205.605(a) inputs with regards to classification verification and verification of compliance with the Big 3.

**Risk Assessment**

This best practice assigns each §205.605(a) substance either a low, high, or undetermined risk status with regards to the following criteria:

- Classification Verification
- Excluded Methods Verification
- Ionizing Radiation Verification
- Sewage Sludge Verification

All assigned risk levels are presented in the attached ACA Risk-based Assessment of 205.605(a) Substances Table.

Each risk assignment was based on the ACA Materials Working Group's review of the literature, including journal articles and similar industry resources, Technical Evaluation Reports, Technical Advisory Panel Reports, NOSB recommendations, NOSB meeting minutes, and National List Petitions, and based on the collective experience of the certifiers participating in the ACA Materials Working Group.

A low or high-risk status was only assigned if at least 80% of the working group agreed with a given status. When an 80% consensus could not be achieved, the status was assigned as undetermined.

A low-risk designation indicates no information is required for a given criteria in order to approve the substance. A high-risk designation indicates that information is required to assess the substance against the given criteria. An undetermined risk status indicates certifier discretion should be exercised in determining whether or not applicable information is required to assess the substance. For example, enzymes have been assessed as low risk with regards to classification verification and high risk with regards to excluded methods verification. This

means it is not necessary to verify the nonsynthetic classification of enzymes, but it must be verified that enzymes are produced and handled without the use of excluded methods.

Note that restriction verification is required in all instances for 205.605(a) inputs. As such, an input was not qualified as high risk with regards to classification verification if its restriction already sufficiently addresses classification verification. For example, while lactic acid was determined to be high risk for classification verification with the requirement to verify it is a product of fermentation, citric acid was assessed as low risk for classification verification since its National List restriction already stipulates that it must be produced by microbial fermentation of carbohydrate substances.

Additionally, if any compliance documentation calls into question the classification or Big 3 status of a material, even if considered low risk and verification is noted as not required within this resource, additional review may be warranted.

**Classification Verification Considerations**

NOP 3012 Interim Instruction: Material Review indicates that certifiers must:

> Make synthetic vs. nonsynthetic or agricultural vs. nonagricultural determinations in compliance with the USDA organic regulations and NOP guidance regarding the classification of materials…

It also notes:

> Certifiers have several options available for determining whether materials may be used in organic production or handling under the USDA organic regulations:
>
> 1. Certifiers 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 process, source materials, and processing aids used to produce the ingredients or final product (…).

NOP 5033 Guidance: Classification of Materials states the following:

> For the majority of materials, classification as synthetic or nonsynthetic, or as agricultural or nonagricultural, is straightforward; however, other materials are more complicated to classify.

The classification of some substances is straightforward and some §205.605(a) substances can be considered nonsynthetic based simply upon the nature of the substance. This is not always the case. In those instances when a classification determination is required, the determination must be made based on the USDA organic regulations and based on NOP guidance regarding the classification of materials. However, it appears that some 205.605(a) substances are improperly classified since most were added to the National List prior to the release of NOP

5033 Guidance: Classification of Materials and NOP 5033-1 Guidance: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic. For example, refer to the ACA's April 3, 2020 comments to the National Organic Standards Board (NOSB) regarding the potential misclassification of L-malic acid and sodium bicarbonate as nonsynthetic. While there is not always consensus on proper classification, it is clear that some §205.605(a) inputs are improperly classified and warrant further investigation by the NOSB to ensure proper classification and placement on the National List. The NOSB has in some cases begun to address questionable classifications, but has not consistently taken up the work topic of evaluating proper classification of existing §205.605(a) substances in accordance with aforementioned NOP guidance documents. This has led to inconsistencies amongst certifiers and lack of clarity with regards to whether classification verification is essential for some of the substances.

The methods certifiers and MROs implement to verify the classification for the identified high-risk substances vary. For example, one group may verify the nonsynthetic status of lactic acid by verifying it is a product of fermentation and accepting attestations to this effect, whereas another group may require the full manufacturing process to assess classification. When there was general consensus regarding the depth of verification required, this supplemental information is included in the attached ACA Risk-based Assessment of 205.605(a) Substances Table. It is also noted in the resource if there was a lack of consensus.

