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An Agricultural Law Research Article

A Legal Guide to the National Organic Program

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I. Introduction

Congress enacted the Organic Foods Production Act (“OFPA”) of 1990¹ to create “national standards governing the marketing of certain agricultural products as organically produced products,” (2) assure consumers that “organically produced products meet a consistent standard,” and (3) facilitate “interstate commerce in fresh and processed food that is organically produced.”² OFPA requires the USDA Secretary to establish national standards for organic production and handling consistent with OFPA. On December 21, 2000, the USDA published a final rule that created these national standards.³ The combination of OFPA and the final rule created the National Organic Program (“NOP”). As of October 21, 2002, for a “producer” or “handler” to sell, label, or represent agricultural products as “organic,” that producer or handler must comply with all applicable requirements set forth in the OFPA and the final rule.⁴

NOP operates through a system in which USDA-accredited agents certify that producers and handlers comply with all applicable NOP requirements. It sets forth standards with which entities and individuals must comply to be accredited as certifying agents, as well as requirements with which producers and handlers of production and handling operations must comply to be certified. The NOP also establishes organic standards that govern crop and livestock production and the handling of these products. These standards require, among other things, that producers and handlers submit an organic system plan that describes all aspects of production and handling.

NOP publishes a national list of substances that are allowed or prohibited for use in organic production and handling. NOP also establishes requirements that govern the labels, labeling, and market information for organic products. NOP permits states to create their own organic programs, subject to conditions and requirements set forth in NOP. NOP enforcement mechanisms ensure that

¹ 7 U.S.C. §§ 6501-6522.

² *Id.* at § 6501.

³ NOP is administered by the Agricultural Marketing Service, an agency of the USDA. See <http://www.ams/nop/indexIE.htm>. For an excellent resource on NOP, see <http://attra.ncat.org/attra-pub/nop.html> and <http://attra.ncat.org/attra-pub/PDF/organcert.pdf> (Appropriate Technology Transfer for Rural Areas (ATTRA)).

⁴ The NOP establishes four categories of “organic” products: (1) “100 percent organic”; (2) “organic”; (3) “made with organic (specified ingredients or food group(s));” and (4) “products with less than 70 percent organically produced ingredients.” These categories are addressed in Part D of this article and are set forth at 7 C.F.R. § 205.301. Unless otherwise indicated, the term “organic” as used in this article collectively refers to products qualifying in any one of these four categories.

certifying agents, producers, and handlers comply with NOP requirements. NOP provisions govern the importation and exportation of organic products, and establishes mediation and adverse action appeals processes.

This article examines the legal aspects of NOP. It focuses on the requirements set forth in the final rule and OFPA. This article is intended to be helpful for lawyers and non-lawyers alike who are interested or involved with organic production and handling.

It is useful to understand how and why NOP was created. The practice of producing organically grown agricultural products has existed for several decades in the United States, evolving from a small-scale and localized system into a highly organized and global production and marketing system.⁵ These changes have spurred the organic industry to establish uniform standards for organic production and marketing.

As a result, private organizations and some states developed a third-party certification system. This system required a third-party to determine that the producer or processor had complied with its particular requirements for organic production, in order to be certified. This allowed the producer or processor to represent to consumers that its product had been produced and processed in accordance with that third-party's standards for organic production. Although this was a positive development for the organic industry, the goal of creating uniform standards for organic production and marketing fell short.

This goal remained unaccomplished because the standards for organic production often differed from one third-party certifier to another, as well from one state to another. Many third parties refused to recognize products that were certified by other certifying organizations because of differing standards, thereby impeding the flow of organic products into the marketplace and across state lines. This lack of uniformity in organic production standards was a significant problem. For example, organic livestock producers that needed organic feed for their operations in order to be certified and processors that needed to purchase organic ingredients for their processing operations were often unable to purchase the feed or ingredients that they needed because the feed or ingredients were certified under standards not recognized by the third-party that certified the producer or processor. Another problem was the lack of effective enforcement mechanisms to combat fraud and other violations.

Recognizing these problems, Congress enacted OFPA and authorized the USDA Secretary to promulgate regulations. The result was NOP, a comprehensive statutory and regulatory framework governing all stages of organic production and handling. For a producer or handler to sell, label, or represent agricultural products as "organic," the producer or handler must comply with all applicable NOP requirements.

⁵ See Carolyn Dimitri & Catherine Greene, *Recent Growth Patterns in the U.S. Organic Foods Market*, Economic Research Service/USDA/AIB-777 (Sept. 2002), available at <http://www.ers.usda.gov/publications/aib777/>; Catherine Greene & Amy Kremen, *U.S. Organic Farming in 2000-2001: Adoption of Certified Systems*, Economic Research Service/USDA/AIB-780 (Feb. 2003), available at <http://www.ers.usda.gov/publications/aib780/>.

II. The National Organic Program

A. Definitions

The definitions provided below are basic to understanding NOP and are used frequently throughout its provisions.

A “producer” is any person engaged in the business of growing or producing food or feed.⁶ The term “handle” is defined as the selling, processing, or packaging of agricultural products.⁷ A “handler” is any person engaged in the business of selling, processing, or packaging agricultural products, but does not include final retailers that do not process agricultural products.⁸ A “handling operation” is “[a]ny operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.”⁹

OFPA defines “livestock” as “any cattle, sheep, goats, swine, poultry, equine animals used for food or in the production of food, fish used for food, wild or domesticated game, or other non-plant life.”¹⁰ The final rule defines “livestock” as

[a]ny cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.¹¹

An “agricultural product” is any agricultural commodity or product in raw or processed form and includes any commodity or product derived from livestock that is marketed for either human or livestock consumption.¹² A “person” can be an individual, group of individuals, or any type of business entity.¹³ “Administrator” means the “Administrator for the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.”¹⁴

⁶ See 7 U.S.C. § 6502(18). See also 7 C.F.R. § 205.2. However, the term “producer” does not include the selling, transporting, or delivering of crops or livestock by a producer of the crops or livestock to a handler.

⁷ See 7 U.S.C. § 6502(8). See also 7 C.F.R. § 205.2.

⁸ See 7 U.S.C. § 6502(9). See also 7 C.F.R. § 205.2.

⁹ See 7 C.F.R. at 205.2. There is no definition of “production operation” contained in the statute or the regulations.

¹⁰ 7 U.S.C. § 6502(11).

¹¹ 7 C.F.R. § 205.2.

¹² See 7 U.S.C. § 6502(1). See also 7 C.F.R. § 205.2.

¹³ See 7 U.S.C. § 6502(15). See also 7 C.F.R. § 205.2.

¹⁴ 7 C.F.R. § 205.2.

B. Applicability

NOP establishes certification requirements and specifies operations exempt or excluded from the certification requirements. NOP also establishes recordkeeping requirements for certified and exempted operations, as well as standards governing the use of allowed and prohibited substances, methods, and ingredients in organic production and handling. Although exempted and excluded operations are not required to comply with certification requirements, they must still comply with other NOP requirements.¹⁵

1. Certification, Exemptions, and Exclusions

Certification

A production or handling operation or part thereof “that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented” as “organic” must comply with the certification requirements and all other applicable NOP requirements, unless exempted or excluded.¹⁶ “Certification” is a determination made by an accredited certifying agent that an operation has complied with all applicable requirements in the OFPA and the final rule.¹⁷

Exemptions

Four types of operations are exempted from certification requirements. The first is a production or handling operation that has a gross annual income from sales of organic products totaling \$5,000.00 or less.¹⁸ This exemption is intended primarily for the benefit of producers who market their product(s) directly to consumers.¹⁹ This would include, for example, producers who sell their product(s) at farmers’ markets or directly to “retail food establishments” for resale to consumers.²⁰ A “retail food establishment” is “[a] restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.”²¹

An operation exempted under the “\$5,000.00 or less” standard must comply, however, with the applicable organic production and handling requirements, except for the requirement that it submit an organic system plan.²² The operation must also comply with the labeling requirements for exempted

¹⁵ Note that exemption and exclusion are separate concepts, each containing its own set of standards.

¹⁶ 7 C.F.R. § 205.100(a).

¹⁷ See *id.* at § 205.2 (defining “certification” or “certified”). The certification requirements are addressed in Part E of this article.

¹⁸ See *id.* at § 205.101(a)(1).

¹⁹ 65 Fed. Reg. 80,547, 80,552 (prefatory comments to final rule with request for comments).

²⁰ See *id.*

²¹ 7 C.F.R. at § 205.2.

²² See *id.* at § 205.101(a)(1). The organic production and handling requirements, including the requirements for submitting an organic system plan, are discussed in Part C of this article.

and excluded operations.²³ In addition, products derived from an operation exempted under the “\$5,000.00 or less” standard cannot be used as ingredients in processed products identified as “organic” produced by another handling operation.²⁴

Any retail food establishment or portion thereof that handles organic products but does not process them is also exempted from the certification requirements.²⁵ There are no other requirements in either the OFPA or the final rule with which a retail food establishment falling under this exemption must comply.

