# **Rules and Regulations**

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#### DEPARTMENT OF AGRICULTURE

#### Agricultural Marketing Service

#### 7 CFR Part 205

[Doc. No. AMS-NOP-22-0063]

RIN 0581-AE13

#### National Organic Program; Market Development for Mushrooms and Pet Food

**AGENCY:** Agricultural Marketing Service, USDA.

#### ACTION: Final rule.

**SUMMARY:** The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) is amending the USDA organic regulations to clarify standards for organic mushrooms and organic pet food. The topics addressed by the rule include mushroom substrate composition and sourcing of mushroom spawn in organic mushroom production, composting requirements for organic mushroom production, composition and labeling requirements for organic pet food, and the use of certain synthetic substances, including taurine, in organic pet food.

#### DATES:

*Effective date:* This rule is effective February 21, 2025.

*Compliance date:* Organic operations must comply with the requirements of this rule by February 22, 2027.

For additional discussion, see section I.C. of this document.

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### I. General Information

### A. Does this final rule apply to me?

You may be affected by this final rule if you are engaged in organic mushroom production, pet food handling, or related activities. Potentially affected entities may include, but are not limited to, the following:

• Organic mushroom producers (including organic spawn producers);

• Organic pet food manufacturers;

• Individuals or business entities that are considering organic certification for pet food or mushroom production (or related activities, such as spawn production);

• USDA-accredited certifying agents (or "certifiers"), inspectors, and certification review personnel.

This list is not exhaustive but identifies key entities that this rule may affect. Other types of entities may also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the regulatory text and discussion below. If you have questions regarding the applicability of this rule to a particular entity, contact the person listed under FOR FURTHER INFORMATION CONTACT.

#### B. Summary of Provisions

Through the amendments in this final rule, AMS is establishing standards for organic mushroom production and pet food handling. The standards are discussed in detail in this document. In summary, the rule: • Establishes definitions for mushroom, mushroom mycelium, mushroom spawn, mushroom spawn media, and mushroom substrate for the purposes of the USDA organic regulations.

• Clarifies that mushrooms are a type of crop and updates the definition of *crops* to include mushrooms.

• Creates a new section of the organic regulations titled "Mushroom Production Practice Standard," to describe standards related to the production of mushrooms, mushroom spawn, and products of mushroom production.

• Specifies allowed substances in organic mushroom spawn media and organic mushroom substrate.

• Requires that uncomposted plant materials used in mushroom substrate be organic when commercially available; requires that operations describe in their organic system plan the procedures and criteria used to search for organic materials and the recordkeeping system used to track purchases of nonorganic plant materials.

• Allows nonorganic wood materials in mushroom substrate and spawn media.

• Requires that operations use organic mushroom spawn when commercially available.

• Describes minimum requirements for compost used in mushroom substrate. (The requirements for compost used in other types of crop production (*i.e.*, plants) are unchanged.)

• Establishes definitions for *pet* and *pet food* for the purposes of the USDA organic regulations and clarifies that pet food is distinct from livestock feed under these regulations.

• Clarifies the requirements for composition and labeling of organic pet food using the existing regulatory framework for processed organic products.

• Allows use of synthetic taurine (an amino acid) in organic pet food, as well as other vitamins and minerals that are approved by the Food and Drug Administration.

# C. Implementation and Compliance Dates

As described in the **DATES** section of this rule, this rule becomes effective on February 21, 2025. However, AMS is allowing an additional two (2) years for organic operations to comply with the requirements of the final rule. Organic operations must comply with the final rule by February 22, 2027.

The compliance date establishes the date by which organic operations must comply with the requirements. However, organic operations may choose to comply with the final rule prior to the compliance date. For example, pet food operations may use taurine in organic pet food starting on the effective date of the final rule.

For a discussion of the public comments related to the rule's implementation and compliance dates, see "Responses to Public Comments on Implementation Timeline" sections below in III.C. for mushrooms and IV.C. for pet food.

#### **II. Background**

#### A. Purpose and Need for the Rule

This final rule amends the USDA organic regulations to establish specific standards for organic mushroom production and organic pet food handling. The purpose of these amendments is to resolve uncertainty and inconsistency in how the organic regulations apply to these two products. Inconsistent certification and enforcement practices for organic mushrooms and pet food fail to meet one of the purposes of the Organic Foods Production Act (OFPA): to assure consumers that organically produced products meet a consistent standard (7 U.S.C. 6501(2)). Based on market penetration data and feedback from stakeholders, AMS believes that creating more consistency in the market and ensuring regulatory certainty will create conditions for growth in these two markets and other latent markets that support them, such as the markets for mushroom substrate and organic slaughter by-products.

Certifiers have been using the organic crop production standards to certify organic mushrooms; however, AMS believes new standards are necessary to adequately address unique aspects of mushroom production that differ significantly from plant production. Certifiers' attempts to interpret the existing crop standards for mushroom production are currently inconsistent, which may lead to producers inconsistently applying the standards to substrate, spawn, and compost for mushroom production.

Similarly, the current organic regulations do not specifically address pet food. Producers and certifiers have

been applying a combination of the handling standards for processed products and the organic livestock feed standards to certify organic pet food, but their practices were not uniform. Neither the handling standards nor the livestock standards are sufficient to address the range of ingredients and nutrients that are necessary for pets. For example, the livestock feed standards include allowances for many of the nutrients that are necessary for pets but prohibit common pet food ingredients, such as slaughter by-products (e.g., animal and poultry by-product meal, animal liver).

This rule also addresses feedback from the organic industry, which has asked USDA to implement outstanding NOSB recommendations, including standards for these two product categories. Stakeholders encouraged AMS to prioritize rulemaking for additional practice standards, including standards for organic pet food and mushrooms, at the March 2022 virtual listening session hosted by AMS. The changes in this rule are based on NOSB recommendations for mushroom production and pet food handling in response to the organic industry's interest in further developing the organic standards for these markets.

Market penetration data supports the idea that the organic mushroom and organic pet food markets have a reasonable expectation of growth if uncertainty and inconsistency are removed as barriers. Both markets currently lag behind their mostcomparable organic sectors. In 2023, sales of organic produce accounted for a 15.2 percent share of all produce sales in the United States,<sup>1</sup> but mushrooms sold as organic only accounted for 9.6 percent of all mushroom sales during the 2023–2024 marketing year.<sup>2</sup> Considering that the consumer experience of purchasing mushrooms is typically similar to purchasing fruits and vegetables (they are packaged similarly and found in the same section of the grocery store), it is reasonable to conclude that some external barrier is inhibiting the organic mushroom market. Similarly, organic pet food accounts for only 0.32 percent of all pet food sales. The closest organic category of comparison for organic pet food is

organic non-food products, which includes other products humans do not eat (*e.g.*, linen/clothing, supplements, and personal care products). All other non-food product types tracked by the Organic Trade Association have at least twice the market share of organic pet food, with the organic products accounting for between 0.76 percent to 3.3 percent of their total market sales.<sup>3</sup>

In conclusion, AMS believes that clear and consistent standards for organic mushrooms and pet food may create the conditions necessary for organic markets to develop. Regulatory certainty encourages investment in nascent markets; investment increases production capacity; and production enables market growth. Clear standards will promote growth in the development of these markets by increasing consistency in certification and enforcement and removing uncertainty as a regulatory barrier to production and certification. Additionally, growth in these markets is likely to ensure consistent demand for organic inputs in underdeveloped markets like organic meat and organic slaughter by-products. Ensuring consistent standards across the organic industry also protects the integrity of the organic seal by building consumer trust in the label.

AMS provides additional discussion of the need for organic mushroom and pet food standards in the respective sections below (see "III.B. Need for Organic Mushroom Standards" and "IV.B. Need for Organic Pet Food Standards").

#### B. National Organic Standards Board (NOSB) Recommendations on Mushrooms and Pet Food

The NOSB is a Federal advisory committee established by OFPA (7 U.S.C. 6518) to provide recommendations to USDA on the development of organic standards and regulations. NOSB recommendations are developed through a rigorous process involving technical information, stakeholder input through public comment, open meetings, and a decisive two-thirds majority vote of the Board. Although the Board cannot direct or bind USDA through its recommendations, USDA uses the NOSB recommendations to inform rulemaking, including this rulemaking.

<sup>&</sup>lt;sup>1</sup>Organic Trade Association. (2024). Organic Industry Survey. p. 41.

<sup>&</sup>lt;sup>2</sup> USDA, National Agricultural Statistics Service. (August 21, 2024). "Mushrooms."

<sup>&</sup>lt;sup>3</sup> Organic Trade Association. (2024). Organic Industry Survey. p. 69.

Several times in its history, the NOSB has recognized the unique production needs of organic mushrooms and pet food and recommended standards specific to each market. The Board recommended organic mushroom standards in April 1995<sup>4</sup> and again in October 2001.<sup>5</sup> Subsequently, the NOSB made a recommendation on organic pet food standards in November 2008,6 and in April 2013, the NOSB recommended amending the National List of Allowed and Prohibited Substances (or "National List") to include taurine for use in pet food.<sup>7</sup> This final rule is AMS's first rulemaking action related to these recommendations. The NOSB recommendations are discussed below.

NOSB Recommendations on Mushroom Production

In 2001, the NOSB recommended standards to:

• Prevent contact between organically produced mushrooms or mushroom growth substrates and prohibited substances;

 Require the use of organic spawn when commercially available;

• Require organically produced agricultural materials in mushroom substrate; and

• Allow nonorganic wood materials (*e.g.*, sawdust) in mushroom substrate if trees have not been treated with prohibited substances for three years prior to harvest and have not been treated with prohibited substances after harvest.

NOSB Recommendations on Pet Food

In November 2008, the NOSB recommended that organic claims on pet food should be regulated under a combination of organic livestock feed standards and organic processed products labeling requirements.<sup>8</sup> The NOSB recommended standards to:

<sup>6</sup> NOSB. (November 19, 2008). "Formal Recommendation from NOSB to NOP: Organic Pet Food Standards." https://www.ams.usda.gov/sites/ default/files/media/NOP%20Final%20 Rec%20Pet%20Food.pdf.

<sup>7</sup>NOSB. (April 11, 2013). "Formal Recommendation from NOSB to NOP: Petition to add Required Synthetic Amino Acids for Pet Food." https://www.ams.usda.gov/sites/default/files/ media/NOP%20Livestock%20 Final%20Rec%20Pet%20Food%20Amino%20

<sup>8</sup>NOSB. (November 19, 2008). "Formal Recommendation from NOSB to NOP: Organic Pet Food Standards." https://www.ams.usda.gov/sites/ • Clarify which animals the pet food requirements would apply to by defining "pets" in the regulations;

• Label organic pet food using a framework consistent with labeling for organic human food, allowing the "organic" claim that requires a minimum of 95 percent organic ingredients and the "made with organic (specified ingredients or food group(s))" claim that requires a minimum of 70 percent organic ingredients;

• Clarify that organic slaughter byproducts can be a component of organic pet food; and

• Allow taurine for use in pet food by adding it to the National List of allowed synthetic substances.<sup>9</sup>

AMS used the NOSB recommendations to inform this rulemaking.

#### C. Community and Stakeholder Feedback

When developing this Market Development rule, AMS considered industry and stakeholder requests for specific mushroom and pet food standards, in addition to the NOSB recommendations. In March 2022, the National Organic Program (NOP) hosted a public listening session to give stakeholders the opportunity to comment on NOP's rulemaking priorities.<sup>10</sup> During the listening session, many stakeholders provided written and oral comment to ask AMS to prioritize rulemaking for products, including mushrooms and pet food, that are currently being certified without standards specific to their unique production categories. Several stakeholders specifically suggested developing mushroom standards and noted that existing crop standards, including compost requirements, were not suited for mushroom production. Similarly, some commenters discussed the importance of establishing consistent pet food standards, naming it as another product that is currently certified without specific standards.

default/files/media/NOP%20Final%20 Rec%20Pet%20Food.pdf.

<sup>9</sup> The 2008 recommendation listed taurine and other additives as "materials for possible petition to the National List for use in Pet Food." In 2013, the NOSB passed a motion to specifically recommend listing taurine "as a feed additive for use in pet food, only." See NOSB. (April 11, 2013). "Formal Recommendation from NOSB to NOP: Petition to add Required Synthetic Amino Acids for Pet Food." https://www.ams.usda.gov/sites/default/files/ media/NOP%20Livestock%20 Final%20Rec%20Pet%20

Food%20Amino%20Acid%20amended.pdf.

<sup>10</sup> USDA, NOP. (March 21, 2022). "National Organic Program priorities listening session." https://www.ams.usda.gov/event/national-organicprogram-priorities-listening-session.

AMS also engaged directly with mushroom experts, producers, and trade associations about organic mushroom production in developing the proposed rule. These discussions affirmed that, without specific standards, certifiers are not consistent in how they apply organic standards to mushroom production. Comments received during the public comment period for the proposed rule confirmed that certifiers interpret the existing standards in different ways. Through industry feedback and comments during the public comment period—submitted by a range of industry parties—AMS learned what aspects of mushroom production need specific standards to ensure consistent application across certifiers and producers. This includes requirements for compost, origin and composition of substrate materials used for growing mushrooms, and origin and composition of spawn.

Discussions with experts in the pet food industry, conducted prior to publishing the proposed rule, revealed that the key challenge with labeling pet food as organic is uncertainty around the allowance of specific ingredients. For example, under the current organic regulation, it is unclear if pet food manufacturers may use meat (i.e., the edible part of animal muscle and organs) or slaughter by-products (i.e., the parts of an animal not typically consumed by humans, such as poultry by-product meal or animal liver) in organic pet food. It is also unclear whether some necessary synthetic ingredients in pet food, such as taurine, are allowed (for additional discussion, see "§ 205.605 National List-Description of Final Policy" in section IV.C).

Additionally, stakeholders have noted that allowing organic slaughter byproducts in organic pet food will allow livestock producers and slaughter facilities to earn organic premiums for these organic slaughter by-products, which would otherwise be sold without a premium for use in nonorganic products. AMS estimates that this rule could ensure consistent demand for over 6 million pounds of organic slaughter by-products annually, which is likely to grow over time.<sup>11</sup>

Overall, this rulemaking addresses a need identified by the NOSB, industry

<sup>&</sup>lt;sup>4</sup>NOSB. (April 24–28, 1995). "Final minutes of the National Organic Standards Board full board meeting." http://www.dairyprogramhearing.com/ getfile32e532e5.pdf?

dDocName=STELPRDC5057442.

<sup>&</sup>lt;sup>5</sup>NOSB. (2001). "NOSB Final Recommendation on Mushroom Practice Standards." https:// www.ams.usda.gov/sites/default/files/media/ Recommended%20Mushroom%20Standards.pdf.

Acid%20amended.pdf.

<sup>&</sup>lt;sup>11</sup> Data from the Institute for Feed Education & Research indicates that approximately 23 percent of the ingredient weight in conventional pet food is animal by-product and meal. This estimate is then applied to the estimate for pounds of organic pet food as reported by the Organic Trade Association and current market prices. Institute for Feed Education & Research. (March 2020). "Pet food production and ingredient analysis." Organic Trade Association. (2022). Organic Industry Survey. p. 56.

stakeholders, and public comments on the proposed rule. AMS expects that the specific standards in this final rule will support the development of organic markets for organic mushrooms and pet food by reducing uncertainty among certifiers, consumers, producers, and manufacturers. A full discussion of public comments received on the proposed rule, and AMS's responses to comments, can be found in later sections.

#### D. Authority

OFPA<sup>12</sup> authorizes the USDA to promulgate regulations to establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods (7 U.S.C. 6503(a)). This rule establishes new production and certification standards for two categories of products that are currently certified but lack specific organic standards. In establishing these standards, this rule supports the three purposes of OFPA: "(1) to establish national standards governing . . . organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in . . . food that is organically produced" (7 U.S.C. 6501).

This rule clarifies how producers and certifiers should apply organic

regulations to mushroom and pet food production, which will assure consumers that the organic label on these products meets a consistent standard. The rule will also assure producers that they operate in a fair and competitive environment with clear rules that all must follow.

USDA administers organic standards through the Agricultural Marketing Service (AMS) National Organic Program (NOP). Final regulations establishing the NOP and the USDA organic regulations were published on December 21, 2000 (65 FR 80548)<sup>13</sup> and were first implemented on October 21, 2002.<sup>14</sup> Through these regulations, AMS oversees national standards for the production, handling, labeling, and sale of organically produced agricultural products.

#### **III. Organic Mushroom Standard**

A. Mushroom Background

Mushroom Biology and Production

Mushrooms are the fleshy, sporebearing, fruiting body of some species of fungus. Mushrooms are just a portion of the fungal organism, which is mostly composed of mycelium, a root-like network of fungal structures (hyphae). Commercially grown mushrooms are typically produced in a stepwise process that propagates (increases) mycelium to ultimately produce mushrooms.

In commercial mushroom production. mycelium is added to media ("spawn media''), such as grains, wood materials, or minerals, that supports its initial development. The mycelium draws nutrients and energy from this media to support its growth. The myceliumcolonized media is called "spawn." Spawn is then inoculated into larger volumes of substrate—a base composed of materials such as grains, wood materials, composted materials, and/or other agricultural materials-where the mycelium develops further, growing throughout the substrate. Depending on the mushroom species, this stage of production may occur in open beds (common for Agaricus bisporus) or in blocks (common for specialty mushrooms), though other methods are also used. Producers can trigger fruiting (*i.e.*, the formation of mushrooms) of the inoculated substrate by establishing the right environmental conditions for that variety—*e.g.*, humidity, temperature, air, and light. Depending on the variety and production system, the inoculated substrate may continue to fruit after the first harvest, and producers may harvest multiple crops of mushrooms from one batch of inoculated substrate in a given production cycle. Once the production cycle is complete and all mushrooms are harvested, a new batch of spawn inoculated into a new batch of substrate is generally needed to produce more mushrooms.