**Excluded Methods Verification Considerations**

Note that if the level for consensus needed to designate a substance as low or high risk was reduced to 70%, all of the substances assigned the risk of "undetermined" with regards to excluded methods verification would have been assessed as low risk. The divergence amongst certifiers for this category was largely based on the differing perspectives of either needing to conduct excluded methods verification for all §205.605(a) inputs regardless of perceived risk, or not requiring excluded methods verification for substances unlikely to be derived from or using organisms.

**Ionizing Radiation Verification Considerations**

Whether a certifier considers a §205.605(a) substance to be low or high risk with regards to ionizing radiation is largely dictated by how its prohibition at §205.105(f) is interpreted. Some certifiers interpret the prohibition to cover all the forms of ionizing radiation (i.e. the "energy sources") detailed at 21 CFR 179.26(a) as applied to all §205.605(a) substances. However, since 21 CFR 179.26(b) stipulates specific applications for the detailed forms of ionizing radiation, some certifiers only verify production and handling without ionizing radiation for the §205.605(a) substances covered by the 21 CFR 179.26(b) permitted applications. This latter interpretation would result in the requirement to verify production and handling without ionizing radiation for just enzymes since no other §205.605(a) substance covered by this best practice is permitted to be treated with ionizing radiation via 21 CFR 179.26(b). As such, animal enzymes and enzymes are the only two §205.605(a) substances to be assessed as high risk with

regards to ionizing radiation verification. All other substances were assigned the risk of "undetermined".

**Sewage Sludge Verification Considerations**

All 205.605(a) substances covered by this best practice are considered to be low risk with regards to the use of sewage sludge.

**Ongoing evaluation**

The ACA Materials Working Group is committed to reassessing all substances covered by this best practice, especially with regards to low-risk designations, on a continual basis. This will be accomplished by:

- Members informing the group when contradictory information is obtained in the course of input reviews.
- Evaluating new/updated Technical Evaluation Reports when published.
- Participating in NOSB meetings both by listening to NOSB deliberations and by actively commenting when substances up for sunset review may warrant classification considerations.

**References and Relevant Regulations**

7 CFR 205.2 Terms defined

7 CFR 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling

7 CFR 205.605(a) 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 Organic Foods Production Act of 1990

NOP 3012 Interim Instruction: Material Review

NOP 5033 Guidance: Classification of Materials

NOP 5033-1 Guidance: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic

NOP Petitioned Substances

NOSB Meeting Minutes

ACA Best Practice for Review of Non-Organic Flavors

ACA Risk-based Assessment of 205.605(a) Substances Table

Notes:

1. Annotation verification is required in all instances for 205.605(a) inputs.
2. If any compliance documentation received calls into question the classification or Big 3 status of a material, even if considered low risk and verification is noted as not required within this resource, additional review may be warranted.

Key:

Low risk = no information is required for a given criteria in order to approve the substance

High-risk = information is required to assess the substance against the given criteria

Undetermined risk = certifier discretion should be exercised in determining whether or not applicable information is required to assess the substance

| 205.605(a) Substance | **Classification** Verification Risk | Classification Verification Notes | Excluded Methods Verification Risk | Ionizing Radiation Verification Risk | Sewage Sludge Verification Risk |
|---|---|---|---|---|---|
| Acids - lactic | High | Verify product of fermentation. | High | Undetermined | Low |
| Acids - citric | Low | | High | Undetermined | Low |
| Agar-agar | Low | | Undetermined | Undetermined | Low |
| Animal enzymes | Low | | High | High | Low |
| Attapulgite | Undetermined | | Undetermined | Undetermined | Low |
| Bentonite | High | Verify not acid-leached, acid-activated, or acid-treated. | Undetermined | Undetermined | Low |