In 2008, consumer plaintiffs filed suit against independent retailers, alleging the retailers had misrepresented or engaged in deceptive practices when they labeled and advertised milk as organic because the producer, allegedly, had not complied with NOP standards.²⁶ The court held the plaintiffs’ claims against the producer and the retailers were barred by preemption.²⁷ The court went on to state that, even if the claims had not been preempted, the claims against the retailers would have failed because final retailers who do not “process or repackage products” are exempt from NOP requirements.²⁸ Furthermore, the court stated, retailers are entitled to rely upon certifications awarded to producers and handlers under the federal scheme and have no duty to inspect the facilities of handlers or producers to ensure compliance with NOP standards.²⁹

A handling operation that only handles agricultural products containing less than seventy percent organic ingredients by total weight of the finished product is also exempted from the requirements for certification.³⁰ This type of operation, however, must comply with (1) the standards for avoiding the commingling and contact of organic products with prohibited substances;³¹ (2) the labeling standards applicable to exempt or excluded operations; (3) the labeling standards for multiingredient packaged products with less than seventy percent organic ingredients; and (4) the recordkeeping requirements for exempted operations.³²

²³ See *id.* Labeling requirements for exempted and excluded operations are discussed in Part D of this article.

²⁴ See *id.*

²⁵ See *id.* at § 205.101(a)(2).

²⁶ See *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practice Litig.*, Nos. 4:08MD01907 ERW, 4:07CV01701 ERW, 4:08CV00254 ERW, 4:08CV00280 ERW, 4:08CV00303 ERW, 4:08CV00305 ERW, 4:08CV00371 ERW, 4:08CV00374 ERW, 4:08CV00382 ERW, 4:08CV00384 ERW, 4:08CV00385 ERW, 4:08CV00386 ERW, 4:08CV00387 ERW, 4:08CV00391 ERW, 4:08CV00444 ERW, 4:08CV00466 ERW, 4:08CV00526 ERW, 4:08CV01460 ERW, 4:08CV01462 ERW, 4:08CV01464 ERW, 2009 WL 1576928 (E.D.Mo. June 3, 2009).

²⁷ *Id.* at *9.

²⁸ *Id.* at *10.

²⁹ *Id.* at *11.

³⁰ See *id.* at § 205.101(a)(3). The total weight of the finished product excludes the weight of water and salt in the product. The standards for calculating the organic composition of a product are discussed in Part D of this article and are found at 7 C.F.R. § 205.302.

³¹ See 7 C.F.R. § 205.2 (defining “prohibited substance” as “[a] substance the use of which in any aspect of organic production or handling is prohibited or not provided for” in the [OFPA] or the final rule).

³² See *id.* at § 205.101(a)(3)(i)-(iii).

The final type of exempted operation is a handling operation that identifies ingredients as “organic” only on the information panel.³³ An “information panel” is

[t]hat part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one useable surface).³⁴

A “principal display panel” is the “part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.”³⁵

This type of exempted operation must comply with (1) the provisions for the prevention of contact of organic products with prohibited substances; (2) the labeling requirements for multiingredient products containing less than seventy percent organically produced ingredients; (3) the labeling requirements for exempted and excluded operations; and (4) the recordkeeping requirements for exempted operations.³⁶

Exclusions

There are two types of operations that are excluded from the requirements for certification.³⁷ The first are handling operations that sell only “organic” products that are packaged or otherwise enclosed in a container before the operation receives or acquires the product and “remain in the same package or container and are not otherwise processed while in the control of the handling operation.”³⁸ The prefatory comments to the final rule explain that this exclusion is designed to avoid creating an unnecessary barrier for handlers who distribute nonorganic products and also want to offer a selection of organic products.³⁹ These operations must comply with the standards for preventing the commingling and contact of organic products with prohibited substances.

The second type of excluded operations are retail food establishments or portions thereof that process on their premises “raw and ready-to-eat food from products that were previously labeled” as “organic.”⁴⁰ These operations must comply with the labeling requirements specifically applicable to agricultural products produced on exempted and excluded operations and the standards for preventing the commingling and contact of organic agricultural products with prohibited substances.⁴¹

With respect to exempted and excluded retail food establishments, the prefatory comments to the final rule state the following:

[T]here is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. Retail food establishments, not exempt under the Act, could at some future date be subject to regulation under the NOP. Any such

³³ See *id.* at § 205.101(a)(4).

³⁴ *Id.* at § 205.2.

³⁵ *Id.*

³⁶ See *id.* at § 205.101(a)(4)(i)-(iii).

³⁷ See *id.* at § 205.101(b)(1)-(2).

³⁸ *Id.* at § 205.101(b)(1).

³⁹ 65 Fed. Reg. 80,547, 80,552 (prefatory comments to final rule with request for comments).

⁴⁰ 7 C.F.R. § 205.101(2).

⁴¹ See *id.* at § 205.101(b)(1)-(ii).

regulation would be preceded by rulemaking with an opportunity for public comment.⁴²

2. Recordkeeping Requirements for Certified, Exempted, and Excluded Operations

Certified Operations

A certified operation must maintain records that relate to the “production or handling of agricultural products sold or labeled as organically produced” for five years beyond the date the records are created.⁴³ The records must include a detailed history of the substances applied to the operation’s fields or agricultural products, the names and addresses of the persons who applied the substances, the dates and rates the substances were applied, and the method used to apply the substances.⁴⁴ The records must “[b]e adapted to the particular business that the certified operation is conducting” and must provide full disclosure of all “activities and transactions” of the operation “in sufficient detail as to be readily understood and audited.”⁴⁵ They must also be sufficient to demonstrate that the operation has complied with all applicable NOP requirements.⁴⁶ The records must be available during normal business hours to representatives of the Secretary, the State official governing a State’s organic program, if applicable, and the certifying agent for inspection and copying.⁴⁷

Exempted Operations

An exempted operation must maintain records sufficient to demonstrate that ingredients identified as “organic” were organically produced and handled and to verify the quantities produced from those ingredients.⁴⁸ The records must be kept for at least three years after they are created.⁴⁹ Representatives of the Secretary and the state official governing a state organic program, if applicable, must be allowed access to the records for inspection and copying during normal business hours.⁵⁰

Excluded Operations

Recordkeeping requirements for excluded operations are confusing and unsettled. There are no recordkeeping requirements in the OFPA or the final rule specifically applicable to excluded operations. In describing the qualifications for excluded operations, the final rule expressly states that the first type of excluded operation—a handling operation that sells “organic” products that are received and maintained in an enclosed package or container and are not processed by the operation—is “excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272”⁵¹ The final rule states that the second type of excluded operation—a retail food establishment or portion thereof that processes raw and ready-to-eat food from products certified as “organic”—is “excluded

⁴² 65 Fed. Reg. 80,547, 80,553 (prefatory comments to final rule with request for comments). An operation that satisfies the criteria for an exempted or excluded operation may voluntarily opt to be certified.

⁴³ 7 U.S.C. § 6511(d).

⁴⁴ See *id.* at § 6511(d)(1)-(2).

⁴⁵ 7 C.F.R. § 205.103(a)(1)-(2).

⁴⁶ See *id.* at § 205.103(a)(3)-(4).

⁴⁷ See *id.* at § 205.103(c).

⁴⁸ See *id.* at § 205.101(c)(1)(i)-(ii).

⁴⁹ See *id.* at § 205.101(c)(2).

⁵⁰ See *id.*

⁵¹ *Id.* at § 205.101(b)(1).

from the requirements in this part, except . . . the requirements for the prevention of contact with prohibited substances as set forth in § 205.272 . . . and . . . the labeling provisions of § 205.310.”⁵²

In neither of these provisions does the final rule reference recordkeeping requirements for either type of excluded operation, leading one to conclude perhaps that no such recordkeeping requirements exist. The AMS, however, signals in its prefatory comments to the final rule that excluded operations are subject to recordkeeping requirements. Specifically, the comments state, in pertinent part, that “[e]ach exempt, excluded, and certified operation should maintain the records which demonstrate compliance with the Act and the regulations applicable to it and . . . establish . . . that the exempt, excluded, or certified operation is and has been in compliance with the Act and the regulations.”⁵³

In response to comments made concerning the recordkeeping requirements for excluded operations, the AMS also stated in its prefatory comments to the final rule the following:

[S]everal commenters argued that excluded operations should be required to comply *with the same recordkeeping requirements as exempt operations*. Some commenters expressed concern over the inability to verify compliance for either exempt or excluded operations and asked that exempt or excluded operations be subject to additional recordkeeping requirements. *We disagree with these commenters* and have retained the provisions from the proposed rule on recordkeeping for excluded operations. Given the nature of these excluded operations . . . we believe that extensive recordkeeping requirements would be an unwarranted regulatory burden.⁵⁴

The AMS’s acknowledgment that it rejected the argument that “excluded operations should be required to comply with the same recordkeeping requirements as exempt operations” indicates that it believes there are separate recordkeeping requirements for exempt and excluded operations. However, the only recordkeeping requirements contained in the final rule apply to certified and exempted operations. There is no reference to excluded operations in either set of recordkeeping requirements.