<sup>&</sup>lt;sup>12</sup> The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this final rule. The text of the codified statute is available at: https:// uscode.house.gov/view.xhtml?path=/prelim@title7/ chapter94&edition=prelim.

<sup>&</sup>lt;sup>13</sup> USDA, AMS. (December 21, 2000). "National Organic Program." Final Rule. 65 FR 80548 (codified at 7 CFR part 205). https:// www.federalregister.gov/documents/2000/12/21/00-32257/national-organic-program.

<sup>&</sup>lt;sup>14</sup> USDA, AMS. (March 20, 2001). "National Organic Program; Correction of the effective date under Congressional Review Act (CRA)." Final Rule. 66 FR 15619. https://www.federalregister.gov/ documents/2001/03/20/01-6836/national-organicprogram-correction-of-the-effective-date-undercongressional-review-act-cra.

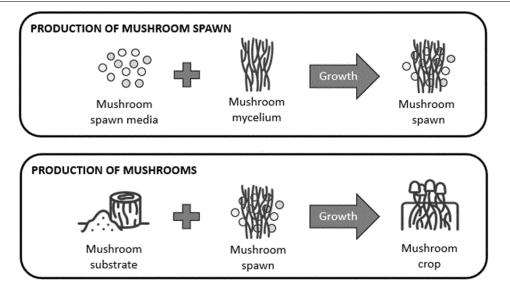


Figure 1. Production of mushroom spawn and mushrooms.

Commercial mushroom production mostly occurs in controlled indoor environments where temperature and humidity can be controlled. However, mushroom production can also occur outdoors, either in managed conditions or by harvesting wild mushrooms. This final rule establishes new production standards for managed mushroom production, whether it occurs indoors or outdoors. It revises the definition of wild crop to include mushrooms, but it does not establish separate production standards for wild mushrooms. Producers who harvest wild mushrooms should continue to follow the wild crop harvesting practice standard at §205.207.

In some cases, a producer may propagate mycelium but not harvest mushrooms. For example, some producers may only produce and sell spawn (colonized media) that other producers will use to inoculate substrate and produce mushrooms. In other cases, a producer may never aim to produce mushrooms (*i.e.*, the fruiting bodies) but will instead produce mycelium biomass that is used in processed products for direct human consumption.

This final rule specifies the production requirements for mushrooms, spawn, and mushroom products sold as organic. It does not alter the requirements related to processed fungi products. The final rule describes the existing crop production requirements that apply to mushroom producers, but, primarily, it specifies requirements for the spawn media, spawn, and substrate used in mushroom production. AMS is aware that some in the mushroom industry use the terms "media" and "substrate" interchangeably. As defined in this final rule, *mushroom spawn media* is the initial base material that is colonized by mycelium to produce spawn, and *mushroom substrate* is the mid-stage base material that is used in larger volumes, inoculated by spawn, and on which mushroom fruiting occurs.

The term "mushroom production" is used throughout the rule to collectively refer to the production of mushrooms, spawn, and other mushroom products, even if a producer is not harvesting or selling the fruiting bodies (mushrooms). For example, an organic spawn producer may not harvest mushrooms, but this final rule still applies to organic spawn producers.

#### The U.S. Mushroom Market

In the 2023–2024 growing season (July 2023 to June 2024), the U.S. mushroom crop volume was 659 million pounds with sales of \$1.09 billion.<sup>15</sup> The *Agaricus bisporus* species of mushrooms accounted for approximately 98 percent of the total sales volume and approximately 92 percent of the total value.<sup>16</sup> *Agaricus* includes white mushrooms (including common, button, and champignon varieties, among others) and brown mushrooms (including crimini/cremini, Swiss, Roman, Italian, and Portobello/ Portabello/Portabella varieties, among others). Outside of the *Agaricus* varieties, there are a multitude of cultivated "specialty" mushrooms, including shiitake, oyster, enoki, maitake, pompom, lion's mane, Reishi, and others. Specialty mushrooms include foraged (wild) mushrooms (*e.g.*, chanterelles, morels) and mushrooms that are intentionally cultivated outdoors.

Organic mushrooms lag behind the overall organic produce market in terms of market share. In 2023–2024, 9.6 percent of all mushrooms produced were sold as organic.<sup>17</sup> The Organic Trade Association reports that organic produce they tracked had a higher market share, with 15.2 percent of all produce being sold as organic in 2023.<sup>18</sup> Agaricus mushrooms accounted for approximately 83 percent of the total production volume of organic mushrooms; the remainder were specialty mushrooms.<sup>19</sup>

# B. Need for Organic Mushroom Standards

This final rule creates specific standards for organic mushroom

<sup>&</sup>lt;sup>15</sup> USDA, National Agricultural Statistics Service, Agricultural Statistics Board. (August 21, 2024). "Mushrooms." https://downloads.usda.library. cornell.edu/usda-esmis/files/r781wg03d/ 9593wm52z/9306vq05c/mush0824.pdf.

<sup>&</sup>lt;sup>16</sup> USDA, National Agricultural Statistics Service, Agricultural Statistics Board. (August 21, 2024). "Mushrooms." https://downloads.usda.library. cornell.edu/usda-esmis/files/r781wg03d/ 9593wm52z/9306vq05c/mush0824.pdf.

<sup>&</sup>lt;sup>17</sup> USDA, National Agricultural Statistics Service, Agricultural Statistics Board. (August 21, 2024). "Mushrooms." https://downloads.usda.library. cornell.edu/usda-esmis/files/r781wg03d/ 9593wm52z/9306vq05c/mush0824.pdf.

<sup>&</sup>lt;sup>18</sup>Organic Trade Association. 2024 Organic Industry Survey. p. 41. https://ota.com/marketanalysis/organic-industry-survey/organic-industrysurvey.

<sup>&</sup>lt;sup>19</sup> USDA, National Agricultural Statistics Service, Agricultural Statistics Board. (August 21, 2024). "Mushrooms." https://downloads.usda.library. cornell.edu/usda-esmis/files/r781wg03d/ 9593wm52z/9306vq05c/mush0824.pdf.

production to promote consistency, fair competition, and market growth. As of August 2024, at least 42 certifying agents certify 288 organic mushroom operations.<sup>20</sup> The lack of mushroomspecific standards means there is significant variation in how these operations are certified. Some certifying agents require mushroom substrate components to be organic while others do not. Likewise, some certifying agents require spawn to be organic while others do not.

This mushroom-specific rule is necessary because mushrooms and mushroom products involve unique production practices and inputs that are not addressed in the current organic standards. There are notable biological differences between mushrooms (which are fungi) and plants. Unlike plants, mushrooms do not photosynthesize to convert energy from light to process nutrients drawn from soil. Instead, they draw on the nutrition and energy found in the substrates on which they grow. The absence of mushroom-specific standards, their unique biological differences, and the resulting inconsistent enforcement, creates an uneven playing field for certified operations. For example, some operations may be required to source organic inputs, incurring additional expenses, whereas others are not. Unfair competition caused by different interpretations of the organic mushroom standards, as well as the possibility of future regulatory changes, may have reduced the willingness of businesses to invest in this sector.

This rule aims to address these problems by developing one clear standard for organic mushroom production, ensuring consistency as directed by OFPA. Certifying agents will have clear rules to follow, and competition among operations will be more fair. This will give businesses greater confidence in the stability of the industry and encourage them to invest in organic mushroom growing operations and organic mushroom inputs.

#### C. Overview of Final Rule Policy and Responses to Comments

This rule amends the USDA organic regulations (7 CFR part 205) to add new provisions for producing mushrooms, spawn, and other mushroom products (collectively "mushroom production") that are sold, labeled, or represented as organic. This action prescribes consistent standards for organic mushroom production, as detailed below.

TABLE 1-OVERVIEW OF REGULATORY CHANGES TO ESTABLISH ORGANIC MUSHROOM PRODUCTION STANDARDS

Section title	Type of action	Rulemaking action
205.2	Adds new terms	Adds Mushroom; Mushroom mycelium; Mushroom spawn; Mushroom spawn media; Mush- room substrate.
205.210	Revises existing terms Adds new section Revises language at (i)–(j)	Modifies <i>Compost; Crop; Wild crop.</i> Adds mushroom production standards to Subpart C. Replaces the term "plant" with the term "crop".

#### §205.2 (Terms Defined)

#### **Description of Final Policy**

The final rule amends § 205.2 by adding five new terms: *mushroom, mushroom mycelium, mushroom spawn, mushroom spawn media,* and *mushroom substrate.* The rule also revises three existing terms: *compost, crop,* and *wild crop.* The additions and revisions are discussed below.

#### 1. Compost

The final rule revises the definition of *compost* to recognize that compost for mushroom production may be different than compost for plant production. The prior definition of "compost" included production requirements (e.g., time, temperature, and carbon-to-nitrogen ratio requirements) that are more applicable to plant production; however, compost for mushroom production is typically produced under different conditions. The final rule removes from the definition those specific compost production requirements, which duplicated the practice standards for other crop production already included in the

organic regulations at § 205.203(c)(2). The resulting definition of *compost* is more general, to encompass the production of compost for either plants or mushrooms. The amended definition also notes that compost may be used in mushroom production as a component of mushroom substrate.

These revisions to the definition of the term *compost* are in no way meant to change existing requirements, policies, or guidance about the use of compost in organic plant production. Likewise, the revision is not intended to expand the definition of *compost* to include all agricultural inputs transformed by microorganisms, such as anaerobic digestate or manure. Terms for the various soil amendments and fertilizers used in organic production are well established by AMS and material review organizations and are not affected by this rule. AMS's intent is to remove the requirements embedded in the definition to account for the fact that compost for mushroom production is not necessarily produced in the same way that compost for plant production is produced.

As noted above, the specific compost production requirements that AMS removed from the definition remain in the regulations at § 205.203(c)(2)—Soil fertility and crop nutrient management practice standard. This final rule does not change those requirements. Organic producers of crops other than mushrooms that use compost must comply with the requirements at §205.203(c)(2). Separately, this final rule adds mushroom-specific requirements for compost used in mushroom substrate at § 205.210(c)(1), as described below in the section titled "Mushroom production practice standard".

AMS is aware of ongoing discussions by the NOSB that may result in a recommendation to update the definition of compost. The changes in this final rule do not prevent or supersede future recommendations on this topic from the NOSB.

#### 2. Crop and Wild Crop

This final rule revises the terms *crop* and *wild crop* to include mushrooms. AMS includes mushrooms in these definitions to clarify that operations

<sup>&</sup>lt;sup>20</sup> USDA, Organic Integrity Database. https:// organic.ams.usda.gov/Integrity/Home. Advanced search features can be accessed at https:// organic.ams.usda.gov/Integrity/Search. Certified

mushroom producers may be found by narrowing a certified product search for "mushrooms" to operations with a certification status of "certified" and limiting results to the "Crops" scope. Output

was manually cleaned to remove unrelated entries. Accessed August 27, 2024.

may use certain crop and wild crop practice standards in subpart C of 7 CFR part 205 to produce mushrooms.

#### 3. Mushroom

The final rule defines *mushroom* as the fleshy, spore-bearing fruiting body of a fungus, although the term "mushroom production" in this rule refers to production of mushrooms, spawn, and other mushroom products. The word "mushroom" is also used to qualify other terms (below) related to mushroom production.

#### 4. Mushroom Mycelium

AMS defines *mushroom mycelium* as a mass of branching, thread-like hyphae (fungal structures). Mushroom mycelium is the main, root-like, mass of a fungus, which can support formation of fruiting bodies (mushrooms).

#### 5. Mushroom Spawn

AMS defines *mushroom spawn* as mushroom spawn media that has been colonized by mycelium. Mushroom spawn can be used to inoculate mushroom substrate.

#### 6. Mushroom Spawn Media

AMS defines *mushroom spawn media* as the base material, such as grain, sawdust, other wood materials, vermiculite, or other minerals, used to make mushroom spawn. Mushroom spawn media, once colonized with mycelium, is defined separately as *mushroom spawn* by these regulations.

#### 7. Mushroom Substrate

AMS defines *mushroom substrate* as the base material (such as grain, wood materials, composted materials, and/or other agricultural materials) on which mushroom production occurs. Components of mushroom substrate can vary depending on the species to be cultivated. After mushroom spawn inoculates mushroom substrate, the mushroom substrate provides the energy and nutrients required for mycelium to flourish and produce mushrooms (although the definition of mushroom substrate does not depend on whether mushrooms are produced or not).

AMS separately defines two types of "base materials" used in mushroom production: *mushroom spawn media* and *mushroom substrate*. For the purposes of organic regulation, the essential difference between them is that mushroom spawn media is the base material used to create mushroom spawn, while mushroom substrate is the base material that is inoculated by mushroom spawn to produce mushrooms. They are defined separately because the rule includes different requirements for mushroom spawn media and mushroom substrate. The composition requirements for mushroom spawn media and mushroom substrate are described at §§ 205.210(d) and (c), respectively.

#### Changes From Proposed to Final Rule

AMS made the following revisions to the proposed definitions in this final rule to clarify intent and meaning:

• AMS made minor changes to each definition related to mushroom production to clarify intent and meaning. AMS added the word "mushroom" at the beginning of several terms so that the terms related to mushroom production appear together in § 205.2.

• AMS removed the word "edible" from the definition of *mushroom*, as edibility is not unique to the mushroom's fruiting body (*i.e.*, various parts of mushroom varieties may be edible), and edibility is not necessarily an attribute of all mushrooms. The word "edible" is not required to describe the term *mushroom*.

#### **Responses to Public Comment**

Public comments related to definitions for the mushroom standards and AMS's responses are discussed below.

#### Media/Substrate

(*Comment*) Some commenters from the mushroom industry argued that some mushroom producers use the terms "substrate" and "media" interchangeably and that defining the terms separately is unnecessary and potentially confusing.

(Response) AMS recognizes that these two terms can be used synonymously to refer to the "base materials" on which fungus grows. However, for the purposes of the organic regulations, AMS believes distinct definitions for mushroom spawn media and mushroom substrate are necessary to address requirements for distinct stages of organic mushroom production. The separate definitions allow AMS to regulate the inputs and management of mushroom spawn media and mushroom substrate differently in § 205.210(c) and § 205.210(d), respectively. To clarify the distinction in the regulations, AMS revised the definition of mushroom spawn media to more closely mirror the definition of mushroom substrate and more clearly highlight the essential difference between the terms as they are used in the final rule.

#### Compost

(*Comment*) Some comments stated that removing the composting process

from the definition of *compost* at § 205.2 would make the definition too broad and incorporate other forms of microbial decomposition other than composting. Commenters noted that products such as sauerkraut, yogurt, beer, and manure digester products such as digestate and biogas could fall under the shortened definition.

(*Response*) The revision of the term *compost* in the final rule is not intended to broaden the meaning of the term beyond the commonly accepted interpretation of the term. Outside this rule's allowance for compost in mushroom production, compost is currently allowed in organic crop production only as provided in § 205.203(c)(2), which includes specific requirements that limit the types of processes that may be used. AMS chose not to leave the specific requirements in the definition for the term because of differences in requirements, formulation, and production of compost for mushroom production at § 205.210(c) and the requirements for other uses at § 205.203.

(*Comment*) Some comments requested that AMS amend the definition of *compost* to acknowledge that compost may be made with allowed synthetic compost feedstocks on the National List (§ 205.601). Other comments suggested that the definition be revised to allow compostable plastic materials, which is a subject currently on the NOSB work agenda.<sup>21</sup> Several comments suggested that AMS adopt the definition of compost used by the American Association of Plant Food Control Officials (AAPFCO).

(Response) AMS has not revised the compost definition to reference the synthetic compost feedstocks on the National List, adopt AAPFCO's definition, or include compostable plastics (bioplastics) as compost feedstocks. This final rule amended the definition of compost only as needed to accommodate the new mushroom production practice standards. The compost feedstocks that currently appear on the National List (e.g., newspaper) continue to be allowed under the regulations. AMS recognizes that the NOSB is currently working on recommendations related to the definition of compost and the requirements for compost in organic crop production in § 205.203(c) (which are not changed by this rule). AMS has not received final recommendations from NOSB and is not making any

<sup>&</sup>lt;sup>21</sup> USDA, NOP. (October 11, 2023). "Work Agenda Request: Compost Production for Organic Agriculture." https://www.ams.usda.gov/sites/ default/files/media/NOSBMemoCompostWork Agenda23.pdf.

additional changes related to those topics in this rule at this time. This final rule does not conflict with or preclude future recommendations or rulemaking related to the current NOSB work agenda topics related to compost. If AMS seeks to revise the definition of compost or the compost requirements in the future, AMS will solicit public comments.

#### Mushroom

(*Comment*) Some comments stated that the proposed definition of *mushroom* was too restrictive by referring only to the fruiting body. Comments noted that the term could be revised to include all parts of the organism to clarify that the regulations in the rule apply to the production of any part of the organism, such as mycelium, spores, and primordia (pinheads).