| | | | | | |
|---|---|---|---|---|---|
| Calcium carbonate | High | A consensus was not achieved on how to verify nonsynthetic classifciation for calcium carbonate based on differing perspectives on the classification of precipitated calcium carbonate. | Undetermined | Undetermined | Low |
| **205.605(a) Substance** | **Classification Verification Risk** | **Classification Verification Notes** | **Excluded Methods Verification Risk** | **Ionizing Radiation Verification Risk** | **Sewage Sludge Verification Risk** |
| Calcium chloride | High | Verify isolated from from natural brines and not produced via the solvay process. | Undetermined | Undetermined | Low |
| Calcium sulfate | Low | | Undetermined | Undetermined | Low |
| Carrageenan | Low | | High | Undetermined | Low |
| Dairy cultures | Low | | High | Undetermined | Low |
| Diatomaceous earth | Low | | Undetermined | Undetermined | Low |
| Enzymes | Low | | High | High | Low |
| Flavors | * | * | * | * | * |
| Gellan gum | Undetermined | | High | Undetermined | Low |
| Glucono delta-lactone | High | In addition to the annotation, verify it is produced via either microbial fermentation or enzymatic oxidation of | High | Undetermined | Low |

| | | | | | |
|---|---|---|---|---|---|
| | | carbohydrate substances. | | | |
| Kaolin | High | Verify not acid-leached, acid-activated, or acid-treated. | Undetermined | Undetermined | Low |
| L-Malic acid (CAS # 97-67-6) | Low | | High | Undetermined | Low |
| **205.605(a) Substance** | **Classification Verification Risk** | **Classification Verification Notes** | **Excluded Methods Verification Risk** | **Ionizing Radiation Verification Risk** | **Sewage Sludge Verification Risk** |
| Magnesium chloride | High | The 2016 Technical Evaluation Report details permitted non-synthetic production practices under the "Magnesium Chloride from Natural Sources" section of Evalulation Question 1. It also details prohibited synthetic production practices under the "Magnesium Chloride Formed by Chemical Synthesis" section of Evaluation Question 1. This information should be verified against complete manufacturing information that includes all inputs. | Undetermined | Undetermined | Low |

| | | | | | |
|---|---|---|---|---|---|
| Magnesium sulfate | High | Verify mined form such as kieserite (magnesium sulfate monohydrate) or epsomite (magnsium sulfate heptahydrate) whithout further synthetic processing. Some mined sources of magnesium are synthetically processed to produce magnesium sulfate, which is not permitted. The synthetic, prohibited form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (consisting of MgCO3) or magnesium hydroxide (obtained from seawater) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. This information should be verified against complete manufacturing information that includes all inputs. | Undetermined | Undetermined | Low |
| **205.605(a) Substance** | **Classification Verification Risk** | **Classification Verification Notes** | **Excluded Methods Verification Risk** | **Ionizing Radiation Verification Risk** | **Sewage Sludge Verification Risk** |
| Microorganisms | Low | | High | Undetermined | Low |
| Nitrogen | Low | | Undetermined | Undetermined | Low |
| Oxygen | Low | | Undetermined | Undetermined | Low |

| | | | | | |
|---|---|---|---|---|---|
| Perlite | Low | | Undetermined | Undetermined | Low |
| Potassium chloride | High | Verify extracted from a non-synthetic source material (mined or from brine). | Undetermined | Undetermined | Low |
| Potassium iodide | High | If not used as a nutrient (permited via 205.605(b)), review full manufacturing process in accordance with formal classification of materials guidance. | Undetermined | Undetermined | Low |
| Pullulan | Low | | High | Undetermined | Low |
| Sodium bicarbonate | High | Verify produced via the Trona Process and not the Solvay Process. | Undetermined | Undetermined | Low |
| Sodium carbonate | High | Verify produced via the Trona Process and not the Solvay Process. | Undetermined | Undetermined | Low |
| Tartaric acid | Undetermined | | High | Undetermined | Low |
| Waxes—nonsynthetic (Wood resin). | Undetermined | | High | Undetermined | Low |
| Yeast | Low | | High | Undetermined | Low |