Moreover, although the AMS states that it “retained the provisions from the proposed rule on recordkeeping for excluded operations,” a review of the proposed rule reveals that there were no such requirements contained in the proposed rule. Thus, it is not entirely clear whether excluded operations must comply with any recordkeeping requirements and, if so, what those requirements would specifically be.⁵⁵

3. Allowed and Prohibited Substances, Methods, and Ingredients

For a certified operation to sell, label, or represent a product as “organic,” it must produce or handle the product without the use of synthetic substances and ingredients, unless the substances or ingredients are specifically listed as allowed on the national list of approved substances (“National List”).⁵⁶ A “synthetic” is “[a] substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or

⁵² *Id.* at § 205.101(b)(2).

⁵³ 65 Fed. Reg. 80,547, 80,553 (prefatory comments to the final rule with request for comments).

⁵⁴ *Id.* at 80,555 (prefatory comments to final rule with request for comments) (emphasis added).

⁵⁵ At § 205.307(c), the final rule references “recordkeeping requirements for exempt and excluded operations under § 205.101.” This point is not discussed in this part of this article but is addressed in Part D.

⁵⁶ 7 C.F.R. § 205.105. See also 7 C.F.R. §§ 205.601 & 205.603.

mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.”⁵⁷

When the NOP regulations went into effect in 2002, OFPA prohibited the use of any synthetic ingredients during the processing or post harvest handling of any product certified as organic under the NOP.⁵⁸ Arthur Harvey challenged the NOP regulation permitting the use of synthetic materials, arguing it directly contravened the language of OFPA.⁵⁹ On appeal, the First Circuit Court of Appeals agreed with Harvey.⁶⁰ On remand, the district court issued a consent decree ordering the Secretary of USDA to revise the regulations within 360 days.⁶¹ Subsequently, however, Congress amended OFPA to allow synthetic materials listed as allowed on the National List to be used in the production and handling of organic products, therefore restoring the invalidated regulations.⁶²

Certified operations must also produce and handle products without the use of prohibited nonsynthetic substances.⁶³ A “nonsynthetic substance” is “[a] substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process”⁶⁴ In addition, certified operations must produce and handle products without the use of “nonagricultural substances” or “nonorganic agricultural substances” in or on processed products, unless the substance is specifically included on the National List.⁶⁵ A “nonagricultural substance” is

[a] substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.⁶⁶

Finally, certified operations must produce and handle products without the use of (1) excluded methods, except for vaccines that are listed as approved on the National List; (2) ionizing radiation; and (3) sewage sludge.⁶⁷ “Excluded methods” are “methods used to genetically modify organisms”⁶⁸

⁵⁷ 7 U.S.C. § 6502(21). See also 7 C.F.R. § 205.2 (defining “ingredient” as “[a]ny substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.”).

⁵⁸ *Harvey v. Veneman*, 396 F.3d 28, 38 (1st Cir. 2005).

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Harvey v. Johanns*, 462 F. Supp. 2d 69, 71 (D. Me. 2006).

⁶² *Id.*

⁶³ See *id.* at § 205.105(b). Some nonsynthetic substances may be listed as an allowed nonsynthetic substance on the National List.

⁶⁴ *Id.* at § 205.2.

⁶⁵ See *id.* at § 205.105(c)-(d). The list of allowed nonagricultural substances and nonorganic agricultural substances is found at 7 C.F.R. §§ 205.605 and 205.606, respectively. The list is discussed in Part G of this article.

⁶⁶ 7 C.F.R. § 205.2. The term “nonorganic agricultural substance” is not defined in either the OFPA nor the final rule.

⁶⁷ See *id.* at § 205.105(e)-(g).

⁶⁸ Plaintiffs, including organic alfalfa farmers, challenged the deregulation of genetically-modified alfalfa (Roundup Ready alfafa) prior to the preparation of an Environmental Impact Statement (EIS) to assess the risk of, among other things, gene transmission between the genetically-modified alfalfa and organic and conventional alfalfa. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *4-5 (N.D. Cal. Feb. 13, 2007). The plaintiffs were concerned that such gene transmission would preclude them from marketing their seed as non-genetically engineered. *Id.* at *5. The district court

or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.”⁶⁹ Such methods include “cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology”⁷⁰ (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology).⁷¹ “Excluded methods” do not include “the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.”⁷²

As originally proposed, NOP did not expressly prohibit the use of excluded methods in all aspects of organic production and handling.⁷³ Instead, the prohibition was included within several requirements and scattered throughout the proposed rule.⁷⁴ Because of this, concerns developed over whether it was clear that the prohibition on excluded methods applied to all aspects of organic production and handling.⁷⁵ In the final rule the AMS created a new provision that prohibits the use of excluded methods and included it in the “Applicability” subpart of the final rule to make it clear that use of excluded methods is prohibited in all aspects of organic production and handling.⁷⁶

“Sewage sludge” is “[a] solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works.”⁷⁷ It includes, but is not limited to, “domestic septage; scum or solid removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge.”⁷⁸ It does not include “ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.”⁷⁹

Although the term “biosolids” is commonly used to refer to “sewage sludge,” the term “biosolids” was not used in the final rule because there was not a standardized definition of “biosolids” under federal regulations.⁸⁰ Therefore, the AMS adopted the definition of “sewage sludge” from the definition used in the Environmental Protection Agency’s (“EPA”) regulations governing the use or disposal of “sewage sludge.”⁸¹ The EPA’s definition of “sewage sludge,” and therefore the NOP’s definition of “sewage sludge,” does not include ash, grit, or screenings. Thus, at first glance one might conclude that the use of ash, grit, or screenings is permitted in organic production. As the prefatory comments explain, however,

held that, under the National Environmental Policy Act, an EIS was required prior to the deregulation. *Id.* at *12. The district court permanently enjoined the future planting of Roundup Ready alfalfa, pending the preparation of the EIS; on June 21, 2010, the Supreme Court reversed and remanded for further proceedings. *Monsanto v. Geertson Seed Farms*, 130 S.Ct. 2743,2749 (2010).

⁶⁹ *Id.* at § 205.2.

⁷⁰ When the Organic Trade Association asserted a claim against the state of Ohio, alleging that Ohio’s rule prohibiting rbST-free claims in labeling was preempted by OFPA, the court was not persuaded by the argument. *International Dairy Foods Ass’n v. Boggs*, Nos. 2:08-CV-268, 2:08-CV-629, 2009 WL 937045, at *14 (Apr. 2, 2009). The court held that nothing in the rule prevented a producer from labeling a product as organic, therefore, the rule was not in conflict with NOP. *Id.* at *18.

⁷¹ *Id.*

⁷² *Id.*

⁷³ 65 Fed. Reg. 80,547, 80,554 (prefatory comments to final rule with requests for comments).

⁷⁴ *See id.*

⁷⁵ *See id.*

⁷⁶ *See id.*

⁷⁷ 7 C.F.R. § 205.2.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ 65 Fed. Reg. 80,547, 80,551 (prefatory comments to final rule with requests for comments).

⁸¹ *See id.* *See also* 40 C.F.R. § 503.1(w) (defining “sewage sludge”).

[w]hile commenters are correct that ash, grit, or screenings from the production of sewage sludge are not prohibited by this definition, these materials are prohibited elsewhere in the regulation. The soil fertility and crop nutrient management practice standard in section 205.203 establishes the universe of allowed materials and practices. These allowed materials and practices are crop rotations, cover crops, plant and animal materials (including their ash), nonagricultural, natural materials, and, under appropriate conditions, mined substances of low and high solubility and synthetic materials included on the National List. Ash, grit, or screenings from the production of sewage sludge cannot be included in any of these categories and, therefore, cannot be used in organic production We have not added specific exclusions for sewage sludge, ash, grit, or screenings because these materials are prohibited through other provisions in the practice standard.⁸²

The standards governing ionizing radiation are not found in either the OFPA or the final rule, but are located in the regulations administered by the Food and Drug Administration that govern the use of irradiation in the production, handling, and processing of food.⁸³ The standards governing the use of ionizing radiation are located at 21 C.F.R. § 179.26.⁸⁴

C. Organic Production and Handling Standards

For a producer or handler of a production or handling operation to sell, label, or represent products as “organic,” the producer or handler must comply with all applicable organic production and handling requirements.⁸⁵ The organic production and handling standards contain requirements for organic system plans, crop production, livestock production, and organic handling.

1. Organic System Plan

A producer or handler of a production or handling operation seeking certification, unless exempted or excluded from the certification requirements, must submit an “organic system plan” to its certifying agent or, if applicable, to the governing official of its state’s organic program.⁸⁶ An “organic system plan” is “[a] plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling” as set forth in OFPA and the final rule’s organic production and handling requirements.⁸⁷ The prefatory comments to the final rule explain that the organic system plan “is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification.”⁸⁸

An organic system plan must describe the practices and procedures that the producer or handler will implement and maintain in its operation.⁸⁹ It must also explain how often these practices and procedures will be performed.⁹⁰ The requirement that the organic system plan explain how often

⁸² 65 Fed. Reg. 80,547, 80,551 (prefatory comments to final rule with request for comments).

⁸³ See 7 C.F.R. § 205.105(f).

⁸⁴ 65 Fed. Reg. 80,547, 80,551 (prefatory comments to final rule with request for comments).