(Response) AMS agrees that the standards at § 205.210 can apply to production of other parts of the organism. However, we have not revised the definition of mushroom to include other parts of the organism in the final rule. The term mushroom refers specifically to the fruiting body, and this definition is similar to how the term is understood and interpreted broadly. The term "mushroom production" in this rule, however, can refer to production of mushrooms, spawn, and other mushroom products. Also see AMS's response to comments about requirements for mycelium biomass used as a direct ingredient for human consumption below in "§ 205.210 (Mushroom production practice standards)", "Responses to Public Comment", "Mycelial Biomass Ingredients."

(*Comment*) Some comments suggested broadening the definitions and applicability of this rulemaking to include a broader spectrum of species in the Fungi Kingdom (*e.g.*, yeast). Comments suggested that AMS describe the rule as a fungi production practice standard by revising "mushroom" to "fungi". Comments from organic advocacy groups also argued that fungi should have its own scope of certification separate from crops, with fungi-specific production standards and specific sections of the National List for materials used in fungi production.

(*Response*) AMS has not expanded the standards to apply to all fungi. Fungi is an extremely large and diverse taxonomic kingdom, of which mushrooms are only a small subset. Expanding the standards to other fungal products, such as yeasts, is beyond the scope of the rule. Developing new regulations for fungi other than mushrooms would require more input and assessment of impacts, as this was not included in the proposed rule.

AMS also has not created a new scope of certification for mushrooms or fungi. "Scope" is a term typically used to describe one of the four *areas of operation* that a certifying agent may be accredited to certify. As defined in § 205.2, the four areas of operation are crop, livestock, handling, and wild crop, or any combination thereof. These four scopes align with the types of Organic Plans listed in OFPA (7 U.S.C. 6513) and inform a range of other requirements and procedures, such as the determination of inspector qualifications and the issuance of certificates from the Organic Integrity Database. Creating a new scope of certification would require a range of regulatory amendments, as well as administrative and technological changes related to certification, accreditation, inspector qualifications, and certificates of organic operation. Furthermore, as with including fungi in the applicability of this rulemaking, the impacts of establishing a new scope of certification for fungi would require more input and assessment.

AMS does not find that a new scope is necessary to accomplish the goals of this rule to provide consistent and clear standards for organic mushroom production that reflect the unique biology of mushrooms. AMS finds it appropriate to include mushrooms in the definition of crop and within the crops scope of certification. OFPA does not define or limit "crops" to include only organisms in the plant kingdom, and currently certified mushrooms are certified under the crop scope of the USDA organic regulations. Additionally, the organic regulations list mushroom inputs in the "crops" section of the National List of Allowed and Prohibited Substances (see 7 CFR 205.601(o)). Across USDA programs, mushrooms are commonly considered a type of agricultural crop similar to other produce, vegetables, and specialty crops. Crops are a highly diverse group of agricultural products that are produced using similarly diverse production systems. The final rule acknowledges this diversity and clarifies how the organic regulations apply to the unique production requirements for mushrooms. The organic regulations continue to ensure certifying agents and inspectors have qualifications and expertise relevant to the scope and complexity of the operations (§ 205.501(a)(4)).

#### Wild Crop

(*Comment*) One comment argued the lack of a definition for *wild mushrooms* could cause confusion since mushrooms are grown and/or harvested with a wide spectrum of production practices. Another comment requested that NOP develop standards for wild-grown mushrooms.

(*Response*) The final rule amends the definition of *wild crop* to include mushrooms, thereby clarifying that wild mushrooms can be certified organic under the wild crop standards at § 205.207. Amendments to the wild crop standards were not included in the proposed rule and are beyond the scope of this rulemaking.

# § 205.210 (Mushroom Production Practice Standard)

#### Description of Final Policy

The final rule adds a new section (§ 205.210) to the USDA organic regulations to add provisions for producing mushrooms, spawn, and other mushroom products (collectively "mushroom production") that are sold, labeled, or represented as organic.

Many of the existing production requirements in subpart C of the USDA organic regulations (7 CFR part 205) can be applied to mushroom production. However, mushroom production also relies on practices that are different from plant production practices. The final rule clarifies which of the existing crop production requirements apply to mushroom production and also adds requirements specific to mushroom production, as described below.

Applicability of Crop Standards in Subpart C—§ 205.210(a)

AMS requires in § 205.210(a) that organic mushroom operations follow most of the existing regulations governing crop production, including §§ 205.200, 205.201, 205.202 as applicable, 205.203(e), 205.206(a)(2)-(3), and 205.206(b)–(f). These sections cover general production requirements (§ 205.200); organic production and handling system plans (§ 205.201); land requirements (§ 205.202); nutrient management prohibitions (§ 205.203(e)); and crop pest, weed, and disease management (§ 205.206). In addition, organic mushroom operations may follow the nutrient management practices in § 205.203(d).

Organic mushroom operations, like all other organic operations, must have an organic system plan that describes how the operation complies with applicable parts of the USDA organic regulations. However, because the methods used to produce mushrooms are different than those to produce plants, the final rule clarifies that not all existing crop production requirements apply to organic mushroom production. Mushroom operations do not need to follow all the requirements in the soil fertility and crop nutrient management practice standard at § 205.203, the seeds and planting stock practice standard at § 205.204, or the crop rotation practice standard at § 205.205. The final rule clarifies that mushroom producers are subject to the same nutrient management prohibitions as plant producers described in § 205.203(e) and may optionally follow the nutrient management practices in § 205.203(d). Conversely, mushroom production does not involve seeds or planting stock, and mushrooms are not grown in rotations for fertility or disease suppression, so the final rule does not require producers to comply with §§ 205.204–205.205.

#### Management of Mushroom Substrate and Mushroom Spawn Media— § 205.210(b)

Paragraph 205.210(b) requires operations to manage mushroom substrate and mushroom spawn media in a way that avoids environmental contamination. The rule requires that mushroom substrate, mushroom spawn media, spent mushroom substrate, and spent mushroom spawn media be managed to avoid the contamination of any crops, mushroom spawn, mushroom substrate, soil, or water by pathogenic organisms, heavy metals, or residues of prohibited substances. This provision is similar to the requirement in § 205.203(c) for other organic crop operations to prevent environmental contamination from materials applied to soil. Likewise, this requirement relates to and supports the requirement in § 205.200 to maintain or improve the natural resources of the operation, including soil and water quality. Paragraph 205.210(b) requires operations to manage materials in a way that avoids contamination throughout the entire mushroom production process, from mushroom spawn creation, to growing mushrooms, to disposal of spent substrate.

Operations that only produce organic mushroom spawn and do not produce organic mushrooms are also subject to the provisions in paragraph (b). Mushroom spawn media is usually incorporated into mushroom substrate. In cases where a mushroom spawn producer disposes of spawn, the operation needs to dispose of spent mushroom spawn media in a manner that avoids contamination of crops, mushroom spawn, mushroom substrate, soil or water by pathogenic organisms, heavy metals, or residues of prohibited substances (§ 205.210(b)).

Composition of Mushroom Substrate— § 205.210(c)

Paragraph 205.210(c) describes the materials allowed in mushroom substrate. The paragraph addresses the acceptable use of five types of materials in mushroom substrate: composted plant and animal materials, uncomposted plant materials, wood materials, nonsynthetic substances, and synthetic substances.

Paragraph 205.210(c)(1) describes requirements for composted plant and animal materials in mushroom substrate. This section details time, temperature, and composition requirements for composting plant and animal materials for use in mushroom production. The final rule requires that compost feedstock reach at least 131 °F for at least three days during the composting process. AMS does not include a maximum temperature for mushroom compost production. The minimum temperature and duration requirements allow mushroom producers the flexibility to compost feedstocks at higher temperatures and/ or for longer periods, if warranted. The compost must not be treated with any prohibited substances per the existing requirements at § 205.203(e)(1)

ÂMS specifies in §205.210(c)(2) that uncomposted plant materials used in mushroom substrate must be organically produced when commercially available. The term *commercially available* is defined at § 205.2. This requirement does not apply to plant materials that are used as compost feedstocks; it applies to plant materials added to mushroom substrate that do not undergo a composting step. Plant materials that are pasteurized or sterilized only, but not composted, are subject to the requirements of this paragraph, meaning they must be organic when commercially available. The requirement for organic plant materials also does not apply to wood materials (see § 205.210(c)(3)).

Paragraph 205.210(c)(2) allows for nonorganically produced, uncomposted plant materials in mushroom substrate when a "functionally equivalent" organically produced input is not commercially available. Functional equivalence references a material's ability to fulfill an essential function in a system of organic production, as described in the definition of *commercially available* at § 205.2. For the purposes of this exception, an "essential function" is a function of the same nature (*e.g.*, the nutritional or structural characteristics the material provides in the mushroom substrate). When a functionally equivalent organic material is not commercially available, nonorganic plant materials may be used in substrate, except that prohibited substances must not be applied to any nonorganic plant material after harvest of the plant material.

Paragraphs 205.210(c)(2)(i) through (iii) include specific requirements for operations that use nonorganically produced, uncomposted plant materials in mushroom substrate. Those operations must include additional elements in their organic system plan (OSP) as described below. The additional information is intended to provide certifiers with the information they require to determine whether functionally equivalent organically produced materials are commercially available for purposes of § 205.210(c)(2).

Paragraph 205.210(c)(2)(i) requires operations to describe in their OSP the procedures used to search for organic materials, as well as the records kept to document searches for organic materials. Procedures should demonstrate that operations contacted a sufficient number of sources to ascertain the commercial availability of organically produced plant materials. A producer must make a reasonable effort to search for organic materials from reasonable sources (i.e., those known to sell organic products). Procedures may include details about how an operation identifies potential sources (or suppliers) of organic materials and how the operation contacts those sources. The operation must also describe the types of records that are kept to document searches. This should include a description of the types of records kept and a description of the recordkeeping system, such as how the operation stores these records. Records may include, but are not limited to letters, email correspondence, phone logs, catalogs, searches of organic databases, receipts, receiving documents, invoices, and inventory control documents.

Paragraph 205.210(c)(2)(ii) requires operations to describe in their OSP the criteria they use to evaluate if functionally equivalent organic materials are commercially available. Operations should describe how they determine the essential function (a function of the same nature, like the nutritional or structural characteristics) that they are not able to meet with organic plant materials, how they identify "functionally equivalent" organic plant materials to search for, and how they verify that "functionally equivalent" organic plant materials are not commercially available to fulfill that essential function.

Operations must establish an essential function to accurately verify if organic plant materials are commercially available. An operation may outline how they identify the essential function needed for a substrate material in their OSP. Additionally, an operation may identify essential functions they need in certain types of production in their OSP to ensure consistent searches.

Operations should have criteria for identifying organic materials that would fulfill the essential function needed in their mushroom substrate in their OSP. This may include resources for determining functionally equivalent organic materials, methods for determining characteristics of materials, or testing procedures. In most cases, the direct organic analog(s) to the nonorganic plant material used should be included in the commercial availability search as a functionally equivalent material. Additionally, organic varieties of different plant materials may need to be considered in the search (e.g., organic soybean hulls may be reviewed as an alternative for conventional cotton seed hulls).

An operation's OSP should include a description of how they evaluate if organic alternatives reviewed are not commercially available in the appropriate form, quality, or quantity to fulfill the essential function of the nonorganic plant material. Form considerations may include, but are not limited to method of harvest, processing, and preparation. Quality considerations may include, but are not limited to, the presence of residues, bacteria, fungus, or other microorganisms, shelf life, and stability. Quantity considerations may include evidence that quantities are not available in sufficiently large or small amounts, given the scale of the operation. Price cannot be a consideration for the determination of commercial availability.

Certifiers should verify that an operation has considered a sufficient number of plant materials in its search to fulfill an essential function in the mushroom substrate. Certifiers must use the definition of *commercially available* (see § 205.2) and the requirements at § 205.210(c)(2) to verify an operation's claim that organically produced plant materials necessary for mushroom production are not commercially available and should verify that a sufficient number of sources have been contacted.

Paragraph 205.210(c)(2)(iii) requires that operations describe in their OSP the recordkeeping system used to document

purchases of nonorganic plant materials (not including wood materials allowed under § 205.210(c)(3)). The OSP must describe how the recordkeeping system can be used to summarize, by type, the amount of nonorganic plant materials purchased. Operations are obligated, generally, to maintain records and make them available for inspection (see § 205.103), but the additional information and summarization, in this case, will allow both certifiers and AMS to verify compliance. Summarized information will allow certifiers to assess the extent to which operations are utilizing nonorganic plant materials. Additionally, it will allow certifiers to compare an operation's use of nonorganic plant material year-to-year to identify trends or patterns. AMS could also request summarized information (via certifiers or from operations directly) to understand the practices around use of nonorganic plant materials in the industry, to target enforcement efforts, and/or inform future rulemaking priorities. Paragraph 205.210(c)(3) allows

Paragraph 205.210(c)(3) allows mushroom operations to use nonorganic wood materials (wood chips, sawdust, logs, or other materials derived from wood) in mushroom substrate. These materials must not be treated with prohibited substances after harvest of the tree or wood source. An operation does not need to search for organic forms of these wood materials (or document any search for organic forms), but it does need to verify that the wood materials were not treated with prohibited substances after harvest. The operation must keep records documenting the verification process.

Paragraphs 205.210(c)(4) and (5), together with the amendment to the definition of *crop* in § 205.2 to include mushrooms, specifically allow mushroom operations to use natural (nonsynthetic) substances and/or certain synthetic substances in mushroom substrate, in accordance with the National List of Allowed and Prohibited Substances ("National List") for organic crop production. These provisions align with the requirements related to allowed and prohibited substances described at § 205.105(a)–(b). Paragraph 205.210(c)(4) allows the use of natural (nonsynthetic) substances in mushroom substrate. Examples include mined gypsum, chalk, and clay. However, operations must not use nonsynthetic substances prohibited for use in organic crop production in § 205.602 of the National List.

Paragraph 205.210(c)(5) permits mushroom producers to use certain synthetic substances that are included in the National List at § 205.601 as

"allowed" for organic crop production. For example, microcrystalline cheesewax listed at § 205.601(o)(1) may be used as a production aid in loggrown mushrooms. Again, §205.210(c)(5), together with the revision to the definition of *crop* in § 205.2 to include mushrooms, clarifies that mushrooms are a type of crop and that the synthetic substances included on the National List at § 205.601 are allowed in organic mushroom production. (For additional discussion, see the section below titled "§ 205.601 National List—Crop"). Any use of these allowed, synthetic substances in mushroom production must follow all applicable substance-specific restrictions from the National List, as well as Federal and State laws and regulations.

#### Requirements for Mushroom Spawn— § 205.210(d)

Paragraph 205.210(d) establishes requirements for spawn used in organic mushroom production. Producers must use organic spawn when commercially available, as defined at § 205.2. When an equivalent organic spawn is not commercially available, a producer may use nonorganic spawn. An equivalent spawn could be a spawn of the same mushroom variety but on a different spawn media. For example, if milletbased spawn is equivalent to sorghumbased spawn and one is commercially available as organic, then the operation must use the organic spawn. Operations that use nonorganic spawn must keep records that demonstrate organic spawn was not commercially available. These records are necessary to comply with the recordkeeping requirements at § 205.103. Records should demonstrate that the operation made an appropriate search for organic spawn and demonstrate that equivalent spawn was not available in the appropriate form, quality, or quantity.

Paragraph 205.210(d)(1) describes the requirements for organic mushroom spawn. Agricultural materials in spawn media must be organic, except for wood materials, such as sawdust (§ 205.210(d)(1)(i)). If the mushroom spawn media contains wood materials, those materials must not be treated with prohibited substances after harvest, in accordance with § 205.210(c)(3). The requirements do not allow for any nonorganic agricultural materials in organic mushroom spawn, except for wood materials.

In addition to any agricultural materials, § 205.210(d)(1)(ii) allows for organic spawn to contain natural (nonsynthetic) and synthetic substances that are allowed in organic production as described in § 205.210(c)(4) and (c)(5). Allowed natural substances are any nonsynthetic substances that do not appear on the National List of prohibited nonsynthetic substances (§ 205.602). Allowed synthetic substances are substances that appear on the National List of allowed synthetic substances (§ 205.601). Any use of these allowed synthetic substances in mushroom production must follow all applicable substancespecific restrictions included in the National List, as well as Federal and State laws and regulations. If a substance on the National List of allowed synthetic substances (§ 205.601) is restricted to a specific use(s) outside of mushroom production, it is not allowed in mushroom production. Additionally, § 205.210(d)(1)(ii) clarifies that compost as described in § 205.210(c)(1) is an allowed component of spawn media. Finally, § 205.210(d)(1)(iii) specifies that organic spawn must be under continuous organic management after the application of mycelium to mushroom spawn media.

Paragraph 205.210(d)(2) includes requirements for operations that make their own spawn for their own mushroom production. In these cases, if a producer is unable to produce organic spawn that meets all the requirements at § 205.210(d)(1), including (d)(1)(i) through (iii), they are still subject to a requirement to use organic agricultural materials when commercially available (except for wood materials, which do not need to be organic) in spawn media. Operations that use nonorganic materials must keep records that demonstrate organic materials were not commercially available. These records are necessary to comply with the recordkeeping requirements at § 205.103. Records should demonstrate that the operation adequately searched for organic materials but could not find functionally equivalent materials in the required form, quality, or quantity.