# Multiple Scopes/Other

## 1. Verification of excluded methods

*References:* §205.2, *§205.105, §205.600, Excluded Methods Terminology Discussion Document February 2013, Discussion Document on Excluded Methods Terminology August 2014, Second Discussion Document on Excluded Methods Terminology August 2014, Excluded Methods Terminology – Third Discussion Document February 2016, Excluded Methods Terminology – Third Discussion Document August 2016, Excluded Methods Terminology August 2016, National Organic Program Excluded Methods Guidance Document August 2017, Excluded Method Determinations October 2018, Excluded Method Determinations April 2019, Excluded Methods Determinations October 2019*

§205.105 states:

> "To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of: ...
>
> (e) Excluded methods…"

Furthermore, §205.2 defines excluded methods as "A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

The National Organic Standards Board (NOSB) has worked extensively on the topic of excluded methods, developing several discussion documents and proposals to clarify excluded method definitions and criteria in response to the increasing diversity in the types of genetic manipulations performed on seed, livestock, and other biologically-based resources used in agriculture.

Affidavits are commonly used by certifiers to verify non-GMO status of an input. However, certifiers vary in the exact language of the affidavit and the party whom is required to sign the affidavit. Even with this variation, some 'best practices' have been identified (although some exceptions may apply for some type of materials for some uses by some certifiers).

Best Practice: In cases when GMO status of a material must be verified for compliance, affidavits are an acceptable form of documentation. Language on affidavits should encompass the entire manufacturing process of the material including the source organism, such that products produced from fermentation by a GMO microorganism are evaluated and prohibited, even if the final product does not contain genetically modified material.

Affidavits that only verify whether the product contains GMO are not sufficient (such as some affidavits from the EU and/or from the Non-GMO Project).

Affidavits should ideally be signed by the original manufacturer of the material, rather than the final handler, distributor, or re-packager.

Certifiers and MROs should utilize both the excluded methods definition at §205.2 as well as the list of excluded methods developed by the National Organic Standards Board to evaluate potential excluded method technology. Excluded methods, as identified by the NOSB, can be incorporated into affidavits for manufacturers.

Associated documents: Excluded Methods Affidavit

## 2. Sanitizer and Disinfectant Review

References: 7 CFR 205.601-605, NOP Guidance 5023, NOP Policy Memo 13-1, Formal NOSB Recommendation on Ancillary Substances

Purpose:

Sanitation measures are part of organic practice standards for the prevention of crop pests, weeds, and diseases, and in organic livestock healthcare management, as provided for at 7 CFR §205.206(a)(2) and §205.238(a)(3), respectively. Sanitizers and disinfectants are also used in post-harvest handling and in the further processing and handling of organic commodities. Many of these sanitizers and disinfectants are EPA registered pesticides with identified active ingredients and often include “other ingredients.” Other ingredients may include inactive ingredients that provide a necessary technical effect upon the active ingredient and are not functional in organic production.

7 CFR 205.601(a), §205.603(a), and §205.605(b) describe the synthetic sanitizer and disinfectant materials allowed for use in USDA organic crop and livestock production, as well as in handling and processing. In addition to National List materials, nonsynthetic and organic substances may come into direct or indirect contact with certified organic products as allowed. Some certification agencies review all sanitizing and disinfection inputs, even those that do not contact organic products, while others only review the materials that may contact the organic product. Materials that make contact with organic products are sometimes considered “last step inputs'' in the sanitizing and disinfecting process. The present document does not address

the review of materials that do not contact organic products, as these are considered "contaminants'' and fall under the purview of the certifier to verify contact prevention as needed. For sanitizer and disinfection materials used in direct contact with organic product or food contact surfaces without a removal event, there is a lack of a clear review standard. The NOP has not endorsed any one specific material review approach, and there is a wide variety of accepted practices among accredited certifiers.