⁸⁵ See 7 C.F.R. § 205.200. See also 7 C.F.R. § 205.200 (requiring that production practices implemented pursuant to the organic production and handling requirements “maintain or improve the natural resources of the operation, including soil and water quality”).

⁸⁶ 7 U.S.C. § 6513. See also 7 C.F.R. § 205.201.

⁸⁷ 7 U.S.C. § 6502(13). See also 7 C.F.R. § 205.2.

⁸⁸ 65 Fed. Reg. 80,547, 80,558 (prefatory comments to final rule with request for comments).

⁸⁹ 7 C.F.R. § 205.201(a)(1).

⁹⁰ See *id.*

the practices and procedures will be performed requires, according the prefatory comments, a plan to include an implementation schedule that describes the timing and sequence of activities such as crop rotation, timing and location of soil tests, or the addition of feed supplements to livestock feed.⁹¹

The prefatory comments describe “practices” as tangible techniques, “such as the method of applying manure, the mechanical and biological methods used to prepare and combine ingredients and package finished products, and the measures taken to exclude pests from a facility.”⁹² The comments describe “procedures” as the decision-making process used to implement the plan, such as the process for locating commercially available, organically produced seed.⁹³

The organic system plan must also describe the monitoring practices and procedures that will be used in the operation to verify that the plan is implemented effectively, including a description of how often the monitoring practices and procedures will be performed.⁹⁴ Elaborating on this requirement, the prefatory comments explain that producers and handlers are required to identify “measurable indicators” that will be used to monitor the degree to which the production objectives for the operation are being met.⁹⁵ For example, if an organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals.⁹⁶ Also, if herd health improvement is an objective stated in the plan, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.⁹⁷ The indicators used to monitor a particular organic system plan are determined by the producer or handler through consultation with the certifying agent.⁹⁸

The organic system plan must include a description of the recordkeeping system that a producer or handler will use in its operation to ensure compliance with the recordkeeping requirements for certified operations.⁹⁹ The prefatory comments state that this description must be sufficient to verify and document an audit trail for the operation and that, with respect to “each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title.”¹⁰⁰ With respect to livestock operations, the description must be sufficient to trace each animal from the time it enters the operation until the animal is removed from the operation.¹⁰¹ For handling operations, the operation must trace each product sold, labeled, or represented as “organic” “from the receipt of its constituent ingredients to the sale of the processed product.”¹⁰²

The organic system plan must also include a description of the management practices that a producer or handler will implement “to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances.”¹⁰³ The plan must list the substances that will be used in the operation, including a description of the substances’ “composition, source, location(s) where it will be used, and

⁹¹ 65 Fed. Reg. 80,547, 80,558 (prefatory comments to final rule with request for comments).

⁹² *Id.*

⁹³ *See id.*

⁹⁴ *See id.* at § 205.201(a)(3).

⁹⁵ 65 Fed. Reg. 80,547, 80,559 (prefatory comments to final rule with request for comments).

⁹⁶ *See id.*

⁹⁷ *See id.*

⁹⁸ *See id.*

⁹⁹ 7 C.F.R. § 205.201(a)(4).

¹⁰⁰ 65 Fed. Reg. 80,547, 80,559 (prefatory comments to final rule with request for comments).

¹⁰¹ *See id.*

¹⁰² *Id.*

¹⁰³ 7 C.F.R. § 205.201(a)(5).

documentation of commercial availability, as applicable.”¹⁰⁴ Finally, the plan must include any information required by the certifying agent to verify that a producer or handler of a production or handling operation has complied with NOP requirements.¹⁰⁵

A producer is permitted to submit a substitute organic system a plan that is designed to comply with the requirements of another federal, state, or local government’s regulatory program.¹⁰⁶ Any substituted plan must comply with all applicable organic production and handling requirements.¹⁰⁷

2. Crop Production

The organic production and handling standards governing crop production include (1) land management requirements; (2) soil fertility and crop nutrient management practice requirements; (3) requirements governing the use of seeds and planting stock; (4) requirements governing crop rotation; (5) requirements for crop pest, weed, and disease management; and (6) requirements governing the harvesting of “wild crops.”

(i). Land Requirements

Under the land requirements, “[a]ny field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as ‘organic,’” must not have had any prohibited substances applied to it for the three years preceding the harvest of the crop.¹⁰⁸ The prefatory comments emphasize that this prohibition relates only to the application of the substance and not to the residual effects of the substance.¹⁰⁹ Thus, a producer could apply a prohibited substance to its soil that remains in the soil beyond three years but begin harvesting organic crops three years from the date of application, even though the crop would be in contact with the prohibited substance. The comments state that if the AMS receives evidence that use of this production practice threatens to compromise organic production, steps must be taken to remedy the situation.¹¹⁰

The field or farm parcel must also “[h]ave distinct, defined boundaries and buffer zones¹¹¹ such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.”¹¹² A “buffer zone” is

¹⁰⁴ *Id.* at § 205.201(a)(2).

¹⁰⁵ *See id.* at § 205.201(a)(6). *See also* 7 C.F.R. § 205.201(b) (stating that “[a] producer may substitute a plan prepared to meet the requirements of another Federal, state, or local government regulatory program for the organic system plan,” as long as “the submitted plan meets all the requirements of this subpart.”).

¹⁰⁶ 7 C.F.R. § 205.201(b). The final rule does not state that handlers are permitted to substitute an organic system plan designed to comply with the requirements of another federal, state, or local government’s regulatory program.

¹⁰⁷ *See id.*

¹⁰⁸ *See id.* at § 205.202(b). *See supra* text accompanying notes 54-76.

¹⁰⁹ 65 Fed. Reg. 80,547, 80,568 (prefatory comments to final rule with request for comments).

¹¹⁰ *See id.*

¹¹¹ The Animal and Plant Health Inspection Service, in deciding whether to deregulate Roundup Ready alfalfa, *see* note XX (footnote above), concluded that deregulation would have no environmental impact on organic alfalfa due to the required distinct, defined boundaries and buffer zones required by NOP. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *5 (N.D. Cal. Feb. 13, 2007).

¹¹² 7 C.F.R. § 205.202(c).

[a]n area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.¹¹³

The land requirements also require a producer to use its field or farm parcel in accordance with the soil fertility and crop nutrient management practice requirements, requirements governing the use of seeds and planting stock, requirements for crop rotation, and requirements for crop pest, weed, and disease management.

(ii). Soil Fertility and Crop Nutrient Management Practice Standard

Under the soil fertility and crop nutrient standards, a producer must “select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.”¹¹⁴ A producer must also manage crop nutrients and soil fertility by rotating crops, using cover crops, and by applying plant and animal materials to the land.¹¹⁵

The plant and animal materials must be managed by the producer “to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.”¹¹⁶ Plant and animal materials include raw animal manure, which must be composted unless (1) it is used to produce a crop that is not for human consumption; (2) put into the soil at least 120 days before “the harvest of a product whose edible portion has direct contact with the soil surface or soil particles”; or (3) put into the soil at least “90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles.”¹¹⁷

Plant and animal materials also include composted plant and animal materials that are produced through a process that creates an initial carbon to nitrogen ratio “of between 25:1 and 40:1,” maintained at a temperature between 131 degrees Fahrenheit and 170 degrees Fahrenheit for three days using an in-vessel or static aerated pile system, or maintained at a temperature of between 131 degrees Fahrenheit and 170 degrees Fahrenheit “for 15 days using a windrow composting system, during which period, the material be must turned a minimum of five times.”¹¹⁸ “Compost” is “[t]he product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil.”¹¹⁹ Plant and animal materials include uncomposted plant materials as well.¹²⁰

The prefatory comments to the final rule explain that the 25:1 to 40:1 range is used to ensure that producers will “establish appropriate conditions under which the additional requirements in this practice standard, most notably the time and temperature criteria, can be achieved with minimal

¹¹³ *Id.* at 205.2.

¹¹⁴ *See id.* at § 205.203(a).

¹¹⁵ *See id.* at § 205.203(b).

¹¹⁶ *Id.* at § 205.203(c).

¹¹⁷ *Id.* at § 205.203(c)(1)(i) - (iii).

¹¹⁸ *Id.* at § 205.203(c)(2)(i)-(iii).

¹¹⁹ *Id.* at § 205.2.