If a producer is not producing organic spawn that meets the requirements at §205.210(d)(1) but organic spawn of the same mushroom species/variety is commercially available, certifiers should place particular attention on evaluating an operation's claim that a suitable organic spawn cannot be made in compliance with § 205.210(d)(1). This paragraph does not allow for the sale of organic spawn that does not meet all requirements at § 205.210(d)(1). In the case of an operation that produces organic spawn for sale as organic, all agricultural materials (except wood materials) in spawn media must be organic (§ 205.210(d)(1)(i)).

Changes From Proposed to Final Rule

AMS made several changes to the regulatory text of the proposed rule when writing this final rule. Changes to the final rule are discussed below and are followed by specific topics and themes from public comment.

• Mushroom spawn and mushroom spawn media requirements (§ 205.210(d)) are now described in a paragraph separate from the mushroom substrate requirements (§ 205.210(c)).

• Wood materials are specifically noted as an allowed nonorganic agricultural material for mushroom substrate (§ 205.210(c)(3)) and mushroom spawn media (§ 205.210(d)(1)(i)).

• Requirements are added for operations to describe in the organic system plan how they search for organic materials for mushroom substrate, evaluate available organic alternatives, and keep records of nonorganic materials used in mushroom substrate (§ 205.210(c)(2)(i)-(iii)).

• Spawn production requirements are clarified for mushroom producers that make spawn on-site for their own organic mushroom production (§ 205.210(d)(2)).

**Responses to Public Comment** 

Below is a summary of comments received regarding organic mushroom production requirements and AMS's responses.

Commercial Availability for Mushroom Substrate

(Comment) Some mushroom producers and trade groups asserted that it is essential to allow nonorganic materials for mushroom substrate when organic materials are not commercially available (also referred to as the "commercial availability exception" in this document). They said it would be impossible to source enough organic materials for substrate. Producers highlighted that substitution or variation of substrate materials can lead to detrimental yield drops and that organic materials are not consistently available year-round. It is unclear if some comments recognized that organic materials would not be required when composted, as some comments provided examples of inputs that are typically composted. A few certifiers and producers voiced support for a commercial availability exception but did not express broader concerns about sourcing.

In contrast, many commenters voiced the desire to remove the proposed commercial availability exception to require only organic materials for

uncomposted portions of substrate. These commenters included some smaller mushroom operations, certifiers, advocacy groups, and trade associations. Some argued that a commercial availability exception would inhibit growth of the market for organic inputs and result in minimal difference between organic and conventional mushrooms. Some commenters requested that organic inputs be required because mushrooms consume the substrate. Some of these commenters also argued that the commercial availability exception would create a cost disadvantage for small producers, who could not claim that organic inputs are unavailable in sufficient quantity as often as large producers. Comments noted that substrate composition is a key difference between organic and nonorganic mushrooms and argued that there should be substantive differences in production methods to justify any organic cost premium.

(*Response*) AMS appreciates commenters' requests for the use of only organic substrate by all mushroom operations. We also recognize that the commercial availability exception for uncomposted plant inputs is a necessity in organic mushroom production for many organic mushroom operations. We remain uncertain if the industry could implement this rule and produce organic mushrooms using only organic inputs without loss of existing production. Therefore, AMS is maintaining commercial availability exceptions in the final rule, as proposed. However, we are adding requirements in the final rule for operations that use nonorganic uncomposted plant materials for mushroom substrate. To use these nonorganic materials for mushroom substrate, operations must describe, in their OSP, the methods and procedures used to search for organic materials; the criteria they use to evaluate if organic materials are commercially available, including comparable substrate materials; and the recordkeeping system used to document purchases of nonorganic materials.

AMS is aware of commenters' concerns that large producers could be able to use the commercial availability exception more often compared to small producers. AMS understands that operations may need to utilize commercial availability exceptions differently based on a number of factors including geographic location, size, and type of mushroom grown. However, AMS believes this is a function of the flexibility of the commercial availability exception, and the additional requirements in the final rule will increase fairness and consistency of implementation for both small and large producers.

(*Comment*) Some commenters stated that commercial availability criteria should be strengthened, and that AMS should include specific requirements related to how operations must search for organic materials.

(*Response*) In the final rule, AMS is requiring operations that use nonorganic uncomposted plant materials in mushroom substrate to describe in their organic system plan (OSP) how they searched for organic materials, evaluated if organic materials were commercially available, and documented these searches. The final rule requires that an operation must look at functionally similar organic alternatives (i.e., at materials that are comparable but not identical) to ensure that various organic alternatives are considered. The OSP requirements will, in turn, better equip certifiers to verify that producers are making sufficient and appropriate efforts to search for organic materials and only using nonorganic materials when organic options are not commercially available. Certifiers will be able to verify compliance by reviewing a producer's OSP and the associated records that document their searches and purchases.

#### Requirements for Wood Materials

(Comment) The proposed rule stated that uncomposted plant materials (which could include wood products) must be organically produced when commercially available. Additionally, the proposed rule stated that any nonorganic plant materials must not be treated with prohibited substances after harvest. Some comments noted that it was not clear if AMS considered wood and wood-based materials (e.g., sawdust, wood chips) to be a type of "plant material" that is subject to the requirements for other plant materials. Comments requested that AMS clarify how wood materials are classified under the organic regulations; specifically, commenters asked if they should be considered a plant material (that must be organic unless not commercially available), or a nonsynthetic material

§ 205.602 of the National List. (*Response*) The final rule clarifies the requirements for wood materials used in mushroom production. AMS revised the final rule to clearly and specifically allow for the use of nonorganic wood materials. Producers do not need to document that organic forms are not commercially available to use wood materials. Nonorganic wood materials

that is not otherwise prohibited at

must not be treated with prohibited materials after harvest.

(Comment) In regard to the requirement that uncomposted plant materials be organic unless commercially unavailable, most commenters stated it would be almost impossible to source organic wood materials for mushroom substrate and mushroom spawn media and that there would need to be different requirements for wood inputs. A few commenters advocated for wood materials to be free from prohibited substances for 3 years before harvest, rather than just free of prohibited treatments post-harvest, as proposed under the requirement for all uncomposted plant materials. In contrast, a few other comments noted that sawmills do not and could not track information on the three years of forest/ timber management prior to tree harvest. Overall, comments noted that organic wood-based products are not available and that requiring organic wood in mushroom products would pose an impossible barrier to organic production.

(Response) AMS revised the final rule to clarify that wood materials used in mushroom substrate and mushroom spawn media do not need to be organic, but prohibited substances must not be applied after harvest. AMS considered comments that requested three years of management before harvest without the use of prohibited substances but has not adopted this requirement in the final rule. While a few operations and certifiers currently verify this condition, it does not seem to be a universal practice in the industry. Requiring documentation that wood materials have been free of prohibited materials for three years before harvest could be costly and require new documentation for entities outside the organic industry. Additionally, this requirement may limit the amount of sawdust, a key mushroom substrate input, that could be available for organic production, as wood from sawmills can be aggregated from many sources. This would require mushroom producers to gather information from many sources to confirm that trees were not treated with prohibited materials for the 3 years prior to harvest. In many cases, this information would not be available, as a sawmill would not likely be able to provide the necessary information. However, sawmills should have information about any treatments made after harvest and should be able to readily provide this information to mushroom producers.

#### **Requirements for Compost**

(*Comment*) Some commenters expressed concern that altering the time, temperature, and turning requirements in mushroom compost could lead to food safety risks.

(Response) AMS established composting requirements for mushrooms (§ 205.210(c)(1)) that accommodate special processes used to prepare substrate for mushroom production. These processes are presently used to produce mushrooms and include the minimum composting time and temperatures required for compost in other organic crop production. Compost must still meet other regulatory requirements for food safety, as applicable, like those related to the Food Safety Modernization Act, including the Product Safety Rule and the Pre-Harvest Agricultural Water Final Rule.

(*Comment*) Some commenters requested that AMS clarify if sterilization of substrate is considered equivalent to composting. Some commenters requested that AMS allow the use of nonorganic sterilized materials in organic mushroom production.

(*Response*) The final rule allows nonorganic plant materials as compost feedstocks, but the sterilization process is different from composting. The composting process transforms starting materials (feedstocks) through biological processes; sterilization eradicates microbes and other life but does not transform starting material(s). Plant materials that are sterilized but never composted to meet the minimum requirements of § 205.210(c)(1) may be used in accordance with 205.210(c)(2). This means they must be organic unless they are not commercially available, in which case nonorganic plant materials may be used. Wood-based components. such as sawdust, may be used in sterilized products without first seeking an organic form, in accordance with §205.210(c)(3).

(*Comment*) Some commenters stated that the proposed requirements for compost in mushroom production, specifically the requirement that compost reach a temperature of at least 131 °F for a minimum of three days, did not accurately reflect the entirety of the composting process used by mushroom producers (especially for Agaricus mushrooms). Specifically, these producers often use a two-phase composting process. Temperatures in the first phase typically go well above 131 °F. In the second phase, temperatures are also brought higher than 131 °F in a pasteurization step but

do not persist. Comments noted that composting practices are varied and diverse, especially between *Agaricus* and specialty mushroom producers, and questioned if the minimum requirements accommodate the variety of composting methods that mushroom producers may use to prepare compost. Relatedly, some comments requested clarification about how guidance documents related to heat-treated manure (NOP 5006) and alternative composting methods (NOP 5021) relate to this rule.

(Response) The final rule maintains that composted plant and animal materials prepared for mushroom substrate must meet minimum requirements of maintaining a temperature of at least 131 °F for at least three days. AMS recognizes that mushroom producers use a wide variety of processes to prepare substrate for mushroom production but is not aware of composting processes for mushrooms that do not achieve the minimum standard of 131 °F for three days. Additionally, the final rule does not require producers to use compost. If a producer uses a process that does not meet the minimum temperature and time requirements of the final rule for compost, the agricultural materials must be organic, unless the material is not commercially available in organic form under § 205.210(c)(2) or the input is a wood material meeting the requirements of § 205.210(c)(3). Producers may continue to use a variety of processes, provided that the producer complies with the organic regulations and the minimum requirements for composted nonorganic plant and animal materials used in mushroom substrate.

#### Spawn

(*Comment*) Several comments stated that spawn and spawn media requirements were not clearly distinguished from requirements for mushroom substrate or that the proposed rule included contradictory requirements for spawn. For example, comments questioned whether nonagricultural products or synthetic substances on the National List are allowed in organic spawn media.

(*Response*) The final rule separates spawn and spawn media requirements from the requirements related to the mushroom substrate (substrate inoculated by spawn). This revision is intended to clearly distinguish the requirements for mushroom spawn media from the requirements for mushroom substrate. Paragraph 205.210(d) indicates that allowed synthetic substances and nonorganic wood materials may be added to spawn media and clarifies other composition requirements for organic spawn.

(*Comment*) Some comments argued the rule should always require organic spawn media, without exception. Commenters argued that organic materials are available in sufficient quantity for organic spawn.

Other commenters stated that there are not enough organic inputs to support organic spawn production. Specifically, a comment argued that there are not enough organic products to supply organic spawn at even a fraction of the total need. The comment noted that 750 to 850 million pounds of *Agaricus* mushrooms are produced annually in the United States, requiring hundreds of thousands of acres of straw and hay.

(*Response*) AMS finds that there is likely sufficient organic spawn media to produce organic spawn in most cases. While 750 to 850 million pounds of Agaricus mushrooms are produced in the United States, less than 110 million pounds are produced organically.<sup>22</sup> These organic mushrooms will use hundreds of millions of pounds of agricultural materials, mostly in their growing substrate (where composting and commercial availability provide flexibility for organic producers). Spawn materials make up less than five percent of the total need for agricultural materials in Agaricus production.<sup>23</sup> The United States produced nearly 2.4 billion pounds of organic hay and straw in 2021, so AMS believes that there should be sufficient organic hay and straw for organic spawn production that requires these inputs.<sup>24</sup>

However, AMŚ understands there may be limited circumstances when needed organic materials may not always be commercially available in all regions at all times of the year. Additionally, AMS understands that sawdust is often used as a spawn media and there are little to no organic wood products available. Because of this, the final rule maintains the proposed requirement that spawn must be organic when commercially available but provides limited exceptions for using nonorganic wood in organic spawn media and nonorganic spawn media when organic spawn and spawn media are not commercially available. This flexibility of the final rule will ensure that mushroom producers can consistently produce spawn to meet the needs of organic mushroom production.

(*Comment*) A comment noted that spawn requirements did not clearly differentiate between the requirements for mushroom producers that only source spawn (from outside their operation) and producers that make their own spawn. Commenters questioned how commercial availability requirements (for sourcing spawn) apply to producers that make their own spawn on-site.

(Response) AMS agrees that the rule should more fully consider those operations that not only source spawn but produce their own spawn for their mushroom production. The final rule more clearly describes spawn requirements for producers that make their own spawn (see § 205.210(d)(2)). The final rule clarifies that producers who produce their own spawn for their own mushroom production must use organic inputs for their spawn media, when commercially available. This revision will allow producers that make their own spawn to continue to do so but also clarifies that the same standard for organic agricultural uncomposted materials that applies to mushroom substrate also applies to spawn media. In the case that organic inputs are not used by a producer for spawn media when organic spawn is commercially available in the market, certifiers should pay close attention to claims that the spawn cannot be made to comply with organic spawn requirements.

(*Comment*) Several comments from certifiers asked for clarification about how to review the ingredients in mycelium cultures used to inoculate spawn media (*e.g.*, ingredients in agar plates) and whether those ingredients are subject to the same requirements as spawn and/or spawn media.

(*Response*) The rule does not specify requirements for mycelium culture materials (*e.g.*, ingredients in agar plates, liquid cultures, or slants). Organic mushroom spawn must be under continuous organic management after the mycelium is applied to the mushroom spawn media (§ 205.210(d)(1)(iii)). Other requirements for spawn and spawn media are described in § 205.210(d).

Commercial Availability for Mushroom Spawn

(*Comment*) A mushroom trade association stated the "variety" of spawn media was not relevant to

<sup>&</sup>lt;sup>22</sup> USDA, National Agricultural Statistics Service, Agricultural Statistics Board. (August 21, 2024). "Mushrooms." https://downloads.usda.library. cornell.edu/usda-esmis/files/r781wg03d/ 9593wm52z/9306vq05c/mush0824.pdf.

<sup>&</sup>lt;sup>23</sup> PennState Extension. (March 6, 2023). "Seeding Substate and Management of Growing Agaricus Bisporus." https://extension.psu.edu/ seeding-substrate-and-management-of-growingagaricus-bisporus.

<sup>&</sup>lt;sup>24</sup> USDA, National Agricultural Statistics Service. (December 2022). "Certified Organic Survey 2021 Summary." https://www.nass.usda.gov/ Publications/AgCensus/2022/index.php.

commercial availability searches, as proposed. The commenter states that the availability of specific spawn media may be impacted by factors even within a media variety (*e.g.*, organic grain in one location may have different contaminants than the same grain grown in another location). Other commenters asked that the term "variety" be removed from the proposed regulatory text related to commercial availability as it is inconsistent with the existing regulatory definition of commercially available.

(Response) AMS agrees that the emphasis on variety creates confusion with the commercial availability criteria. In this final rule, AMS has removed the proposed reference to "variety" in favor of functional equivalence for both spawn media and substrate. This change more clearly aligns with the definition of *commercially available*. This requirement may mean operations need to check the organic variety of a nonorganic input in many cases. Commercial availability allows for determinations based on quality of the product, which may include contaminants.

(*Comment*) Some comments argued the rule should always require organic spawn, without exception. Comments argued that requiring organic spawn would support organic spawn producers. Some comments noted that removing any allowance for nonorganic spawn could also help assure consumers that organic mushrooms meet a consistent standard. Other comments acknowledged the need for a commercial availability exception for organic spawn. A mushroom trade association stated that many mushroom strains are proprietary, and if a given strain is not produced in organic form, it likely cannot be obtained or produced by any other source.

(Response) A key goal of the final rule is to establish consistent standards for mushroom production, which includes the production of spawn and other related products. However, AMS disagrees with comments that argue organic spawn is available for all spawn production and should be required without any exceptions. AMS recognizes that organic spawn, especially for certain proprietary strains, may not be available. The final rule allows for use of nonorganic spawn when organic spawn is not commercially available. Producers will be able to continue using these strains if equivalent organic spawn is not commercially available.

#### "Ready-to-Use" Products

(*Comment*) Comments asked for clarification about how the standards apply to "ready-to-use" or "ready-tofruit" mushroom logs, blocks, or kits, and whether a 2019 NOP memo to certifiers on the topic remains in effect. Comments noted that these products commonly contain nonorganic wood products (*e.g.*, sawdust) as substrate, and questioned whether this would continue to be allowed under the final rule.

(Response) This final rule replaces the 2019 memo from NOP to certifiers and continues to allow the use of nonorganic wood materials as mushroom substrate (§ 205.210(c)(3)). These products (collectively referred to here as "RTU products" or "RTUs") are sometimes marketed as "ready-to-use spawn" or "spawn kits," but they can be generally described as mushroom substrate that has been inoculated with spawn and is readily able to produce harvestable mushrooms in situ with proper humidity and temperature control. In contrast, spawn does not contain substrate necessary to readily grow mushrooms and needs to be combined with substrate to produce a crop. As such, RTU products do not fall under the definition and description of "spawn" in this final rule.

