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Best Practices for Common Material Review Issues

Version 3

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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.

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.



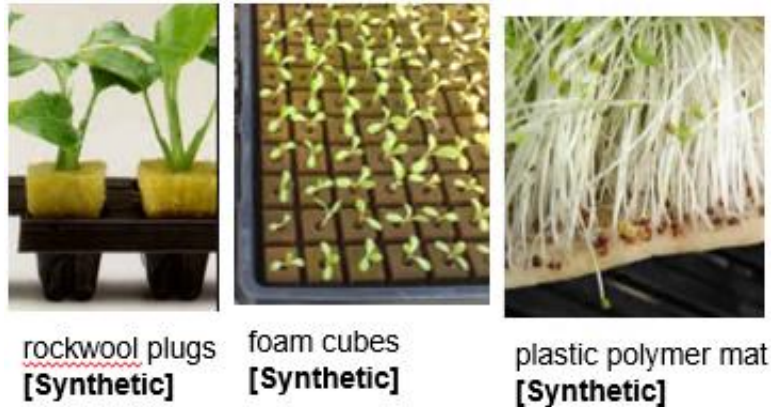
potting mix
(soil, compost,
vermiculite)
[Nonsynthetic]



coconut coir,
peat moss
[Nonsynthetic]



Blended plant fiber
mat
[Nonsynthetic]



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. An analysis of the full manufacturing process of the mineral is not necessary in every case.

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-packer the product. This approach is based on an understanding that distributors/re-packer 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: The minerals listed below do not require additional documentation or further review to confirm non-synthetic status. 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.

- 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.

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 131°F (55°C) 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 1×10^3 (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 one of the three 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 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.

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.

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 inert; 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)

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>

- *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](#)

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

References: §205.237, §205.603(c), §205.603(d), §205.604, 21 CFR §§570-571, § 573, § 582, § 584, and § 589, Association of American Feed Control Officials (AAFCO) Official Publication

Synthetic feed additives and supplements permitted for use in organic livestock production are listed at §205.603(c) and (d). These include (1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium ; (2) Trace minerals, used for enrichment or fortification when FDA approved; and (3) Vitamins, used for enrichment or fortification when FDA approved.

FDA approved trace minerals and vitamins are published in 21 CFR §§570-571, § 573, § 582, § 584, and § 589. The FDA also recognizes the list of additives and feedstuffs published in the Association of American Feed Control Officials (AAFCO) Official Publication, which is updated and published annually.

The allowance of FDA approved vitamins and minerals under §205.603(c) and (d) applies to synthetic vitamins and minerals. Non-synthetic vitamins and minerals are permitted for use as livestock feed additives and supplements, provided that they are not prohibited for this use at §205.604. Examples include non-synthetic humates and boron.

Best Practice: The listing for approved feed additives and supplements at §205.603(c) and (d) applies to synthetic vitamins and minerals. Non-synthetic vitamins and minerals used as ingredients in livestock feed additives and supplements do not need to be verified to be FDA approved, but they must not be prohibited at §205.604.

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

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 (word doc for download): [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) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via Oligonucleotides CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes TALENs (Transcription activator-like effector nucleases) 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 Genome Elimination FasTrack Fast flowering
Synthetic biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems
Cloned animals and offspring	Somatic nuclear transfer
Plastic 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

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	