¹²⁰ *See id.* at § 205.203(c)(1)-(3). Composted plant and animal materials must be produced through a specific scientific process. This process is set forth in the regulations and is not discussed in this article.

producer oversight.”¹²¹ The comments also state that the producer is required to develop in its organic system plan the management strategies and monitoring techniques that will be used in its composting system.¹²²

A producer may use, for the purpose of managing soil fertility and crop nutrients, (1) crop nutrients or soil amendments that are listed as an allowed synthetic substance on the National List; (2) a “mined substance of low solubility”; (3) a mined substance of high solubility, as long as the mined substance is used in accordance with the conditions set forth on the National List for prohibited nonsynthetic materials prohibited from use in organic crop production; (4) ash derived from the burning of a plant or animal material, subject to certain exceptions; and (5) “plant or animal material that has been chemically altered by a manufacturing process,” subject to certain exceptions.¹²³

Ash derived from the burning of plant or animal material cannot be used in organic crop production if the burned material has been “treated or combined with a prohibited substance.”¹²⁴ Ash cannot be used if it is listed as a prohibited nonsynthetic substance on the National List.¹²⁵ In addition, ash cannot be used in crop production if it is produced from burning that was conducted for the purpose of disposing of crop residues produced on an operation.¹²⁶ “Crop residues” are plant parts, including stalks, stems, leaves, roots, and weeds, that remain in a field after a crop is harvested.¹²⁷ Burning may be used, however, if it is used to curb the spread of disease or to stimulate seed germination.¹²⁸ A plant or animal material that has been chemically altered by a manufacturing process can only be used if the plant or animal material is listed as an allowed synthetic substance on the National List.¹²⁹

A producer cannot use fertilizers or composted materials containing a synthetic substance unless it is listed as an allowed substance on the National List.¹³⁰ A producer is also prohibited from using sewage sludge, also referred to as biosolids, as defined by the Environmental Protection Agency’s regulations governing the use and disposal of biosolids.¹³¹

(iii). Seeds and Planting Stock Practice Standard

As a general rule, a producer must use organically grown seeds, annual seedlings, and planting stock in their operations.¹³² An “annual seedling” is “[a] plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.”¹³³ “Planting stock” is “[a]ny plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.”¹³⁴

¹²¹ 65 Fed. Reg. 80,547, 80,565 (prefatory comments to final rule with request for comments).

¹²² *See id.*

¹²³ 7 C.F.R. § 205.203(d)(1)-(5).

¹²⁴ *Id.* at § 205.203(d)(4).

¹²⁵ *See id.*

¹²⁶ *See id.* at § 205.305(e)(3).

¹²⁷ *See id.* at § 205.2.

¹²⁸ *See id.*

¹²⁹ *See id.* at § 205.203(5).

¹³⁰ *See id.* at § 205.203(e)(2).

¹³¹ *See id.* *See generally* 40 C.F.R. Part 503. *See supra* text accompanying notes 69-76.

¹³² *See* 7 C.F.R. § 205.204(a).

¹³³ *Id.* at § 205.2.

¹³⁴ *Id.*

There are five exceptions to this general rule. First, a producer may use nonorganically produced, untreated seeds and planting stock “when an equivalent organically produced variety is not commercially available.”¹³⁵ However, organically produced seeds must always be used when producing edible sprouts.¹³⁶ Second, nonorganically produced seeds and planting stock that have been treated with a substance listed as an allowed substance on the National List of synthetic substances “may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available.”¹³⁷ Third, nonorganically produced annual seedlings may be used in an organic crop production operation if a temporary variance has been granted.¹³⁸ The requirements and conditions for obtaining a temporary variance are discussed below. Fourth, nonorganically produced planting stock that will be used “to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year.”¹³⁹ Fifth, seeds, annual seedlings, and planting stock that have been treated with a prohibited substance may be used if the application of the substance is required by either federal or state phytosanitary regulations.¹⁴⁰

(iv). Crop Rotation Practice Standard

A producer must implement a “crop rotation” practice in its operation.¹⁴¹ “Crop rotation” is

[t]he practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.¹⁴²

The crop rotation must (1) maintain or improve “soil organic matter content”; (2) allow for pest management in annual and perennial crops; (3) manage plant nutrients; and (4) provide for erosion control.¹⁴³ Crop rotation includes, but is not limited to, “sod, cover crops, green manure crops, and catch crops” that meet these four requirements.¹⁴⁴

(v). Crop Pest, Weed, and Disease Management Practice Standard

A producer must also implement management practices designed to prevent crop pests, weeds, and diseases.¹⁴⁵ The required management practices include, but are not limited to (1) the crop rotation practice standard; (2) soil and crop nutrient management practices standard; (3) sanitation measures designed to remove “disease vectors, weed seeds, and habitat for pest organisms”; and (4) cultural methods that “enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevent prevalent pests, weeds, and diseases.”¹⁴⁶

¹³⁵ *Id.* at § 205.204(a)(1).

¹³⁶ *See id.*

¹³⁷ *See id.* at § 205.204(a)(2).

¹³⁸ *See id.* at § 205.204(a)(3). The provisions governing when a temporary variance may be granted pursuant to § 205.204(a)(3) are found at 7 C.F.R. § 205.290.

¹³⁹ *See* 7 C.F.R. § 205.204(a)(4).

¹⁴⁰ *See id.* at § 205.204(a)(5).

¹⁴¹ *See id.* at § 205.205.

¹⁴² *See id.* at § 205.2.

¹⁴³ *See id.* at § 205.205(a) - (d).

¹⁴⁴ *Id.*

¹⁴⁵ *See id.* at § 205.206.

¹⁴⁶ *Id.* at § 205.206(a)(1) - (2).

“Disease vectors” are “[p]lants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.”¹⁴⁷ “Cultural methods” are methods that are “used to enhance crop health and prevent weed, pest, or disease problems without the use of substances.”¹⁴⁸

Pests may be controlled by mechanical or physical methods that include using predators or parasites of the pest species, development of habitat that supports natural enemies of the pest species, and nonsynthetic means such as traps and repellents.¹⁴⁹ Weeds may be controlled by mulching with biodegradable materials or by plastic or other types of synthetic mulches if removed from the field when the growing or harvest season has ended.¹⁵⁰ “Mulch” is “[a]ny nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.”¹⁵¹

Hand weeding, mechanical cultivation, mowing, livestock grazing, and flame, heat, or electrical means may also be used to control weeds.¹⁵² Disease problems can be controlled by using management practices that prevent the spread of disease organisms or by applying “nonsynthetic biological, botanical, or mineral inputs.”¹⁵³ If any of these practices are used and do not sufficiently control pests, weeds, or diseases, a “biological or botanical substance” included on the National List of allowed synthetic substances may be used.¹⁵⁴ The conditions for using the substance must be included in the organic system plan.¹⁵⁵ Finally, a producer is prohibited from using lumber treated with arsenate or any other prohibited materials “for new installations or replacement purposes in contact with soil or livestock.”¹⁵⁶

(vi). Wild Crop Harvesting Practice Standard

In addition to the standards discussed above, the final rule establishes requirements that pertain specifically to the production and handling of “wild crops.”¹⁵⁷ A “wild crop” is “[a]ny plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.”¹⁵⁸

Any wild crop that is intended to be sold, labeled, or represented as “organic” must be harvested from an area that has not had any prohibited substance applied to it for the three years preceding the harvest of the crop.¹⁵⁹ Wild crop harvesting must be done in a manner that is not destructive to the environment and that “will sustain the growth and production of the wild crop.”¹⁶⁰

¹⁴⁷ *Id.* at § 205.2.

¹⁴⁸ *Id.* See also 7 C.F.R. § 205.2 (stating that examples of cultural methods include “the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks”).

¹⁴⁹ See 7 C.F.R. § 205.206(b)(1)-(3).

¹⁵⁰ See *id.* at § 205.206(c)(1), (6).

¹⁵¹ *Id.* at § 205.2.

¹⁵² See *id.* at § 205.206(c)(2)-(5).

¹⁵³ See *id.* at § 205.206(d)(1)-(2).

¹⁵⁴ See *id.* at § 205.206(e).

¹⁵⁵ See *id.*

¹⁵⁶ *Id.* at § 205.206(f).

¹⁵⁷ See *id.* at § 205.207.

¹⁵⁸ *Id.* at § 205.2.

¹⁵⁹ See *id.* at § 205.207(a). See also 7 C.F.R. § 205.105.

¹⁶⁰ 7 C.F.R. § 205.207(b).

The prefatory comments explain that the term “site” is used in the final rule’s definition of “wild crop,” rather than the term “land,” which was the term used in the proposed rule, to make clear its intent that the final rule allows for the certification and harvest of aquatic plants.¹⁶¹ The comments also explain that producers of wild crops must comply with the applicable organic system plan requirements.¹⁶² Finally, the comments state that the AMS expects certifying agents to incorporate mapping and boundary conditions into the organic system plan requirements for operations that harvest wild crops.¹⁶³

3. Livestock Production Requirements

The organic production and handling requirements for livestock production establish requirements governing the (1) origins of livestock; (2) composition of livestock feed; (3) health care practices for livestock; and (4) living conditions for livestock.

(i). Origin of Livestock

As a general rule, livestock products intended to be sold, labeled, or represented as “organic” must be produced from livestock raised “under continuous organic management from the last third of gestation or hatching.”¹⁶⁴ There are three exceptions to this general rule.

First, poultry or edible poultry products must be raised under continuous organic management from no later than the second day of life.¹⁶⁵ Second, milk or milk products must be produced from dairy animals “that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products”¹⁶⁶ However, in the event that a producer converts an “entire, distinct herd” of dairy animals from a nonorganic production system into an organic one, the producer may provide for the first nine months of the first year in which the herd is converted “a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with [the] organic crop requirements.”¹⁶⁷ For the final three months of the year, producers may provide feed to the herd in accordance with the livestock feed requirements.¹⁶⁸

Whenever a herd is converted, however, producers must raise all dairy animals from the last third of gestation in accordance with applicable standards set forth in the OFPA and the final rule.¹⁶⁹ The prefatory comments state that “the conversion provision cannot be used routinely to bring nonorganically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.”¹⁷⁰

The third exception applies to “breeder livestock.”¹⁷¹ “Breeder livestock” are “[f]emale livestock whose offspring may be incorporated into an organic operation at the time of their birth.”¹⁷² Breeder

¹⁶¹ 65 Fed. Reg. 80,547, 80,566 (prefatory comments to final rule with request for comments).