Because RTU products contain both substrate and spawn, both must be produced and managed according to the applicable requirements of this final rule in order to produce organic mushrooms. Organic RTU mushroom production products must be produced by a certified organic operation in accordance with § 205.210. The spawn used to inoculate the substrate must comply with § 205.210(d). The substrate must comply with § 205.210(c), which includes an allowance for nonorganic wood materials. This final rule ensures that RTU products must follow the same regulations as other inoculated mushroom substrate under § 205.210 for organic mushroom production.

#### **Mycelial Biomass Ingredients**

(*Comment*) Comments asked AMS to change the standards or clarify how the standards apply to edible "mycelial biomass" used as an ingredient in food, beverages, supplements, and other processed products for direct human consumption. Comments also referred to these ingredients by other terms, such as "mycelium biomass," "mycomass," "full spectrum mycoproduct material," "mycofermented mycelium," "mycofermented grain," or "myceliated grain." Comments generally described these ingredients as being produced similarly to spawn, but with a longer growth time after the mycelium is applied to substrate. In general, a substrate material (*e.g.*, grain, such as millet or rice) is inoculated with a culture and grown (or fermented) until nearly all the substrate is consumed by the mycelium and bio-converted into fungal tissue. The entire mycelial mass, including any un-converted substrate, may be dried or otherwise processed and used as an ingredient.

(Response) AMS appreciates the detailed technical comments submitted about these ingredients (collectively referred to as "mycelial biomass" in this response). AMS agrees with comments recognizing the differences between mycelial biomass used as an ingredient for direct human consumption, versus spawn used as a crop input to produce fruiting bodies which are then harvested for direct human consumption. AMS also recognizes that organic spawn meeting the requirements at § 205.210(d)(1) for use as a crop input to produce organic mushrooms may not comply with the requirements for use as an ingredient in an organic processed product.

AMS has not developed standards that are specific to mycelial biomass ingredients. However, this rule does not preclude or prevent the ongoing organic certification of mycelial biomass ingredients used in processed products. Ingredients used in organic processed products must follow the handling requirements in § 205.270 and ingredient composition requirements in § 205.301. Given that the substrate used to produce the mycelial biomass is included as part of the mycelial biomass ingredient in a processed product, the substrate must comply with the requirements at § 205.301 for agricultural substances to be organic. Additionally, any non-agricultural or nonorganic ingredients must comply with applicable provisions of the National List of substances allowed in processed products (§§ 205.605 and 205.606). AMS understands, based on comments received on the proposed rule, that this reflects the current practice of certifiers that currently certify edible mycelial biomass ingredients for direct human consumption and other processed products that may contain these ingredients.

#### Exemptions

(*Comment*) Some comments expressed a concern that exempting mushroom producers from certain crop production requirements could lead to other types of crop production systems being allowed to avoid applicable regulations.

(*Response*) This rule does not create or change the requirements for crop production other than mushrooms. Section 205.210 specifically recognizes the provisions of the organic crop standards that apply to organic mushroom production and establishes specific requirements that allow for the different production practices used to grow mushrooms. Establishing practice standards for other specialized crop production systems is outside the scope of this rule. This rule does not preclude future rulemaking regarding other types of specialized crop production systems.

(*Comment*) A comment argued that mushroom producers should not be exempt from crop rotation requirements that apply to plant producers. They noted that rotation could support broad organic requirements to improve natural resources, support nutrient cycling, promote ecological balance, and conserve biodiversity.

(*Response*) The rule does not require that mushroom producers rotate crops, or species of mushrooms, on their operations. Due to the nature of mushroom production, it is not clear how a mushroom producer would conduct crop rotations. Mushroom operations, however, must meet requirements at § 205.200 to maintain or improve the natural resources of the operation, including soil and water quality. For these reasons, the final rule does not require mushroom operations to follow crop rotation standards at § 205.205.

#### §205.601 (National List-Crop)

#### Description of Final Policy

Section 205.105 of the organic regulations describes the allowed and prohibited substances in organic production and handling. That section states that synthetic substances may be used in organic production only if they are specifically included on the National List of allowed synthetic substances (§ 205.601).

The final rule revises the definition of *crop* (§ 205.2) to clarify that mushrooms are a type of crop. This means that the National List for crop production is applicable to mushroom production.

The final rule also updates the paragraph headings at § 205.601(i) and (j) to replace the term "plant" with "crop" in the phrases "As plant disease control" and "As plant or soil amendments." These paragraphs describe the types of synthetic substances, grouped by function, that may be used in organic crop production. The revisions are intended to clarify that subsections 205.601(i) and (j) of the National List, along with other substances for crop production listed throughout § 205.601, are relevant for mushroom production.

Substances used in mushroom production must also be used in accordance with any restrictions or annotations noted on the National List and only if permitted under applicable Federal and State laws and regulations. For example, the U.S. Environmental Protection Agency reviews pesticide product labels as part of the licensing/ registration process and must approve the label language before a pesticide can be sold or distributed in the United States. It is a violation of Federal law to use a pesticide in a manner inconsistent with its labeling.

#### Changes From Proposed to Final Rule

Following analysis of public comments, AMS has not made any changes to the proposed National List modifications in this final rule.

#### **Responses to Public Comment**

Below is a summary of comments received regarding these changes to the National List (§ 205.601) and AMS's responses.

(*Comment*) Some of the comments that argued for a new scope of certification for fungi (described earlier) also argued that AMS should create a new section of the National List for fungi inputs that is separate from the list for crop production in § 205.601. Comments argued that substances on the National List for crop production do not apply to mushroom production, and those substances should be specifically petitioned for addition to the new section of the National List.

(*Response*) AMS is not creating a separate section of the National List for fungi inputs, as requested, nor is AMS requiring inputs currently on the National List for use in crop production to be reviewed again for use in mushroom production. The crops section of the National List (§§ 205.601 and 602) is already an established location for identifying mushroom production inputs, like the listing of microcrystalline cheesewax at § 205.601(o)(2) for use in log grown mushroom production.

Use of the crops section of the National List is also consistent with current practices of certifiers that certify mushrooms as a crop. These certifiers refer to the regulations and § 205.105 and the crops section of the National List (§§ 205.601 and 205.602) to determine allowed and prohibited materials for organic mushroom production. Furthermore, materials on the National List are subject to specific restrictions and annotation and may not be allowed for mushrooms. For these reasons, AMS does not view this as an expansion of allowable inputs, but rather, maintaining current practice. Stakeholders may refer to the National List Petition Guidelines for information on amending the National List.<sup>25</sup>

Responses to Public Comment on Implementation Timeline

In the proposed rule, AMS specifically requested feedback about whether a one-year implementation period would be appropriate for the rule and what an appropriate implementation timeframe would be if one year was not appropriate. Comments on this topic as it related to the mushroom standards, and AMS's responses to comments, are discussed below.

(*Comment*) Some comments argued that an extended implementation period would be needed if the final rule were to include specific changes they requested. For example, comments that requested AMS create a separate standard and scope of certification for all fungi also suggested that five years would be necessary for changes so sweeping. Others argued that a five-year implementation period would be adequate if the rule were to require that all mushroom substrate inputs be organic without exception.

(*Response*) As previously discussed, AMS has declined to expand the standards to apply to all fungi or create a separate scope of certification for all fungal products, and AMS has retained an exception in the final rule for mushroom operations to use nonorganic inputs under specific conditions (see "Responses to Public Comment" in the above subsections labeled "§ 205.2 (Terms defined)" and "§ 205.210 (Mushroom production practice standards)"). As these changes were not adopted, a five-year implementation period is not necessary.

(*Comment*) Some mushroom producers and a mushroom industry association stated that a one-year implementation period would be inadequate because there is not enough supply of organic agricultural or forestry byproduct to meet the demand.

(*Response*) In response to these and other comments, the final rule allows nonorganic wood materials (*i.e.*, sawdust, chips, logs, or other wood materials). Furthermore, it allows for nonorganic plant materials in

<sup>&</sup>lt;sup>25</sup> USDA, NOP. "How to File a Petition." https:// www.ams.usda.gov/rules-regulations/organic/ national-list/filing-petition#NLpetitionGuidelines.

mushroom substrate when organic is not commercially available. For these reasons, AMS does not agree with the comment that the rule requires a long implementation period.

However, in recognition of the changes in the final rule, AMS is providing a two-year implementation period to allow operations to update organic system plans, procedures, and recordkeeping systems to comply with the final rule.

(*Comment*) Some commenters argued that a one-year implementation period would be too brief. Certifiers noted that one year does not allow enough time to notify operations of changes, collect updated organic system plan forms, and conduct inspections to the new requirements. Additionally, some certifiers said the recent Strengthening Organic Enforcement final rule is demanding certifier resources. These commenters requested a longer (*e.g.*, two- to three-year) implementation period for the rule.

(*Response*) AMS is selecting an implementation approach for the final rule that recognizes time is required for certifiers and operations to understand the rule and then update forms, procedures, and recordkeeping systems. AMS believes that a two-year implementation period, for both the mushroom standards and the pet food standards, provides the regulatory certainty that the rule seeks to establish and will minimize business disruptions for organic operations and certifying agents.

#### **IV. Organic Pet Food Standard**

#### A. Pet Food Background

This final rule regulates organic claims on pet food by amending the existing regulatory framework for processed organic products (§ 205.270, Organic handling requirements) to clarify the composition and labeling requirements for organic pet food. These amendments allow organic pet food to be labeled and sold as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))." The changes clarify that pet food is distinct from livestock feed, which has its own composition and labeling requirements (see §§ 205.237 and 205.301(e)). This rule defines *pet* as "Any domestic animal not used for the production and sale of food, fiber, or other agricultural-based consumer products." The rule defines pet food as "Any commercial feed prepared and distributed for pet consumption." Throughout this rule, the term pet food is used to refer to all pet foods, including food for pets other than dogs

and cats, unless otherwise noted. Feed for zoo animals falls outside the scope of this rule, as zoo animals are not domestic animals and do not fit the definition of *pet*.

This rule regulates what organic pet food can contain and how organic claims may be used on pet food. Other aspects of the manufacturing, marketing, and sale of pet food—including its healthfulness and safety, nutritional value, and suitability for pets—fall under the authority of the Food and Drug Administration (FDA) and State regulatory bodies. All pet food manufacturers, organic or otherwise, must comply with relevant Federal and State laws and regulations pertaining to pet food safety.

#### General Overview of U.S. Pet Food Regulations

Pet food labels are regulated at the Federal and State levels. At the Federal level, FDA is responsible for overseeing and enacting the requirements of the Federal Food, Drug, and Cosmetic Act, which requires pet food to be safe, properly manufactured, and adequately labeled.<sup>26</sup> FDA requires certain information on pet food labels: Proper identification of the product, a net quantity statement, the name and place of the manufacturer or distributor, and a proper listing of all ingredients.<sup>27</sup> Some States enforce their own labeling regulations in addition to those administered by FDA. Most of these States follow versions of the Model Bill recommendations of the Association of American Feed Control Officials (AAFCO), an independent non-profit organization.28

Pet food is often formulated as a complete nutrition product—*i.e.*, the sole source of nourishment for pets. It typically contains ingredients from agricultural sources, minerals, vitamins or other nutrients, flavorings, preservatives, and processing aids to meet the nutrient requirements of the animal and the processing needs for the pet food.<sup>29</sup> Many ingredients from agricultural sources such as meat, poultry, and grains are considered safe and do not require FDA's pre-market approval. Other substances (including

supplemental nutrients) do not require FDA's pre-market approval if they are on an FDA-maintained list of ingredients Generally Recognized as Safe (GRAS), otherwise they must have approval as food additives.<sup>30</sup> The National Academy of Sciences' National Research Council (NRC) and AAFCO provide information on the nutrient requirements of dogs and cats at each stage of life (e.g., growth, reproduction, adult maintenance) to guide the formulation of nutritionally adequate pet foods. NRC has listed and described essential nutrients in its 2006 publication "Nutrient Requirements of Dogs and Cats." <sup>31</sup> On its website, AAFCO maintains more recently updated Nutrient Profiles for the various stages of life. The minimum nutrient levels specified in the AAFCO Nutrient Profiles are generally consistent with NRC Nutrient Requirement tables and are updated periodically as NRC recommendations change.

This rule does not supersede the requirements of FDA or State regulatory bodies. Instead, this rule is intended to work jointly with those requirements and more narrowly regulate what manufacturers must do to label their pet food "100% organic," "organic," or "made with organic (specified ingredients or food group(s)). Additionally, by including organic pet food in the organic regulations, the rule clarifies the process for adding substances to the National List specifically for use in organic pet food. Future amendments to the National List could be made, as necessary, in accordance with the process, requirements, and criteria described in OFPA (see 7 U.S.C. 6517 and 6518).

#### Organic Pet Food Industry and Market

Pet food is a large and growing market in the United States. According to recent data from the American Pet Products Association (APPA), roughly 82 million homes own a pet.<sup>32</sup> Pet ownership increased during the COVID– 19 pandemic when many people chose to adopt pets while working from home. According to an American Society for the Prevention of Cruelty to Animals

<sup>&</sup>lt;sup>26</sup> FDA. (February 17, 2022). "FDA's regulation of pet food." https://www.fda.gov/animal-veterinary/ animal-health-literacy/fdas-regulation-pet-food.

<sup>&</sup>lt;sup>27</sup> FDA. (February 3, 2023). "Pet food." *https://www.fda.gov/animal-veterinary/animal-food-feeds/pet-food*. FDA's animal food labeling regulations are located at 21 CFR part 501.

<sup>&</sup>lt;sup>28</sup> AAFCO. "Labeling & labeling requirements." https://www.aafco.org/resources/startups/labelinglabeling-requirements/. Accessed May 1, 2023.

<sup>&</sup>lt;sup>29</sup> FDA. (February 15, 2024). "Pet Food." https:// www.fda.gov/animal-veterinary/animal-food-feeds/ pet-food.

<sup>&</sup>lt;sup>30</sup> FDA. (August 4, 2023). "Current animal GRAS notices inventory." *https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory.* 

<sup>&</sup>lt;sup>31</sup> National Research Council. (2006). "Nutrient requirements of dogs and cats." *https:// nap.nationalacademies.org/catalog/10668/nutrientrequirements-of-dogs-and-cats.* 

<sup>&</sup>lt;sup>32</sup> American Pet Products Association. "Pet industry market size, trends & ownership statistics." Retrieved September 3, 2024. https:// americanpetproducts.org/industry-trends-and-stats. Accessed September 3, 2024.

(ASPCA) survey, around 23 million homes (nearly one in five homes in the United States) adopted a cat or dog during the pandemic.<sup>33</sup>

In 2023, the pet food/treat market in the United States was valued at \$64.4 billion and was projected to increase to \$66.9 billion in 2024.<sup>34</sup> However, the organic pet food market remains small in comparison: as of 2021, the organic pet food market was less than one percent of the total pet food market.<sup>35</sup> In 2023, sales of organic pet food dropped to \$120 million, a decline of 7.4 percent from the previous year.<sup>36</sup> The organic pet food market is relatively new, with few organic brands having been able to penetrate the market. AMS expects that as the number of organic options for pets increases, an untapped market of consumers may seek to purchase organic pet food for the same reasons that they purchase other organic foods.

#### B. Need for Organic Pet Food Standards

The lack of specific standards for organic pet food has created inconsistency and uncertainty around labeling and composition requirements for organic pet food. Certifiers have used various combinations of the standards for livestock feed and processed products, neither of which are entirely sufficient. The handling standards are appropriate for verifying the processing, handling, product composition, and labeling requirements for multiingredient processed agricultural products, but they lack specific allowances for nutrients that are necessary for pets. Conversely, the livestock feed standards include allowances for many of the nutrients that are necessary for pets, but they prohibit common pet food ingredients, such as slaughter by-products.

These regulatory gaps have increased the risk for businesses in the organic pet food market, hindered production innovation, and limited the market for organic slaughter by-products. This rule addresses these inconsistencies and creates clearer regulatory standards specifically for slaughter by-products and nutrients in organic pet food.

#### **Organic Slaughter By-Products**

The term "organic slaughter byproducts" refers to the parts of an organic animal, managed and slaughtered according to the organic regulations, that humans do not typically eat, such as offal, gristle, and bone. These by-products come from organically managed animals, but livestock producers do not often receive organic premiums for them due to an insufficient market for organically produced slaughter by-products.

Section 205.237(b)(5) prohibits feeding slaughter by-products to mammals or poultry. This is a necessary precaution for livestock raised as food for human consumption; however, slaughter by-products are a commonly used protein source in pet food. In the past, some certifying agents have used the composition requirements for organic livestock feed (§ 205.301(e)) to certify pet food as organic, but livestock feed produced under the organic standards may not sufficiently address the nutritional needs of pets. Some certifying agents have allowed organic slaughter by-products in pet food, while other certifiers have not. These contradictions create uncertainty for businesses that currently produce organic pet food and are a barrier to businesses that would like to start producing organic pet food or selling slaughter by-products to the organic pet food market.

Slaughter by-products make up approximately 23 percent of the composition of conventional pet food, in part to meet protein levels required by Federal and State regulations.<sup>37</sup> AMS estimates that there are currently over 12 million pounds of organic meat and organic slaughter by-products used in pet food annually. Prior to the publication of this final rule, it was unclear if pet food manufacturers could use meat or slaughter by-products in organic pet food. This uncertainty has likely limited the growth of the organic pet food market. By clarifying that these products can be used in organic pet food, this rule could broaden the market and increase demand for those organic livestock products. Based on feedback from stakeholders, AMS finds it likely that organic meat and slaughter byproduct demand will grow over time beyond this estimate after implementation of this rule.