The ACA Materials Working Group sought to develop consistent guidelines for the review of sanitizers and disinfectants in the various scopes of organic production and handling, but was unable to reach a consensus and come to one or two best practices for the overall review of sanitizers and disinfectants. However, the group did agree on the review of active ingredients in sanitizers and disinfectants, as identified on a label or other readily available documentation, as a minimum for reviewing these materials. A number of organizations represented in the working group use additional review steps to evaluate the compliance of other ingredients in sanitizer and disinfectant products. Both the agreed upon active ingredient review criteria and the additional review steps where the working group diverged are summarized in the table below.

| Active ingredient* review: |
| --- |
| - Review active ingredients for compliance based on scope, observing any use restrictions in a National List annotation:<br>Crops: active must be nonsynthetic or on §205.601(a) or §205.605 when used in post-harvest handling;<br>Livestock: active must be nonsynthetic or on §205.603(a) or §205.605 when used in post-harvest handling;<br>Processing and handling: active must be on §205.605.<br>*"Active ingredients" are ingredients that the manufacturer has identified as the materials that act to repel, destroy, prevent, or mitigate pests or microorganisms in the product. |

<table>
<tr><td colspan="2">Additional review steps may include:<br>- No additional review steps.<br>- Verify EPA, FDA or FSIS registration and use in accordance with approved label instructions.<br>- Confirmation that any non-active substances are included in the Technical Report or are commonly used in the manufacture of a specific active ingredient.<br>- Other substances that meet the definition of ancillary substance are reviewed by an organization according to their own policy on ancillary substances (handling production only).</td></tr>
<tr><td>Crops and Livestock:<br>● Confirmation that other ingredients are either nonsynthetic or included on the 2004 EPA List 4A or 4B‡.</td><td>Handling/Processing:<br>● Confirmation that other ingredients (excluding ancillaries or equivalent determination) are included on the National List at §205.605, or 2004 EPA List 4A or 4B‡ if used in post-harvest handling.</td></tr>
</table>

‡ 2004 EPA Lists 4A and 4B are considered obsolete by the EPA and are no longer maintained. The NOSB intends to amend the allowance for inert ingredients in pesticide products in the future. See "Resolution on EPA List 4 Inerts" for more information: https://www.ams.usda.gov/sites/default/files/media/NOSBResolutionList4InertsRec_webpost.pdf

## 3. Compliant Use of Materials in Organic Production and Handling

References: §205.201(a)(2), 205.400(f)(2), NOP 2615

§205.201(a)(2) requires that "the producer or handler of a production or handling operation ... must develop an organic production or handling system plan," and that "An organic production or handling system plan must include:

> … (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;"

In addition, §205.400(f)(2) requires that "A person seeking to receive or maintain organic certification under the regulations in this part must

(f) Immediately notify the certifying agent concerning any:

… (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part."

Certifiers vary in how they respond to an operator's use of a material prior to notifying the certification agency. Some certifiers issue a notice of noncompliance, citing §205.201(a)(2) and 205.400(f)(2) for the use of any material prior to notifying the certifier. Other certifiers only issue a notice of noncompliance if the material used by the operator is prohibited for that use. If the material was used prior to notifying the certifier, but the material was used compliantly, the certifier does not issue a notice of noncompliance.

Best practice: It is strongly recommended that certifiers encourage operators to contact them prior to the use of any new input material. Determining compliance of inputs is a complex process, and encouraging operator-determined compliance is not recommended. If a client uses a material prior to notifying their certifier, they are at risk of using a prohibited material, which could jeopardize their organic certification status.

Operators using new inputs must at minimum notify the certifier of updates to the materials being used annually per continuation of certification requirements detailed at §205.406(a)(1).

That said, the producer or handler of a production or handling operation does not need to notify the certifying agent prior to the use of a new input material that does not affect its compliance with the Act and the regulations.

Certifiers may consider input materials to not affect the compliance of an operation if:

- The material is approved by a material review organization, such as OMRI, WSDA, or CDFA; approved by the EPA; or approved by the client's own certifier for use in organic production or handling, and it is used by the operator for the approved use, according to any applicable restrictions. The material's use must not affect the formulation or label of a certified product.
- The material is not approved by a material review organization, the EPA, or by the client's own certifier, but the product is found to be permitted for the operator's use and the operator used it in accordance with any applicable restriction. The material's use must not affect the formulation or label of a certified product. If this situation

occurs, it is again recommended that the certifier reiterate to the operation that it is best practice for operators to contact them prior to the use of any new input material.