¹⁶² *See id.*

¹⁶³ *See id.*

¹⁶⁴ *See* 7 C.F.R. § 205.236(a).

¹⁶⁵ *See id.*

¹⁶⁶ *Id.* at § 205.236(a)(2).

¹⁶⁷ *Id.* at § 205.236(a)(2)(i).

¹⁶⁸ *See id.* at § 205.236(a)(2)(ii).

¹⁶⁹ *See id.* at § 205.236(a)(2)(iii).

¹⁷⁰ 65 Fed. Reg. 80,547, 80,570 (prefatory comments to final rule with request for comments).

¹⁷¹ 7 C.F.R. § 205.236(a)(3).

¹⁷² *Id.* at § 205.2.

stock can be transferred from a nonorganic operation to an organic one at any time.¹⁷³ If breeding stock transferred into the operation is gestating and any offspring of that animal are to be raised as organic, then the breeding stock must be transferred no later than the last third of gestation.¹⁷⁴

A livestock producer is prohibited from selling, labeling, or representing livestock or edible livestock products as “organic” if the livestock has been transferred from an organic operation to a nonorganic one.¹⁷⁵ A producer is also prohibited from selling, labeling, or representing any breeder stock or dairy stock as “slaughter stock” if the breeder stock has not been “under continuous organic management since the last third of gestation.”¹⁷⁶ “Slaughter stock” is “[a]ny animal that is intended to be slaughtered for consumption by humans or other animals.”¹⁷⁷ Finally, a livestock producer is required to “maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.”¹⁷⁸

(ii). Livestock Feed

As a general rule, livestock must be given a feed ration that is composed entirely of organically produced agricultural products and, if applicable, organically handled agricultural products.¹⁷⁹ The term “feed” is defined as “edible materials which are consumed by livestock for their nutritional value.”¹⁸⁰ “Feed” includes grains, hay, silage, pasture, and fodder.¹⁸¹ Synthetic and nonsynthetic substances that are listed as allowed on the National List may be used as feed additives and supplements.¹⁸² A “feed additive” is a substance that is added to feed “in micro quantities to fulfill a specific nutritional need,” such as “essential nutrients in the form of amino acids, vitamins, and minerals.”¹⁸³ A “feed supplement” is a

combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be . . . [d]iluted with other feeds when fed to livestock; . . . [o]ffered free choice with other parts of the ration if separately available; or . . . [f]urther diluted and mixed to produce a complete feed.¹⁸⁴

A livestock producer may not use animal drugs to promote an animal’s growth, provide feed supplements or additives in excess of the amount needed for the animal’s nutrition and health maintenance, use plastic feed pellets for roughage, or use feed formulas that contain urea or manure.¹⁸⁵ An “animal drug” is “[a]ny drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended . . . , that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.”¹⁸⁶ Producers are also prohibited from feeding “mammalian or poultry slaughter by-products to mammals or poultry” and from using “feed,

¹⁷³ See *id.* at § 205.236(a)(3).

¹⁷⁴ See *id.*

¹⁷⁵ See *id.* at § 205.236(b)(1).

¹⁷⁶ See *id.* at § 205.236(b)(2).

¹⁷⁷ *Id.* at § 205.2.

¹⁷⁸ *Id.* at 205.236(c).

¹⁷⁹ See *id.* at § 205.237(a).

¹⁸⁰ *Id.* at § 205.2.

¹⁸¹ See *id.* See also 7 C.F.R. § 205.237(a).

¹⁸² 7 C.F.R. § 205.237(a).

¹⁸³ See *id.* at § 205.2.

¹⁸⁴ *Id.*

¹⁸⁵ See *id.* at § 205.237(b)(1) - (4).

¹⁸⁶ *Id.* at § 205.2. See also 21 U.S.C. §§ 301-395 (Federal Food, Drug, and Cosmetic Act) & 21 U.S.C. § 321(g)(1)-(2) (defining “drug” and “counterfeit drug”).

feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.¹⁸⁷ Additionally producers cannot provide “feed or forage to which any antibiotic including inophores had been added” and may not “prevent, withhold, restrain, or otherwise restrict ruminant animals from actively obtaining feed grazed from pasture during the grazing season.”¹⁸⁸

New grazing provisions were adopted in February 2010 and go into effect June 17, 2010. These new regulations require the producer to provide “not more than an average of 70 percent of a ruminant’s dry matter demand from dry matter fed.”¹⁸⁹ This is calculated as an average over the entire grazing season for each type and class of animal.¹⁹⁰ Producers must graze ruminant animals throughout the entire grazing season for the geographic region, which must be at least 120 days per calendar year¹⁹¹. Additionally, producers must provide a pasture of “sufficient quality and quantity to graze throughout the grazing season” and must provide “all ruminants under the organic system plan with an average of not less than 30 percent of their dry matter intake from grazing.”¹⁹² There are exceptions to these grazing requirements for breeding bulls and livestock that are temporarily denied pasture access for approved reasons.¹⁹³

The new grazing regulations also include recordkeeping requirements. Producers are required to “describe the total feed ration for each type and class of animal.” This must include all feed produced on-farm, all feed purchased from off-farm sources, the percentage of each feed type (including pasture) in the total ration, and a list of all feed supplements and additives.¹⁹⁴ Additional recordkeeping requirements include documenting “the amount of each type of feed actually fed to each type and class of animal,” “changes that are made to all rations throughout the year in response to seasonal grazing changes,” and “the method for calculating dry matter demand and dry matter intake.”¹⁹⁵

(iii). Livestock Health Care Practice Standard

An organic livestock producer is required to “establish and maintain preventive livestock health care practices.”¹⁹⁶ These practices include selecting livestock suited for site-specific conditions and for resistance to prevalent diseases and parasites, providing a feed ration that satisfies nutritional requirements for particular livestock, and establishing housing, pasture conditions, and sanitation practices that minimize the spreading of diseases and parasites.¹⁹⁷

A producer must also administer vaccines and other “veterinary biologics” when needed.¹⁹⁸ “Biologics” are defined as “[a]ll viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.”¹⁹⁹

¹⁸⁷ 7 C.F.R. § 205.237(b)(5)-(6).

¹⁸⁸ *Id.* at § 205.237(b)(7)-(8).

¹⁸⁹ *Id.* at § 205.237 (c)(1). Dry matter fed does not include dry matter grazed from residual forage or vegetation rooted in pasture. *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.* at § 205.237 (c)(2).

¹⁹³ *Id.* at § 205.237 (c)(2)(i)-(ii). *See also* 7 C.F.R. § 205.239(b) (1)-(8) and 7 C.F.R. § 205.239 (c)(1)-(3)

¹⁹⁴ *Id.* at § 205.237(d)(1).

¹⁹⁵ *Id.* at § 205.237(d)(2)-(4).

¹⁹⁶ 7 C.F.R. § 205.238(a)

¹⁹⁷ *See id.* at § 205.238(a)(1)-(3).

¹⁹⁸ *See id.* at § 205.238(6). *See supra* text accompanying note 60.

¹⁹⁹ *Id.* at § 205.2.

In addition, a producer must provide living conditions that allow “for exercise, freedom of movement, and reduction of stress” appropriate for the particular species of livestock.²⁰⁰ Physical alterations to an animal that are necessary to promote the welfare of the animal, such as debeaking poultry or removing horns from livestock, must be done in a manner that minimizes the animal’s pain and stress.²⁰¹

When use of these preventive practices and veterinary biologics do not sufficiently prevent sickness in livestock, a producer is allowed to administer synthetic medications to the livestock, as long as the medication is listed on the National List as a synthetic substance allowed for use in organic livestock production.²⁰² Parasiticides that are included on the National List of allowed synthetic substances may be used on breeder stock and dairy stock, subject to certain conditions.²⁰³ For breeder stock, the parasiticide must be used before the last third of gestation, but not during lactation for offspring intended to be sold, labeled, or represented as “organic.”²⁰⁴ The parasiticide must be applied to dairy stock at least ninety days before the production of milk or milk products intended to be sold, labeled, or represented as “organic.”²⁰⁵

A producer is prohibited from selling, labeling, or representing any animal or edible product derived from an animal that has been treated with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for organic livestock production, or any nonsynthetic substance not included on the National List of nonsynthetic substances allowed for use in organic livestock production.²⁰⁶ A producer is prohibited from administering any animal drug, other than vaccinations, when there is no presence of illness in the livestock.²⁰⁷ In addition, a producer is prohibited from administering hormones for the purpose of growth promotion, administering synthetic parasiticides to livestock on a routine basis, and from administering parasiticides to slaughter stock.²⁰⁸ A producer is also prohibited from administering animal drugs in violation of the Federal Food, Drug, and Cosmetic Act.²⁰⁹

Finally, a livestock producer is prohibited from denying medical treatment to a sick animal with the intention of preserving the animal’s organic status.²¹⁰ A producer must use “all appropriate medications . . . to restore an animal to health when methods acceptable to organic production fail.”²¹¹ Livestock that has been treated with a prohibited substance must be clearly identified and cannot be sold, labeled, or represented as organically produced.²¹²

(iv). Livestock Living Conditions

A livestock producer must create and maintain living conditions for livestock that

²⁰⁰ See *id.* at § 205.238(a)(4).