Vitamins, Minerals, and Amino Acids

Most dry and wet pet foods are multiingredient products, as multiple ingredients are needed to meet the nutritional needs of a pet. The product that forms the largest share of the pet food market is kibble,<sup>38</sup> or dry "complete and balanced" <sup>39</sup> pet food, which is intended to supply a pet's daily nutritional needs of essential vitamins, minerals, and amino acids.

Prior to the publication of this rule, there has been uncertainty about which nutrients are allowed in organic pet food. Some certifying agents have used the composition requirements for organic livestock feed (§ 205.301(e)) to identify allowable nutrients in organic pet food. Those standards allow the use of FDA-approved vitamins and minerals that appear on the National List of allowed substances for livestock production (§ 205.603(d)(2) and (3)), many of which are commonly used in pet foods. Other certifiers have used the handling standards in § 205.270, which allow nutrient vitamins and minerals that appear on the National List of allowed substances for processing/ handling at §§ 205.605 and 205.606. However, these standards do not explicitly allow the vitamin and mineral ingredients that appear on the National List for livestock production at § 205.603(d), which may also be important for pet food. Neither the livestock production nor the processing/ handling lists of allowed synthetic nutrient vitamins and minerals is sufficient to address the range of essential nutrients for pet food.

Furthermore, neither section of the National List allows for certain synthetic amino acids, such as taurine, that are commonly used in pet food. Taurine is a synthetic amino sulfonic acid that is a necessary part of a healthy diet for many pets (all cats and some dog breeds). For that reason, AAFCO's cat nutrient profiles require taurine, and it is a common synthetic additive in pet foods for other pets. Taurine is essential for pet health and adequate taurine levels cannot always be achieved using organic agricultural ingredients alone. The natural form of taurine is present in raw meat but not in processed pet food in its final form, as taurine is destroyed by heat, which is applied during pet food processing to comply with pet food

<sup>&</sup>lt;sup>33</sup> ASPCA. "New ASPCA survey: Vast majority of dogs and cats acquired during pandemic still in their homes." https://www.aspcapro.org/resource/ new-aspca-survey-vast-majority-dogs-and-catsacquired-during-pandemic-still-their-homes. Accessed September 3, 2024.

<sup>&</sup>lt;sup>34</sup> American Pet Products Association. "Pet industry market size, trends & ownership statistics." *https://americanpetproducts.org/ industry-trends-and-stats.* Accessed September 3, 2024.

<sup>&</sup>lt;sup>35</sup> Organic Trade Association. (2022). Organic Industry Survey. p. 108.

<sup>&</sup>lt;sup>36</sup> Organic Trade Association. (2024). Organic Industry Survey. p. 74.

<sup>&</sup>lt;sup>37</sup> Institute for Feed Education & Research. (March 2020). "Pet food production and ingredient analysis."

<sup>&</sup>lt;sup>38</sup>Kibble accounted for 62.8 percent of all pet food sales in 2020. Pet Food Processing. (December 1, 2020). "State of the US pet food and treat industry, 2020." https://www.petfood processing.net/articles/14294-state-of-the-us-petfood-and-treat-industry-2020.

<sup>&</sup>lt;sup>39</sup> FDA. (February 28, 2020). "Complete and Balanced Pet Food." https://www.fda.gov/animalveterinary/animal-health-literacy/complete-andbalanced-pet-food.

safety standards.<sup>40</sup> To compensate for this loss, pet food manufacturers often add synthetic forms of taurine to certain pet foods. As synthetic taurine was previously not approved for organic pet food, some certifiers limited the types of pet food that could be certified as organic to single-ingredient treats. This limited the growth of the overall organic pet food market.

#### Final Rule Response

This final rule resolves these problems by, first, establishing that organic pet food is regulated as a processed product rather than as livestock feed. This allows organic pet food to include slaughter by-products from certified organic animals, which remain under continuous organic management through the slaughter process. This clarification creates consistency between certifying agents, removes uncertainty for pet food manufacturers, and expands the market for organic livestock producers who sell slaughter by-products. Allowing slaughter by-products in organic pet food will likely increase demand for certified organic slaughter by-products and create additional income streams for organic livestock producers and meat processors. AMS expects that the changes brought about by this final rule will encourage additional growth in the small organic pet food market and other latent organic markets that support it, such as the market(s) for organic slaughter by-products.

Second, this final rule clarifies the vitamins, minerals, and amino acids that are allowed as ingredients in organic pet food to ensure that pet food manufactures can formulate pet foods that meet the daily nutritional needs of pets. It permits the use of the vitamin and mineral feed additives referenced in §§ 205.603(d)(2) and (3) in pet food, and it adds taurine to the National List at § 205.605(b) as an allowed nonorganic ingredient in organic pet food. Revising the organic regulations to clearly allow the essential nutrients required in pet food will allow companies to produce multi-ingredient dry and wet pet food products that are certified organic and meet the complete nutritional needs of pets.

Third, this rule regulates pet food under the existing composition and labeling requirements for processed products referenced in § 205.270 rather than under the requirements for livestock feed. This allows producers to make the organic labeling claims: "100 percent organic," "organic," or "made with organic (specified ingredient or food group(s))." These labeling claims are regulated under the USDA organic regulations (§§ 205.301, 205.303, and 205.304) and are used extensively by certified organic handlers. "100 percent organic" is used to label any product with 100 percent organic ingredients, "organic" products must contain at least 95 percent organic ingredients, and "made with organic" products must contain at least 70 percent organic ingredients. The regulations established in this final rule also permit the identification of organically produced ingredients in the ingredient statement of certain products (§§ 205.301(d) and 205.305). In the first three cases, any nonorganic ingredient(s) must also meet specific criteria.41

By clarifying that pet food can be labeled with the various organic claims described above, the rule provides pet food manufacturers with the flexibility to make and market a range of products that contain organic ingredients. In turn, AMS expects the rule could increase the availability of organic products for consumers and bolster markets for organic ingredients by increasing demand.

In conclusion, this rule addresses inconsistencies in how certifying agents are applying the current organic regulations to pet food. It also resolves regulatory uncertainties that artificially increase risk in the organic pet food market. Addressing these inconsistencies and uncertainties should create the conditions necessary for organic pet food and related markets to grow.

#### C. Overview of Final Rule Policy and Responses to Comments

This final rule amends the USDA organic regulations (7 CFR part 205) by defining "pet" and "pet food" in the regulations and adding a new paragraph for pet food in § 205.270, organic handling requirements. This action integrates organic pet food standards into existing USDA organic labeling categories for agricultural products (subpart D of part 205) and specifies the ingredients that can be included in pet food labeled "100 percent organic," "organic," "made with organic (specified ingredients or food group(s))," or in products with less than 70 percent organic ingredients (ingredient list claims only). Table 2 summarizes the amendments to the USDA organic regulations that add pet food composition and labeling standards.

#### TABLE 2—OVERVIEW OF REGULATORY CHANGES TO ESTABLISH PET FOOD STANDARDS

Section title	Type of action	Rulemaking action
205.270	Adds new paragraph	

#### § 205.2 (Terms Defined)

#### Description of Final Policy

The final rule amends § 205.2 by adding two new terms, *pet* and *pet food*. 1. Pet

The rule defines *pet* as "any domestic animal not used for the production and sale of food, fiber, or other agriculturalbased consumer products." This term establishes a distinction between animals raised as pets and animals raised for food or fiber (*i.e.*, "livestock," as defined at § 205.2). Animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products are "livestock" under the USDA organic regulations (§ 205.2) and must be produced under all applicable organic livestock requirements. Feed requirements for organic livestock are described at § 205.237 and do not apply to organic pet food, and vice versa.

#### 2. Pet Food

The rule defines *pet food* as "any commercial feed prepared and distributed for pet consumption." The definition for *pet food* distinguishes organic pet food products from organic livestock feed products. This action is

<sup>&</sup>lt;sup>40</sup> Spitze, A.R., Wong, D.L., Rogers, Q.R., & Fascetti, A.J. (2003). "Taurine concentrations in animal feed ingredients; cooking influences taurine

content." Journal of Animal Physiology and Animal Nutrition, 87(7–8), 251–262. https://pubmed.ncbi. nlm.nih.gov/12864905/.

<sup>&</sup>lt;sup>41</sup>USDA, AMS. (April 2018). "Organic Labels Explained." https://www.ams.usda.gov/sites/ default/files/media/OrganicLabelsExplained.png.

consistent with the NOSB's recommendation.<sup>42</sup> It also addresses concerns from pet food manufacturers that applying livestock feed composition requirements to pet food could limit product formulation and participation in the organic market due to the lack of available organic protein sources, especially rendered products like poultry meal. Unless otherwise noted, the term *pet food* refers to all pet foods, including food for pets other than dogs and cats. Feed for zoo animals is not included in the definition, as zoo animals are not domestic animals and therefore fall outside the definition of pets.

#### Changes From Proposed to Final Rule

Following analysis of public comments, AMS has not made any changes to the proposed definitions of *pet* and *pet food* in this final rule. See the following section for a more detailed discussion of public comments on these definitions and AMS's response to those comments.

#### **Responses to Public Comment**

Below is a summary of comments received regarding organic pet food definitions and AMS's responses.

(Comment) Some commenters, including AAFCO, requested that AMS align its definitions with the AAFCO Model Bill and State feed laws. AAFCO suggested that the proposed definition of *pet* should be changed to align with the Model Bill which defines a pet as a dog or a cat only. AAFCO also suggested that AMS consider additional definitions for *specialty pet* ("any animal normally maintained in a household, such as, but not limited to, rodents, ornamental birds, ornamental fish, reptiles, amphibians, ferrets, hedgehogs, marsupials, and rabbits not raised for food or fur" and specialty pet food ("any commercial feed prepared and distributed for consumption by specialty pets"). In contrast, other commenters, including a feed industry association and several organic certifying agencies, supported AMS's definitions for *pet* and *pet food*, stating that the definitions are clear and would work well within the existing regulatory frameworks for pet food.

(*Response*) AMS acknowledges and appreciates AAFCO's work developing industry standards. However, AMS has chosen not to modify or add to the

proposed definitions of *pet* or *pet food* in this final rule. AMS acknowledges that the definition of *pet* in this rule is broader than AAFCO's definition, but this rule regulates organic food for all types of pets equally and does not present unique requirements for different categories of pets or specialty pets. Without any differences in labeling or composition requirements for different types of pets in this rule, AMS does not find it necessary to distinguish between types of pets and prefers to use a single and inclusive term (*pet*) for all types of pets. Importantly, this rule does not change a manufacturer's obligations to comply with Federal or State requirements that may have different requirements for pet food and specialty pet food. AMS's decision to use a broad and inclusive definition of *pet* in this rule ensures that the organic regulations are flexible to accommodate any other detailed Federal and State requirements for pet food and specific types of pets.

(*Comment*) Some comments questioned AMS's definition of *pet food* as a type of "commercial feed . . . for pet consumption." These comments stated that standards for "food" products and ingredients are higher than standards for "feed" products and ingredients, with differences in quality and safety standards. They argued that defining *pet food* as a type of feed would confuse consumers about whether organic pet food was human grade.

(*Response*) The final rule does not revise the definition of *pet food*, as we do not believe that the market expects the term *pet food* to mean a product meets human grade food standards. Therefore, we do not expect that the term will mislead consumers. For the purposes of the organic regulations, AMS finds that the broad and common term *pet food* is most appropriate. See additional discussion of comments related to human grade standards for pet food in section "§ 205.270 (Organic handling requirements)" below.

# § 205.270 (Organic Handling Requirements)

#### **Description of Final Policy**

This final rule adds a new paragraph (d) to § 205.270—organic handling requirements—to describe requirements for the composition, processing, and labeling of organic pet food. New paragraph (d) specifies the types of processing aids and ingredients that are allowed in organic pet food. By including pet food as part of the organic handling requirements in § 205.270, and therefore clearly separating pet food standards from the livestock feed

composition and labeling standards, the rule ensures that pet food is not subject to the prohibition on the use of slaughter by-products that exists for livestock feed. The rule allows slaughter by-products in pet food under the same composition and labeling requirements for other multi-ingredient products described at § 205.301(a) through (d) and (f). The term organic slaughter by*products* refers to the parts of organic animals that humans do not typically eat, such as offal, gristle, and bone. It does not refer to substandard animal products from diseased animals, uninspected animals, condemned animals, or animals deemed unfit for human consumption.

The final rule (§ 205.270(d)) permits organic pet food, like other processed organic products regulated under § 205.270, to contain nonorganic substances allowed by the National List in § 205.605 (such as taurine, as finalized by this rule) and § 205.606. These ingredients may be used in processed pet food products labeled as "organic" or "made with organic (specified ingredients or food group(s))," in accordance with § 205.301(b) and (c), respectively. Additionally, the rule allows the feed additive vitamins and minerals in § 205.603(d)(2) and (3) to also be used for enrichment or fortification of pet food.

Paragraph 205.270(d) also clarifies that pet food with organic claims must be labeled pursuant to subpart D of the organic regulations. For instance, organic pet food must be labeled according to the product composition requirements at § 205.301(a) through (d) and (f). In addition, pet food may use the following labeling categories: (a) "100 percent organic;" (b) "organic," (c) "made with organic (specified ingredients or food group(s));" or (d) products containing less than 70 percent organic ingredients (organic ingredients identified on the ingredient statement only). This action, in combination with the new definition for *pet food*, as distinct from livestock feed, allows the labeling of organic pet food using the same framework as multi-ingredient processed food products (rather than the requirements for livestock feed). The requirements for livestock feed composition (§ 205.301(e)) and livestock feed labeling (§ 205.306) do not apply to pet food.

The changes to § 205.270 do not replace or modify requirements pertaining to pet food that are applicable under other Federal or State laws or regulations. This rule regulates only the organic claims on pet food. All other aspects of pet food formulation,

<sup>&</sup>lt;sup>42</sup> NOSB. (November 19, 2008). "Formal recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP): Organic pet food standards recommendation." https://www.ams.usda.gov/sites/ default/files/media/NOP%20Final%20 Rec%20Pet%20Food.pdf.

production, labeling, and sale must follow the relevant Federal and State laws and regulations.

#### Changes From Proposed to Final Rule

Following analysis of public comments, AMS has not made any substantive changes to the proposed organic handling requirements in this final rule. The final rule adds pet food requirements at § 205.270(d) rather than § 205.270(c), as proposed, to minimize impacts related to documents and policies that currently reference the requirements at § 205.270(c). The final rule also removes references to "the applicable portions of" Subpart D, as proposed, in favor of a clear and direct reference to Subpart D. AMS expects all operations, including pet food manufacturers, to comply with the applicable portions of Subpart D that are relevant to the product types and claims of the certified product. This rule clarifies that livestock feed composition and labeling are not applicable to pet food.

#### **Responses to Public Comment**

Below is a summary of comments received regarding organic pet food handling requirements and AMS's responses.

(*Comment*) Several thousand commenters, responding to a mass comment campaign initiated by an organic advocacy group, requested that AMS ensure that organic pet food, including any livestock products used as ingredients in pet food, meet "human grade" food standards.

(Response) This final rule does not require the use of "human grade" standards for organic pet food or its ingredients. All organic livestock products are subject to the organic regulations, as well as other State and Federal regulations that may apply. AMS understands that other organizations, including AAFCO, have defined "human grade" and/or have recommended detailed guidelines for use of the "human grade" claim on pet food. For example, under the "human grade" guidelines recommended by AAFCO, each ingredient must be stored, handled, processed, and transported under human food laws and regulations, and facilities must be registered with the FDA as a human food and animal food facility, among other requirements. Adopting such standards in the final rule would go well beyond the scope of the proposed requirements. However, nothing in this rule prevents organic pet food operations from additionally making truthful "human grade" claims on organic pet food products.

(*Comment*) The mass comment campaign noted above also requested that no fallen or condemned animals (or portions of animals) or animals that die by means other than slaughter be allowed in organic pet food. Some other individual commenters echoed these requests, requesting that AMS require USDA inspection of slaughtered animals or facilities slaughtering animals to ensure no condemned animals are used in pet food.

(Response) AMS agrees with the commenters that organic pet food must not contain condemned, diseased, or otherwise unsanitary animal products, and the final rule should in no way be misconstrued to permit them. AMS has not revised the final rule to address these topics because AMS did not propose specific language on this topic and because other laws and regulations, including organic regulations, exist that address these issues. Under the current regulations, organic slaughter facilities must be certified organic and are subject to annual on-site inspections from their certifier. The organic regulations specifically prohibit seriously crippled and non-ambulatory animals from being sold or slaughtered as organic (§ 205.242(a)(2)).

Additionally, organic regulations require that organic livestock be slaughtered in compliance with USDA Food Safety Inspection Service (FSIS) regulations, FSIS Directives, and other laws (§ 205.242(b) and (c)). The FSIS regulations (*e.g.*, 9 CFR part 309 and part 314) include specific regulations related to handling condemned (*e.g.*, diseased) animals/or animal parts. They also include regulations related to animals that have died other than by slaughter (*i.e.*, dead animals) and diseased, dying, and disabled animals.

Finally, ÅMŠ is not including a requirement for USDA inspection of slaughter plants associated with organic slaughter for pet food. Not all animals in the United States are slaughtered at USDA-inspected facilities. For example, some facilities are inspected by States only. Therefore, AMS is not including a requirement that slaughter facilities be USDA-inspected; however, organic facilities, including slaughter facilities, are still subject to annual on-site inspections by their organic certifier.