If an operator uses a material prior to notifying the certifier, but the material does not affect the compliance of the operation as determined above, the certifier does not need to issue a notice of noncompliance to §205.201(a)(2) or 205.400(f)(2).

Operators must always notify certifiers prior to the use of a material that affects the formulation or label of a certified product.

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# Attachments

The following documents are included as attachments to this best practice: Off-Farm Manure Verification and Excluded Methods Affidavit.

# OFF-FARM MANURE VERIFICATION

Use this form to provide information on bulk off-farm manure materials. Have the supplier of your manure complete this form. *(Note: This form does not apply to packaged and labeled products.)*

I have supplied _____ with manure.
(client)

**MANURE** Type of animals: _____

**Check manure type**

- ❑ liquid manure
- ❑ solid
- ❑ semi-solid
- ❑ dehydrated
- ❑ pelleted
- ❑ other: _____

Does the manure contain ingredients added to the manure after it is removed from the animal area (pit additives, fly sprays, odor control digesters, etc.)? No further review of livestock bedding materials is needed.

- ❑ No
- ❑ Yes _____ (list inputs added)

**Manager Name (print)**_____
**Company/Farm Name** _____
**Address** _____ **City** _____ **State**___ **Zip** _____
**Phone** _____ **Email** _____
**Signature of Manager** _____ **Date** _____

# EXCLUDED METHODS

7 CFR section 205.105 requires that "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be produced and handled without the use of excluded methods, ionizing radiation, and sewage sludge.

§205.2 defines excluded methods as "a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

PROHIBITED EXCLUDED METHODS INCLUDE, BUT ARE NOT LIMITED TO:

| ***Method and synonyms*** | ***Types*** |
|---|---|
| Targeted genetic modification (TagMo)<br>syn. Synthetic gene technologies<br>syn. Genome engineering<br>syn. Gene editing<br>syn. Gene targeting | Sequence-specific nucleases (SSNs)<br>Meganucleases Zinc finger nuclease (ZFN)<br>Mutagenesis via Oligonucleotides<br>CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes<br>TALENs (Transcription activator-like effector nucleases)<br>Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System |
| Gene Silencing | RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides |
| Accelerated plant breeding techniques | Reverse Breeding<br>Genome Elimination<br>FasTrack<br>Fast flowering |
| Synthetic biology | Creating new DNA sequences<br>Synthetic chromosomes<br>Engineered biological functions and systems |
| Cloned animals and offspring | Somatic nuclear transfer |
| Plastid transformation | |
| Cisgenesis | The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation. |
| Intragenesis | The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant. |
| Agro-infiltration | |

| | |
|---|---|
| Transposons – Developed via use of in vitro nucleic acid techniques | |
| Induced mutagenesis | Developed through in vitro nucleic acid techniques. Does not include mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities. |

# AFFIDAVIT

*This form must be completed by the manufacturer of the input.*

MANUFACTURER: _____

INPUT: _____

Description of processing (how is the product made):

_____

❑ True ❑ False The above product has been produced and handled without the use of excluded methods, genetic engineering, or genetically manipulated organisms or ingredients, as described above. The product listed above is not derived from products or ingredients that contain genetically modified organisms (GMO) and has not been produced with GMO processing aids. *Microbial substrate, feedstocks, or culture media consumed or removed are not required to be produced without excluded methods.*

❑ True ❑ False The above product has been produced and handled without the use of sewage sludge.

❑ True ❑ False The above product has been produced and handled without the use of ionizing radiation, as described in the Food and Drug Administration regulation, 21 CFR 179.26.

| Signature | Date |
|---|---|
| | |

| | | |
|---|---|---|
| Printed Name | Title | |
| Company Name | | |
| Address | | |
| City | State | Zip |
| Phone | Email | |