²⁰¹ See *id.* at § 205.238(a)(5). See also 65 Fed. Reg. 80,547, 80,572-73 (prefatory comments to final rule with request for comments) (giving debeaking and horn removal as examples of physical alterations).

²⁰² See 7 C.F.R. § 205.238(b). This list is found at 7 C.F.R. § 205.603.

²⁰³ See *id.* at § 205.238(b)(1)-(2).

²⁰⁴ See *id.* at § 205.238(b)(1).

²⁰⁵ See *id.* at § 205.238(b)(2).

²⁰⁶ See *id.* at § 205.238(c)(1).

²⁰⁷ See *id.* at § 205.238(c)(2).

²⁰⁸ See *id.* at § 205.238(c)(3)-(5). See *id.* at § 205.2 (defining “routine use of parasiticide”).

²⁰⁹ See *id.* at § 205.238(c)(6).

²¹⁰ See *id.* at § 205.238(7).

²¹¹ See *id.*

²¹² See *id.*

accommodate the health and natural behavior of animals on that producer's operation.²¹³ Such living conditions include access to fresh air, the outdoors, exercise, clean and dry bedding, and access to pasture for ruminants.²¹⁴ Living conditions also include providing livestock access to shelter that allows for "natural maintenance, comfort behaviors, and opportunity to exercise," establishes a temperature level and air circulation suitable to the particular species of livestock, and reduces the threat of livestock injury.²¹⁵ A producer is allowed, however, to temporarily confine an animal as a result of inclement weather, the animal's stage of production, existing conditions that could jeopardize the animal's health, safety, or well-being, or when soil or water quality is threatened.²¹⁶

The manure from a livestock operation must be managed "in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients."²¹⁷ Under the final rule, "manure" is defined as "[f]eces, urine, other excrement, and bedding produced by livestock that has not been composted."²¹⁸

4. Handling Requirements

The handling requirements include general requirements for the handling of "organic" products, standards for managing pests in organic handling facilities, and handling requirements for preventing the commingling and contact of organic products with prohibited substances.

(i). Organic Handling Requirements

A handler may use mechanical or biological methods to process organic products "for the purpose of retarding spoilage or otherwise preparing the agricultural product for market."²¹⁹ Such methods include, but are not limited to "cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container."²²⁰

A handler may use nonagricultural substances and nonorganically produced agricultural products "[i]n or on a processed agricultural product intended to be sold, labeled, or represented as 'organic,'" if the substance or product is not commercially available in organic form.²²¹ Nonagricultural substances and nonorganically produced agricultural products may also be used if the substance or product is used "[i]n or on a processed agricultural product intended to be sold, labeled, or represented as 'made with organic (specified ingredients or food group(s)).'"²²² However, in both instances the nonagricultural substance or nonorganically produced product that is used must be listed as an allowed substance or product on the National List.²²³

²¹³ See *id.* at § 205.239(a).

²¹⁴ See *id.* at § 205.239(a)(1) - (3).

²¹⁵ See *id.* at § 205.239(4)(i)-(iii).

²¹⁶ See *id.* at § 205.239(b).

²¹⁷ *Id.* at § 205.239(c).

²¹⁸ *Id.* at § 205.2.

²¹⁹ *Id.* at § 205.270(a).

²²⁰ *Id.* See also 7 C.F.R. § 205.2 (defining "processing").

²²¹ 7 C.F.R. § 205.270(b)(1). See *supra* text accompanying note 60 (defining "nonagricultural substance").

²²² 7 C.F.R. § 205.270(b)(2). The labeling phrase "made with organic (specified ingredients or food group(s))" is one the labeling categories created under the NOP. The labeling categories and other labeling requirements are discussed in Part D of this article.

²²³ 7 C.F.R. § 205.270(b). See § 205.605 for the list of allowable nonagricultural substances and § 205.606 for the list of allowable nonorganically produced agricultural products.

A handler is prohibited from using ionizing radiation in or on agricultural products intended to be sold, labeled, or represented as “organic.”²²⁴ Ionizing radiation cannot be used in or on any ingredients labeled as “organic.”²²⁵ Handlers are also prohibited from using excluded methods, except for vaccines that are listed as approved on the National List.²²⁶

A handler is also prohibited from using in or on agricultural products intended to be sold, labeled, or represented as “organic,” or in or on any ingredients labeled as “organic,” any “volatile synthetic solvent or other synthetic processing aid,” unless the solvent or aid is listed as allowed on the National List.²²⁷ However, nonorganic ingredients used in products that are labeled as “made with organic (specified ingredients or food group(s))” are not subject to this prohibition.²²⁸

(ii). Facility Pest Management

A handler of an organic facility is required to implement practices designed to prevent pests.²²⁹ Permitted practices include, but are not limited to, the removal of habitat, food sources, and breeding areas for pests; prevention of pest access to handling facilities; and manipulation of environmental factors, such as humidity and temperature, designed to prevent pest reproduction.²³⁰ A handler of an organic facility may manage existing pests by using mechanical or physical control such as traps, light, or sound.²³¹ A handler can also use lures and repellents that contain nonsynthetic or synthetic substances as long as those substances are used in accordance with the standards set forth in the National List.²³² If neither the preventative pest practices or practices for controlling pests existing in the facility are successful, a nonsynthetic or synthetic substance listed as allowed on the National List may be applied to the organic facility.²³³

In the event that none of the pest management practices described in the previous paragraph effectively prevent or control pests in an organic facility, a synthetic substance not allowed under the National List may be used.²³⁴ In order to take this final measure, however, the handler and the certifying agent must agree on the substance that will be used, the method of its application, and the measures that will be implemented to prevent contact of organic products or ingredients with the substance.²³⁵

If a synthetic or nonsynthetic substance is used to control pests, the handler must update the handling operation’s organic system plan to indicate that the substance was used and how the

²²⁴ 7 C.F.R. § 205.270(c)(1). See *supra* text accompanying notes 61-76.

²²⁵ See 7 C.F.R. § 205.270(c)(1).

²²⁶ See *id.* See also *id.* at § 205.105(e)-(f).

²²⁷ 7 C.F.R. § 205.270(c)(2).

²²⁸ See *id.*

²²⁹ See *id.* at § 205.271(a). The first paragraph of the requirements contained in the facility pest management practice standard, § 205.271(a), states that the “producer or handler of an organic facility must use management practices to prevent pests” All other provisions in § 205.271 refer only to handlers, as do the prefatory comments accompanying this particular requirement. The reader should be aware that the discussion of the pest management standard in this article refers only to handlers and does not refer to producers.

²³⁰ 7 C.F.R. § 205.271(a)(1)-(3). Environmental factors include such things as light, temperature, air flow, and humidity.

²³¹ See *id.* at § 205.271(b)(1).

²³² See *id.* at § 205.271(b)(2).

²³³ See *id.* at § 205.271(c).

²³⁴ See *id.* at § 205.271(d).

²³⁵ See *id.* Presumably, this requirement applies irrespective of whether the synthetic or nonsynthetic substance is listed as prohibited or allowed in the National List.

substance was applied.²³⁶ The updated plan must also list all of the measures that were implemented to prevent contact with organic products and ingredients in the facility and the substance that was used.²³⁷

Notwithstanding any of these pest management practices, “a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations.”²³⁸ In such event, however, the handler must implement measures to prevent contact of organic products and ingredients with the substance used.²³⁹

(iii). Prevention of Commingling and Contact With Prohibited Substances

The organic production and handling requirements also set forth specific standards for preventing the commingling and contact of organic between nonorganic products organic products with prohibited substances.²⁴⁰ This standard prohibits a handler from using “packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant.”²⁴¹ It also prohibits a handler from using or reusing

any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.²⁴²

5. Temporary Variances

Under certain circumstances, producers and handlers can obtain temporary variances from the (1) soil fertility and crop nutrient management standard; (2) seed and planting stock standard; (3) crop rotation standard; (4) crop, pest, weed, and disease management standard; (5) origin of livestock standard; (6) livestock feed standard; (7) livestock health care practice standard; (8) livestock living conditions standard; (9) organic handling requirements; (10) facility pest management standard; and the (11) commingling and contact with prohibited substance prevention standard.²⁴³ The Secretary may issue a temporary variance due to natural disasters, “[d]amage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption[,]” and for certain research purposes.²⁴⁴

If a temporary variance is established, the Secretary must provide written notification to certifying agents “applicable to the certifying agent’s [sic] certified production or handling operations and specify the period it shall remain in effect, subject to extension”²⁴⁵ Once a temporary variance has been established, the certifying agent is required to notify any operations that it certifies

²³⁶ See *id.* at § 205.271(e).