(*Comment*) Several commenters asked for clarification about how vitamins and minerals listed in §§ 205.603(d)(2) and (3) should be reviewed for use in organic pet food. Commenters asked about whether AAFCO-approved vitamins and minerals would be allowed, and other questions related to the applicability of NOP Guidance 5030, "Evaluating Allowed Ingredients and Sources of Vitamins and Minerals for Organic Livestock Feed".

(Response) The final rule permits the vitamin and mineral feed additives referenced in § 205.603(d)(2) and (3), which include vitamins and minerals that are FDA approved. AMS defers to applicable FDA regulations and guidance in determining which specific substances are FDA approved.43 Section 4.2.3 of NOP Guidance 5030, "Evaluating Allowed Ingredients and Sources of Vitamins and Minerals for Organic Livestock Feed," contains additional information to help determine whether certain vitamins or minerals are allowed under § 205.603(d)(2) and (3). For the purpose of determining compliance for organic pet food, if the vitamin or mineral is allowed under § 205.603(d)(2) or (3), then it is also allowed for use in organic pet food.

#### §205.605 (National List)

#### **Description of Final Policy**

The final rule modifies the National List to allow the use of synthetic taurine in pet food. The rule adds taurine to § 205.605, which describes nonorganic nonagricultural substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." The amendment for taurine also specifies that taurine can be used only in pet food and not in other organic multi-ingredient products.

This addition implements an NOSB recommendation to add taurine to the National List as an allowed substance for use exclusively in pet foods. AMS agrees with NOSB's rationale and recommendation. As described above, taurine is essential for pet health and adequate taurine levels cannot always be achieved using organic agricultural ingredients alone.

#### Changes From Proposed to Final Rule

Following analysis of public comments, AMS has not made any changes to the proposed National List modifications (§ 205.605) in this final rule.

FDA. (August 2024). "CVM GFI #293—FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients." https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents/cvmgfi-293-fda-enforcement-policy-aafco-definedanimal-feed-ingredients.

FDA. (August 2024). "CVM GFI #294—Animal Food Ingredient Consultation (AFIC)." https:// www.fda.gov/regulatory-information/search-fdaguidance-documents/cvm-gfi-294-animal-foodingredient-consultation-afic.

<sup>&</sup>lt;sup>43</sup> FDA has recently announced that it would not renew its MOU with AAFCO and review its procedures for reviewing animal food ingredients. To assist with the transition, FDA has released two draft Guidance for Industry documents:

#### **Responses to Public Comment**

Below is a summary of comments received regarding organic pet food National List standards and AMS's responses.

(*Comment*) One commenter, a pet food trade association, argued that the rule should allow for the use of a broader range of amino acids in organic pet food, rather than allowing taurine only. They suggested replacing the proposed rule's addition of taurine to the National List with the statement "Amino acids, used for enrichment or fortification when FDA-approved for use only in pet food."

(Response) AMS understands the potential need for other amino acids in pet food production apart from taurine. However, taurine is a common synthetic additive in pet food that is vital nutrition for all cat breeds (and some dog breeds) and cannot be obtained in adequate amounts from pet food that does not include synthetic taurine. This decision follows NOSB's recommendation to add only taurine to the National List. NOSB has not recommended other animo acids for use in organic pet food. Therefore, this rule only includes the addition of taurine to the National List.

Individuals may petition to add other substances to the National List for use in organic pet food, following the National List Petition Guidelines.<sup>44</sup> Because organic pet food must meet all applicable Federal and State laws and regulations, any person or organization petitioning to add a substance to the National List for use in organic pet food must ensure the use of that substance is consistent with applicable Federal and State laws and rules. Synthetic substances petitioned for use in pet food will be evaluated according to the existing criteria in OFPA (7 U.S.C. 6517 and 6518) and the USDA organic regulations (7 CFR 205.600).

(*Comment*) Some commenters claimed that it is not necessary to include taurine on the National List because it exists naturally in foods such as eggs, red algae, and meats. Additionally, some commenters asked if taurine should be allowed in all pet food or just cat food, because cats need additional taurine in food whereas dogs are able to physiologically synthesize taurine by consuming foods containing the amino acids cysteine and methionine. Other commenters requested that taurine should be included as an allowed substance specifically for cats and dogs, rather than for pets generally.

(Response) In 2013, the NOSB Livestock Subcommittee proposed adding taurine to the National List as an allowed substance for use exclusively in pet foods to meet nutritional requirements for cats. After public comments argued that taurine can also be necessary for dogs' nutrition, NOSB issued its final recommendation for taurine to be allowed in pet food generally. AMS agrees with NOSB's rationale and recommendation on the basis that taurine is essential for pet health and that synthetic taurine must be added to pet food, in certain cases, to reach the levels that are necessary for pet health.

Responses to Public Comment on Implementation Timeline

AMS requested feedback about whether a one-year implementation period would be appropriate for the rule. Comments that are specifically related to the pet food standards implementation, and AMS's responses to comments, are discussed below.

(*Comment*) Some commenters stated that an extended implementation period is not necessary for the pet food portion of the rule, as the rule does not restrict operations compared to current practices. A commenter noted that certifiers already use the framework described in the proposed rule for the certification of pet food. Commenters noted that if the final rule adopted the proposed rule as-is, a one-year implementation timeline would be sufficient.

(*Response*) AMS agrees that pet food operations will not need to make any major changes to comply with the final rule. In fact, by allowing the use of taurine (an amino acid) in organic pet food, the final rule is less restrictive than existing standards. However, AMS is providing a two-year implementation period for the final rule, including the pet food requirements, to allow operations and certifying agents time to understand the rule and update forms and inspection procedures to reflect the final rule.

AMS notes that operations are not restricted from complying with the final rule prior to the compliance date. For example, pet food operations may use taurine in organic pet food starting on the effective date of the final rule.

#### V. Regulatory Analyses

*Executive Orders 12866, 13563, 14094, and the Regulatory Flexibility Act* 

This rule does not meet the criteria of a "significant regulatory action" under Executive Order 12866, as supplemented by Executive Order 13563 and updated by Executive Order 14094. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on "small entities" and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605(b) of the RFA allows an agency to certify that a rule will not have a significant economic impact on a substantial number of small entities instead of preparing a regulatory flexibility analysis, provided that the agency sets forth the factual basis for such certification. AMS has concluded and hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities: therefore, an analysis is not included. Below, AMS presents information about the industry and the possible effects of the rule on small entities to support this conclusion.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses. SBA's size standards are expressed in terms of number of employees or annual receipts and indicate the maximum allowed for an entity to be considered small.<sup>45</sup>

*Mushroom Producers.* AMS has considered the economic impact of this rulemaking on small mushroom producers. At the time of this analysis, small organic mushroom producers were listed under NAICS code 111411 (Mushroom Production) as grossing equal to or less than \$4,500,000 per year.<sup>46</sup> AMS estimates that out of 239 domestic operations reporting sales of organic mushrooms, approximately 4 operations exceed that threshold.<sup>47</sup>

<sup>&</sup>lt;sup>44</sup> USDA, NOP. How to File a Petition. *https://www.ams.usda.gov/rules-regulations/organic/national-list/filing-petition#NLpetitionGuidelines.* 

<sup>&</sup>lt;sup>45</sup> U.S. SBA. (March 17, 2023). Table of size standards. https://www.sba.gov/document/support-table-size-standards.

<sup>&</sup>lt;sup>46</sup> U.S. SBA. (March 17, 2023). Table of size standards. https://www.sba.gov/document/support-table-size-standards.

<sup>&</sup>lt;sup>47</sup> The National Agricultural Statistics Service was unable to supply a precise tabulation of large organic operations due to disclosure concerns. AMS estimated the number of large mushroom operations and sales from large mushroom operations using the proportion of conventional mushroom operations by sales from the USDA's 2022 Census of Agriculture, available here: https://

While most organic mushroom operations that would be affected by this rule are small entities, this rule only has the potential to impose minor costs on them related to paperwork burden (see "Paperwork Reduction Act" section below) and costs associated with sourcing organic spawn and substrate materials, when commercially available. AMS concludes that this rule will not have a significant economic impact on a substantial number of these small entities.

Pet Food Operations. AMS has considered the economic impact of this rulemaking on small organic pet food producers. At the time of this analysis, small organic pet food producers were listed under NAICS code 311111 (Dog and Cat Food Manufacturing) as employing equal to or fewer than 1,250 employees.48 AMS estimates that given the small size of the organic pet food market, most of the 29 domestic organic pet food operations are small entities. Pet food operations may incur small one-time paperwork costs (see "Paperwork Reduction Act" section below), but the rule establishes standards for organic pet food handling that align with many existing industry practices. Additionally, the rule allows operations to use additional inputs (e.g., taurine) in organic pet food, which provides pet food operations more production options without additional costs. AMS concludes that this rule will not have a significant economic impact on a substantial number of these small entities.

Certifying agents. This final rule also affects certifying agents that certify organic mushroom or pet food operations. At the time of this analysis, the SBA defined small agricultural service firms, which include certifying agents, as those having annual receipts equal to or less than \$19,500,000 (NAICS code 541990—All Other Professional, Scientific and Technical Services). There are currently 73 USDAaccredited certifying agents, and AMS believes most of these certifying agents are small entities. Certifying agents must already comply with existing regulations and already certify these operations. Certifying agents may incur minor one-time paperwork costs (see "Paperwork Reduction Act" section below). However, this rule reduces the current burden of creating and maintaining certifier-level policies for the certification of organic mushroom

production and organic pet food handling. AMS concludes that this rule will not have a significant economic impact on a substantial number of these small entities.

#### Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations to avoid unduly burdening the court system. This rule complies with these requirements. This rule cannot be applied retroactively. Additionally, to prevent duplicative regulation, States and local jurisdictions are preempted under OFPA from creating accreditation programs for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 6503 through 6507 of OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA.

Pursuant to section 6507(b)(2) of OFPA, a State organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the State and for the certification of organic farm and handling operations located within the State. Such additional requirements must (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of OFPA, this rulemaking does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301–399i), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136y).

OFPA at 7 U.S.C. 6520 provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under the statute that adversely affects such person or is inconsistent with the organic certification program established under OFPA. OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

#### Executive Order 13132

Executive Order 13132 mandates that Federal agencies consider how their policymaking and regulatory activities impact the policymaking discretion of States and local officials and how well such efforts conform to the principles of federalism defined in said order. This executive order pertains only to regulations with clear federalism implications.

ÂMS has determined that this rulemaking conforms with the principles of federalism described in E.O. 13132. The rule does not impose substantial direct costs or effects on States, does not alter the relationship between States and the Federal government, and does not alter the distribution of powers and responsibilities among the various levels of government. States had the opportunity to comment on any potential federalism implications during the proposed rule's comment period. No States provided public comment on the federalism implications of this rule. Therefore, AMS has concluded that this rulemaking does not have federalism implications.

#### Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation. After consultation with the USDA Office of Tribal Relations, AMS determined that a Tribal consultation for this rulemaking was not necessary, as it was unlikely to impact Tribes. If a Tribe requests consultation in the future, AMS will work with the

*index.php.* The same distribution is assumed to apply to organic mushroom operations.

<sup>&</sup>lt;sup>48</sup> U.S. SBA. (March 17, 2023). Table of size standards. https://www.sba.gov/document/support-table-size-standards.

Office of Tribal Relations to ensure meaningful consultation is provided.

#### Civil Rights Impact Analysis

AMS has reviewed this rulemaking in accordance with the Departmental Regulation 4300–4, Civil Rights Impact Analysis, to address any major civil rights impacts the rule might have on minorities, women, and/or persons with disabilities. After a careful review of the rule's intent and provisions, AMS determined there is no evidence that this final rule will have adverse civil rights impacts on organic producers identifying as minorities, women, and/ or persons with disabilities. Additionally, this final rule does not impose any requirements related to eligibility for benefits and services on protected classes, nor does the rule have the purpose or effect of treating classes of persons differently.

Protected individuals have the same opportunity to participate in NOP as non-protected individuals. USDA organic regulations prohibit discrimination by certifying agents. Specifically, 7 CFR 205.501(d) of the current regulations for accreditation of certifying agents provides that "No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status." Paragraph 205.501(a)(2) requires certifying agents to "[d]emonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart," including the prohibition on discrimination. The granting of accreditation to certifying agents under § 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's client operation. Further, if certification is denied, § 205.405(d) requires that the certifying agent notify the applicant of their right to file an appeal to the AMS Administrator in accordance with §205.681.

These regulations provide protections against discrimination, thereby permitting all producers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the rules and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This action in no way changes any of these protections against discrimination.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) (PRA), AMS is requesting OMB approval for a new information collection totaling 2,371 hours for the reporting and recordkeeping requirements contained in this final rule. OMB previously approved information collection requests (ICR) associated with the NOP and assigned OMB control number 0581-0191. AMS intends to merge this new information collection, upon OMB approval, into the previously approved collection request (OMB control number 0581–0191). Below, AMS describes and estimates the annual burden (*i.e.*, the amount of time and cost of labor) for entities to prepare and maintain information to participate in the voluntary labeling program. OFPA, as amended, provides authority for this action.

*Title:* National Organic Program: Market Development for Mushrooms and Pet Food.

OMB Control Number: 0581–0347. Expiration Date of Approval: Three

years from OMB date of approval. *Type of Request:* New collection.

#### Abstract

Information collection is necessary to implement the reporting requirements for organic mushroom production and pet food handling under the USDA organic regulations (7 CFR 205.210 and 205.270). This final rule establishes USDA organic requirements in the mushroom and pet food sectors to support consistent interpretation and remove regulatory uncertainty. By doing so, it supports the purposes of OFPA, namely, "to establish national standards" for products marketed as organic and "to assure consumers that organically produced products meet a consistent standard." (7 U.S.C. 6501). Additional information on the purpose and need for this rule is included in the BACKGROUND section of this rule.

#### TABLE 3—TOTAL PAPERWORK BURDEN

#### Overview

Information collection and recordkeeping will be required to demonstrate compliance with new provisions in § 205.210 and amendments to § 205.270 of the USDA organic regulations, 7 CFR part 205, that establish standards for mushroom production and pet food handling. These amendments will require onetime additional reporting for already certified pet food and mushroom operations, accredited certifying agents, and inspectors. Existing organic mushroom and pet food operations will need to read the rule and review their organic system plans (OSPs) for compliance. Certifiers will have to read the rule and review the updated plans, and certifiers and inspectors will require training on the new regulation.

Additionally, the final rule adds allowances for nonorganic plant materials to be used in mushroom substrate when functionally equivalent organic materials are not commercially available. This allowance will require additional documentation for organic mushroom operations. AMS is estimating that organic mushroom operations will have annual reporting and recordkeeping paperwork burdens to utilize this exception. The estimates have been updated to reflect this change.

#### **Burden Estimates**

This burden estimate accounts for certified organic mushroom operations and certified organic pet food operations updating OSPs, mushroom operations verifying and keeping records of commercial availability exceptions for organic substrate, certifiers reviewing updated OSPs, and certifiers training inspectors to comply with the final rule.

#### Number of Respondents: 519.

*Frequency of Response:* One time only and annual (for mushroom operations).

Annual Hour Burden: 2,371 total hours; 1,219 one-time hours; 1,152 annual hours.

The 519 respondents include 322 certified organic operations (288 mushroom operations and 34 pet food operations), 56 certifying agents, and 141 inspectors.

Total reporting burden	Total number of reporting respondents	Total reporting hours—all	Total recordkeeping hours—all	Total all costs
Summary of Tables 4, 5, & 6	519	1,795	576	\$121,696.63

#### **Certified Organic Operations**

AMS estimates that 322 certified organic mushroom and organic pet food operations may need to update their OSPs to comply with the final rule.<sup>49</sup>

AMS estimates that each certified organic mushroom and pet food operation will require one response of two reporting hours to read the rule and update their OSPs. AMS estimates that each respondent will require no additional recordkeeping hours, as these operations already have and store OSPs. This results in a total one-time hour burden of 644 hours for certified organic mushroom and pet food operations across 322 responses.

Because the rule allows organic mushroom operations to use nonorganic plant inputs in mushroom substrate if an organic input of a similar function is not commercially available, the operation must verify and record if organic inputs of similar function are not commercially available. AMS estimates that each operation will need to verify and document inputs approximately two times a year. Each verification will require one response of one reporting hour and one recordkeeping hour. This results in a total annual hour burden of 1,152 hours for certified organic mushroom operations across 576 responses. See table 4 below for a summary of these estimates for certified organic operations.

#### TABLE 4—CERTIFIED ORGANIC OPERATIONS

Respondent categories	Number of respondents	Wage <sup>50 51</sup> + benefits <sup>52 53</sup>	Total reporting hours	Total recordkeeping hours	Total costs
USDA Certified Mushroom Producers & Pet Food Han- dlers—Domestic (One-time) USDA Certified Mushroom Producers & Pet Food Han-	268	\$56.22	536	0	\$30,134
dlers—Foreign (One-time)	54	42.22	108	0	4,560
USDA Certified Mushroom Producers—Domestic (Annual— Commercial Availability) USDA Certified Mushroom Producers—Foreign (Annual—	239	56.22	478	478	53,746
Commercial Availability)	49	42.22	98	98	8,275
USDA Organic Operations—All	322		1,220	576	96,715

#### **Certifying Agents**

AMS estimates that 56 certifying agents will need to review 322 OSPs from certified organic mushroom and pet food operations.

AMS estimates that on average, certifying agents will require one response of one reporting hour to review OSPs for each organic mushroom and pet food operation they certify, resulting in a total of 322 hours over 322 responses. Additionally, AMS estimates each certifying agent will require one response of two hours to read the rule and provide training to staff and inspectors on the new requirements. AMS estimates that these are one-time burdens and each respondent requires no additional reporting/recordkeeping hours as these operations already review and store OSPs (the burden to review and store these is captured under the existing ICR, OMB control number 0581–0191). This results in a total onetime hour burden of 434 hours for certifying agents across 378 responses. See table 5 below for a summary of the estimates for certifying agents.

Bureau of Labor Statistics. (June 18, 2024). "Employer Costs for Employee Compensation Summary." https://www.bls.gov/news.release/ eccc.nr0.htm. Accessed August 27, 2024.

<sup>53</sup> International benefit rates are based on an average tax wedge of OECD countries (34.9% of wage rates). OECD. "OECD comparative indicators." https://stats.oecd.org/Index.aspx? DataSetCode=AWCOMP. Accessed August 27, 2024.

<sup>&</sup>lt;sup>49</sup> USDA. Organic Integrity Database. https:// organic.ams.usda.gov/IntegrityPlus/Search.aspx. To obtain the relevant data, search for "mushroom" and "pet, dog, canine, cat, feline" in the "Certified Products" field. Accessed August 27, 2024.

<sup>&</sup>lt;sup>50</sup> Domestic hourly wage rates are based on the National Compensation Survey: Occupational Employment and Wages, May 2023, published by the Bureau of Labor Statistics. Bureau of Labor Statistics. "May 2023 National Occupational Employment and Wage Estimates." https:// www.bls.gov/oes/current/oes\_nat.htm. Accessed August 27, 2024.

<sup>&</sup>lt;sup>51</sup>International wage rates are estimated based on the proportional average of World Bank GDP per capita rates for Organization for Economic Co-Operation and Development (OECD) countries compared to the U.S. (72.2%). World Bank. "GDP per capita, PPP (current international \$)." https:// data.worldbank.org/indicator/

NY.GDP.PCAP.PP.CD. Accessed August 27, 2024. <sup>52</sup> Domestic benefit rates are based on data from Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation. Wages account for 70.3% and Benefits account for 29.7% of total average employer compensation costs.

#### TABLE 5—CERTIFYING AGENTS

Respondent categories	Number of respondents	Wage <sup>54 55</sup> + benefits <sup>56 57</sup>	Total reporting hours	Total costs
USDA U.SBased Certifiers—Mushrooms USDA Foreign-Based Certifiers—Mushrooms USDA U.SBased Certifiers—Pet food USDA Foreign-Based Certifiers—Pet food	32 10 10 4	\$50.00 37.54 50.00 37.54	303 69 49 13	\$15,150 2,590 2,450 488
USDA Certifiers—All	<sup>58</sup> 56		434	20,678

#### Inspectors

AMS estimates that 141 organic inspectors will need to receive training on the final rule.<sup>59</sup>

AMS estimates that each organic inspector will require one response of one reporting hour to receive training on the final rule. AMS estimates that each respondent will require no additional recordkeeping hours. This results in a

TABLE 6—INSPECTORS

total annual hour burden of 141 hours for organic inspectors across 141 responses. See table 6 below for a summary of these estimates for inspectors.

Respondent categories	Number of respondents	Wage <sup>60 61</sup> + benefits <sup>62 63</sup>	Total reporting hours	Total costs
USDA U.Sbased Inspectors USDA Foreign based Inspectors	106 35	\$32.53 \$24.43	106 35	\$3,448 855
USDA Inspectors—All	141		141	4,303

#### Comments

AMS published a proposed rule and request for public comment in the **Federal Register** on March 11, 2024 (89 FR 17322). The 60-day notice regarding paperwork impacts is embedded in the proposed rule and provides stakeholders an opportunity to comment on the accuracy of the information collection request. The 60-day comment period ended on May 10, 2024. AMS asked four specific information collection request questions in the proposed rule:

<sup>56</sup>Domestic benefit rates are based on data from <sup>56</sup>Domestic benefit rates are based on data from Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation. Wages account for 70.3% and Benefits account for 29.7% of total average employer compensation costs. Bureau of Labor Statistics. (June 18, 2024). "Employer Costs for Employee Compensation Summary." https://www.bls.gov/news.release/ eccc.nr0.htm. Accessed August 27, 2024. 1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility.

2. The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

4. Ways to minimize the burden of the collection of information on those who

<sup>59</sup> This estimate is based on data from the International Organic Inspectors Association (IOIA) Membership Directory, available at *https:// www.ioia.net/member-directory*. Based on adjustments due to public comment (see "Comments," below), AMS estimates that half of inspectors are present in the IOIA Membership Directory and adjusts the number of inspectors receiving training proportionally by the percentage of certifiers certifying organic mushroom or pet food operations.

<sup>60</sup> Domestic hourly wage rates are based on the National Compensation Survey: Occupational Employment and Wages, May 2023, published by the Bureau of Labor Statistics. Bureau of Labor Statistics. "May 2023 National Occupational Employment and Wage Estimates." https:// are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

During the comment period, AMS received two comments (discussed below) that provided feedback on the initial paperwork burden of the rule.

(*Comment*) A comment stated that the number of inspectors estimated by AMS in the proposed rule's paperwork burden was too low because the directory of inspectors from the International Organic Inspectors Association does not include non-

<sup>61</sup> International wage rates are estimated based on the proportional average of World Bank GDP per capita rates for Organization for Economic Co-Operation and Development (OECD) countries compared to the U.S. (72.2%). World Bank. "GDP per capita, PPP (current international \$)." https:// data.worldbank.org/indicator/NY.GDP.PCAP. PP.CD. Accessed August 27, 2024.

<sup>62</sup> Domestic benefit rates are based on data from Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation. Wages account for 70.3% and Benefits account for 29.7% of total average employer compensation costs. Bureau of Labor Statistics. (June 18, 2024). "Employer Costs for Employee Compensation Summary." https://www.bls.gov/news.release/ eccc.nr0.htm. Accessed August 27, 2024.

<sup>63</sup> International benefit rates are based on an average tax wedge of OECD countries (34.9% of wage rates). OECD. "OECD comparative indicators." https://stats.oecd.org/Index.aspx?DataSetCode= AWCOMP. Accessed August 27, 2024.

<sup>&</sup>lt;sup>54</sup> Domestic hourly wage rates are based on the National Compensation Survey: Occupational Employment and Wages, May 2023, published by the Bureau of Labor Statistics. Bureau of Labor Statistics. "May 2023 National Occupational Employment and Wage Estimates." https:// www.bls.gov/oes/current/oes\_nat.htm. Accessed August 27, 2024.

<sup>&</sup>lt;sup>55</sup> International wage rates are estimated based on the proportional average of World Bank GDP per capita rates for Organization for Economic Co-Operation and Development (OECD) countries compared to the U.S. (72.2%). World Bank. "GDP per capita, PPP (current international \$)." https:// data.worldbank.org/indicator/ NY.GDP.PCAP.PP.CD. Accessed August 27, 2024.

<sup>&</sup>lt;sup>57</sup> International benefit rates are based on an average tax wedge of OECD countries (34.9% of wage rates). OECD. "OECD comparative indicators." *https://stats.oecd.org/ Index.aspx?DataSetCode=AWCOMP*. Accessed

August 27, 2024.

<sup>&</sup>lt;sup>58</sup> Some certifiers may certify both pet food and mushroom operations but are counted as separate entities in this column.

www.bls.gov/oes/current/oes\_nat.htm. Accessed August 27, 2024.

members or members that do not wish to share their information. Additionally, the comment stated that the estimated wages were too low.

(Response) AMS has adjusted the estimated number of total inspectors based on this comment. Absent specific data, we assume that the IOIA database contains half (50 percent) of all inspectors, changing our total number from 185 inspectors present in the IOIA database as of August 27, 2024, to 370 inspectors. AMS acknowledges that without specific input this estimate may be imprecise. To further account for this adjustment and acknowledge that not all inspectors will inspect the 288 mushroom or pet food facilities, AMS adjusted the percentage of inspectors impacted by the paperwork costs to be proportional to the percentage of certifiers that certify operations for mushroom production or pet food handling.

AMS did not adjust the source for hourly wages in the burden estimates for the final rule. AMS acknowledges that costs may be higher for inspectors in some areas. However, without comprehensive data from another source, AMS believes that the Bureau of Labor Statistics estimates for wages remain the most accurate estimates for wages to use in burden estimates.

(*Comment*) One comment argues the requirement in § 205.210(b) that mushroom operations manage substrate in such a way to avoid environmental contamination may be duplicative with § 205.203(c), given that both would seem to apply to mushroom operations. On the other hand, another comment states that reiterating the requirement for mushroom operations is critical.

(Response) Paragraph 205.210(b) specifically adds requirements that operations must prevent mushroom substrate and spawn media from contaminating crops, spawn, mushroom substrate, soil, or water. AMS acknowledges that this is similar to § 205.203(c). However, the regulatory text at § 205.210(a) specifies the crop requirements applicable to organic mushroom production and specifically excludes § 205.203(c) to prevent duplicative requirements. AMS is not adjusting these requirements and finds them to be necessary and nonduplicative.

#### List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Livestock, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 205 as follows:

#### PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6524.

■ 2. Amend § 205.2 by:

■ a. Revising the definitions of "Compost" and "Crop";

■ b. Adding in alphabetical order definitions for "Mushroom", "Mushroom Mycelium", "Mushroom spawn", "Mushroom spawn media", "Mushroom substrate", "Pet", and "Pet food"; and

■ c. Revising the definition of "Wild crop".

The revisions and additions read as follows:

#### §205.2 Terms defined.

*Compost.* The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil or as a component of mushroom substrate.

*Crop.* Pastures, cover crops, green manure crops, catch crops, mushrooms, or any plant or part of a plant intended to be marketed as an agricultural product, fed to livestock, or used in the field to manage nutrients and soil fertility.

*Mushroom.* The fleshy, spore-bearing fruiting body of a fungus.

*Mushroom mycelium.* A mass of branching, thread-like hyphae (fungal structures).

*Mushroom spawn.* Mushroom spawn media colonized by mushroom mycelium that can be used to inoculate mushroom substrate.

*Mushroom spawn media.* The base material, such as grain, wood materials, or minerals, used to make mushroom spawn.

Mushroom substrate. The base material, such as grain, wood materials, composted materials, and/or other agricultural materials, on which mushroom production occurs.

*Pet.* Any domestic animal not used for the production and sale of food, fiber, or other agricultural-based consumer products. *Pet food.* Any commercial feed prepared and distributed for pet consumption.

\*

*Wild crop.* Any mushroom, plant, or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

■ 3. Add § 205.210 to read as follows:

## §205.210 Mushroom production practice standard.

(a) The producer must manage mushroom production in accordance with the provisions of §§ 205.200, 205.201, 205.202 as applicable, 205.203(e), and 205.206(a)(2) and (3) and (b) through (f). The producer may manage crop nutrients for mushroom production in accordance with the provisions of § 205.203(d).

(b) The producer must manage mushroom substrate and mushroom spawn media, including spent mushroom substrate and mushroom spawn media, in a manner that does not contribute to contamination of crops, mushroom spawn, mushroom substrate, soil, or water by pathogenic organisms, heavy metals, or residues of prohibited substances.

(c) Mushroom substrate may be composed of the following materials in accordance with the conditions specified in this paragraph:

(1) Composted plant and animal materials. Compost used in mushroom substrate must be described in the organic system plan. It must be produced through a process that maintains a temperature of at least 131 °F for at least three days;

(2) Uncomposted plant materials. Uncomposted plant materials must be organically produced: *Except*, that, nonorganically produced uncomposted plant materials may be used when a functionally equivalent organically produced material is not commercially available. Prohibited substances must not be applied to nonorganically produced uncomposted plant materials after harvest. Operations that use nonorganically produced uncomposted plant materials in mushroom substrate (except for wood materials allowed under paragraph (c)(3) of this section) must describe in the organic system plan:

(i) The procedures used to search for organic materials and the records kept to document searches;

(ii) The criteria used to evaluate if functionally equivalent organic materials are commercially available; and (iii) The recordkeeping system used to document purchases of nonorganic materials, including a summary of the type(s) and total amount of each nonorganic material used in mushroom substrate.

(3) Wood chips, sawdust, logs, or other materials derived from wood that have not been treated with a prohibited substance after harvest;

(4) Nonsynthetic substances, except those on the National List of nonsynthetic substances prohibited for use in organic crop production (§ 205.602); and

(5) Synthetic substances on the National List of synthetic substances allowed for use in organic crop production (§ 205.601).

(d) Mushroom spawn must be organic: *Except*, that, nonorganic mushroom spawn may be used to produce an organic crop when an equivalent organic mushroom spawn is not commercially available.

(1) Organic mushroom spawn requirements.

(i) Agricultural materials used as mushroom spawn media must be organic: *Except*, that, nonorganic wood materials in compliance with paragraph (c)(3) of this section are allowed.

(ii) Mushroom spawn media may contain materials allowed in mushroom substrate at paragraphs (c)(1), (4), and (5) of this section.

(iii) Organic mushroom spawn must be under continuous organic management after the mycelium is applied to the mushroom spawn media.

(2) Organic mushroom operations that produce their own mushroom spawn for their own organic mushroom production must use organic agricultural materials for mushroom spawn media, unless a functionally equivalent organic agricultural material is not commercially available: Except that, wood materials in compliance with paragraph (c)(3) of this section are allowed.

■ 4. Amend § 205.270 by adding paragraph (d) to read as follows:

#### §205.270 Organic handling requirements.

(d) In addition to the substances described in paragraph (b) of this section, substances allowed under § 205.603(d)(2) and (3) may be used in or on pet food intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(b) and (c). Pet food must be labeled pursuant to subpart D of this part. ■ 5. Amend § 205.601 by revising paragraphs (i) introductory text and (j) introductory text to read as follows:

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

\*

(i) As crop disease control.

- \* \* \*
- (j) As crop or soil amendments.

■ 6. Amend § 205.605 by redesignating paragraphs (b)(36) and (37) as paragraphs (b)(37) and (38), respectively and adding new paragraph (b)(36) to read as follows:

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

\* \* \* \* (b) \* \* \* (36) Taurine—for use only in pet food.

\* \* \* \* \*

#### Erin Morris,

Associate Administrator, Agricultural Marketing Service. [FR Doc. 2024–30211 Filed 12–20–24; 8:45 am] BILLING CODE P

#### DEPARTMENT OF AGRICULTURE

**Food and Nutrition Service** 

7 CFR Parts 247, 250, 251, 253, and 254

[FNS-2023-0026]

RIN 0584-AE92

#### Food Distribution Programs: Improving Access and Parity

**AGENCY:** Food and Nutrition Service (FNS), U.S. Department of Agriculture (USDA).

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Nutrition Service is correcting a final rule that appeared in the **Federal Register** on October 31, 2024. The document makes access and parity improvements in USDA's food distribution programs to support access for eligible populations and streamline requirements for program operators.

DATES: Effective December 30. 2024. FOR FURTHER INFORMATION CONTACT: Gregory Walton, Program Analyst, Food Distribution Policy Branch, Supplemental Nutrition and Safety Programs, U.S. Department of Agriculture's Food and Nutrition Service, 1320 Braddock Place, 3rd Floor, Alexandria, Virginia 22314 at 703–305– 2746 or *Gregory.Walton@usda.gov.*  **SUPPLEMENTARY INFORMATION:** In FR Doc. 2024–24966 appearing on page 87228 in the **Federal Register** of Thursday, October 31, 2024, the following corrections are made:

■ 1. § 247.5 [Corrected]

On page 87244, in the third column, in amendatory instruction 4, correct paragraphs (b)(15) through (17) to read as follows:

(b) \* \*

(15) Ensuring that program participation does not exceed the State agency's caseload allocation on an average monthly basis;

(16) Making publicly available a list of all CSFP local agencies on a publicly available internet web page. The State agency must post the name, address, and telephone number for each local agency. The list must be updated, at a minimum, on an annual basis; and

(17) Posting the State Plan that is currently in use on a publicly available internet web page.

2. § 247.9 [Corrected]
i. On page 87245, in the first and second columns, in amendatory instruction 9 correct paragraphs (b)(1) and (d)(3)(xxiv) to read as follows: (b) \* \* \*

(1) The State agency may accept as income-eligible for CSFP benefits any applicant that documents that they are certified as fully eligible for the following Federal programs: the Supplemental Nutrition Assistance Program, the Food Distribution Program on Indian Reservations, Supplemental Security Income (SSI), the Low Income Subsidy Program, or the Medicare Savings Programs.

- \* \* \*
- (d) \* \* \*
- (3) \* \* \*

(xxix) Payments to the Assiniboine Tribe of the Fort Belknap Indian community and the Assiniboine Tribe of the Fort Peck Indian Reservation (Montana) (Pub. L. 98–124, sec. 5);

■ 3. § 251.4 [Corrected] On page 87250, in the first column, instruction 26 for § 251.4, correct instruction 26.f. to read as follows:

f. Removing the term "donated commodities" wherever it appears in paragraph (g) and adding in its place the term "USDA Foods";

■ 4. § 253.2 [Corrected]

On page 87254, in the first and second columns, in amendatory 36, correct the definitions of "Indian Tribal Organization (ITO) and "State agency" to read as follows:

\* \* \* \* \*