²³⁷ See *id.*

²³⁸ See *id.* at § 205.271(f).

²³⁹ See *id.*

²⁴⁰ See *id.* at § 205.272(a).

²⁴¹ See *id.* at § 205.272(b)(1). The labels, labeling, and market information requirements are located at subpart D of the regulations and are located at §§ 205.300 - 205.311.

²⁴² 7 C.F.R. § 205.272(b)(1).

²⁴³ See *id.* at § 205.290(a). Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

²⁴⁴ 7 C.F.R. § 205.290(a)(1)-(3).

²⁴⁵ *Id.* at § 205.290(c).

to which the variance is applicable.²⁴⁶

D. Labels, Labeling, and Market Information

Numerous NOP standards, requirements, and restrictions govern the labeling and use of marketing information for organically produced products. More specifically, there are (1) guidelines governing the use of the term “organic”; (2) specific labeling categories based on product composition; (3) requirements for what terms and references can be displayed in conjunction with each of the labeling categories; (4) methods for calculating the percentage of organic composition in a product; (5) labeling requirements for livestock feed; (6) standards for labeling nonretail containers used for shipping and storage of “organic” products; (7) standards for labeling products in other than packaged form sold, labeled, or represented as “organic” at the point of retail sale; (8) labeling requirements and restrictions for products produced on an exempted or excluded operation; and (9) standards governing the use of the USDA seal on organically produced products. The labels, labeling, and market information requirements are designed to prevent abuses in the marketing of organic products and to assure consumers that organic products and ingredients are labeled in a consistent, reliable, and predictable manner.

The prefatory comments state that the labels, labeling, and market information requirements must be implemented in such a way that they do not conflict with other federal labeling requirements.²⁴⁷ The comments also state that the implementing regulations for the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act must be followed when labeling meat, poultry, and egg products.²⁴⁸ In addition, the comments state that the Food and Drug Administration’s regulations governing the placement of information on food product packages, the Federal Trade Commission regulations implemented pursuant to the Fair Packaging and Labeling Act, and the Alcohol Tobacco and Firearms regulations implementing the Federal Alcohol Administration Act must also be followed, as applicable to the nature of the particular product.²⁴⁹

The final rule defines a “label” as a

display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.²⁵⁰

²⁴⁶ See *id.* at § 205.290(d). See also § 205.290(b) (stating that the governing state official or certifying agent for a State organic program may recommend that a temporary variance be established, but such recommendation must be based on at least one of the reasons listed in § 205.290(a)(1)-(3)).

²⁴⁷ 65 Fed. Reg. 80,547, 80, 576 (prefatory comments to final rule with request for comments).

²⁴⁸ See *id.* See also 9 C.F.R. pt. 317 (implementing regulations for the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act); 21 U.S.C. §§ 601-695 (Federal Meat Inspection Act); 21 U.S.C. §§ 451-470 (Poultry Products Inspection Act); and 21 U.S.C. §§ 1031-1056 (Egg Products Inspection Act).

²⁴⁹ 65 Fed. Reg. 80,547, 80,576 (prefatory comments to final rule with request for comments). See also 16 C.F.R. pt. 500 (Federal Trade Commission implementing regulations under the Fair Packaging and Labeling Act); 27 C.F.R. pts. 4,5, and 7 (Alcohol Tobacco and Firearms regulations implementing the Federal Alcohol Administration Act).

²⁵⁰ 7 C.F.R. § 205.2.

“Labeling” is “[a]ll written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.”²⁵¹

1. Use of the Term “Organic”

A person may only “sell or label an agricultural product as organically produced . . . if such product is produced and handled in accordance” with OFPA and the final rule.²⁵² In addition, “no person may affix a label to, or other [sic] provide market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance” with the OFPA and the final rule.²⁵³

Currently, USDA does not regulate the labeling of organic personal care products.²⁵⁴ Producers and handlers of organic personal care products may voluntarily seek USDA certification; provided NOP standards are met, such products may be labeled as USDA-certified organic.²⁵² In 2009, All One God Faith, Inc. filed suit to enjoin producers from labeling personal care products as organic unless the products met NOP standards.²⁵³ The court, based upon the primary jurisdiction doctrine, declined to impose standards upon personal care products when USDA had not imposed such standards.²⁵⁴ The court stated that USDA has exclusive jurisdiction over the labeling and marketing of “organic” products.²⁵⁵ At present, following a recommendation by the NOSB, NOP is considering whether it will begin to regulate organic personal care products.²⁵⁶

A product that is produced in the United States for export to a foreign country that is “produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer.”²⁵⁷ However, the shipping containers and documents must comply with the requirements for labeling nonretail containers that are used only for shipping or storage of “organic” products.²⁵⁸ A product that is produced in a foreign country and exported into the United States must be produced and handled in accordance with NOP certification requirements and must be labeled in accordance with the applicable labels, labeling, and market information requirements.

In 2007, the California Court of Appeal for the Fifth District held that a contract for the sale of “NOP organic” raisins merely required organic certification under NOP.²⁵⁹ In this case, the defendant

²⁵¹ *Id.*

²⁵² 7 U.S.C. § 6505(a)(1)(A). *See also* 7 C.F.R. § 205.300(a).

²⁵³ 7 U.S.C. § 6505(a)(1)(B).

²⁵⁴ *All One God Faith, Inc. v. Hain Celestial Group, Inc.*, No. C09-03517 JF (HRL), 2009 WL 4907433, at *5 (N.D.Cal. Dec. 14, 2009).

²⁵² *Id.* at *4-5.

²⁵³ *Id.* at *8.

²⁵⁴ *Id.* at *7.

²⁵⁵ *Id.* at *8.

²⁵⁶ Memorandum from the National Organic Program to the National Organic Standards Board (April 23, 2010) (on file with USDA).

²⁵⁷ 7 C.F.R. § 205.300(b).

²⁵⁸ *See id.*

²⁵⁹ *Horne v. Global Organics, Ltd.*, No. F050698, 2007 WL 4157598, at *9 (Cal.App. 5 Dist. Nov. 26, 2007).

argued that the plaintiff had breached the contract by failing to supply raisins properly certified as organic for shipment to the European Union.²⁶⁰ The court stated that, because the terms of the contract merely called for “NOP organic” raisins, the supplier was not responsible for providing more than NOP certification.²⁶¹

In the prefatory comments to the final rule, the AMS states that OFPA

provides the Secretary with the authority to review use of the term, “organic,” in agricultural product names and the names of companies that produce agricultural products. While we believe that the term, “organic,” in a brand name context does not inherently imply an organic production or handling claim and, thus, does not inherently constitute a false or misleading statement, we intend to monitor the use of the term in the context of the entire label. We will consult with the [Federal Trade Commission] and [the Food and Drug Administration] regarding product and company names that may misrepresent the nature of the product and take action on a case-by-case basis.²⁶²

2. Labeling Categories and Calculation of Organic Composition

There are four labeling categories for organic products and products with organic ingredients: (1) products sold, labeled, or represented as “100 percent organic”; (2) products sold, labeled, or represented as “organic”; (3) products sold, labeled, or represented as “made with organic (specified ingredients or food group(s))”; and (4) products with less than seventy percent organically produced ingredients.²⁶³ The labeling category that a particular product falls within is based entirely on the percentage of organic composition in that particular product.

There are three formulas used to calculate the percentage of organic composition in a product.²⁶⁴ One formula applies to products containing ingredients that are in solid form, another to products containing ingredients that are liquid in form, and another to products containing ingredients in both solid and liquid form. Water and salt are excluded as ingredients in all three formulas. The percentages that are calculated under each of these formulas must be rounded down to the nearest whole number.²⁶⁵

For products containing ingredients that are in solid form only, the percentage of organic composition is determined by “[d]ividing the total net weight . . . of combined organic ingredients at formulation by the total weight . . . of the finished product.”²⁶⁶ For products containing only liquid ingredients, organic composition is determined by “[d]ividing the fluid volume of all organic ingredients . . . by the fluid volume of the finished product”²⁶⁷ If a product containing only liquid ingredients is “identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.”²⁶⁸ For products containing ingredients in both liquid and solid form,

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² 65 Fed. Reg. 80,576, 80,547 (prefatory comments to final rule with request for comments).

See also 7 U.S.C. § 6519(b) (authorizing the Secretary to review use of the term “organic”).

²⁶³ See 7 C.F.R. § 205.301.

²⁶⁴ See *id.* at § 205.302.

²⁶⁵ See *id.* at § 205.302(b).

²⁶⁶ *Id.* at § 205.302(a)(1).

²⁶⁷ *Id.* at § 205.302(a)(2).

²⁶⁸ *Id.*

organic composition is calculated by “dividing the combined weight of the solid ingredients and the weight of the liquid ingredients of the finished product.”²⁶⁹

The handler who places the label on the product package is responsible for calculating the organic composition of the product.²⁷⁰ The handler is permitted to use the information given by the certified operation in making this calculation. The calculation must be verified by the handler’s certifying agent.²⁷¹

100% Organic

For a raw or processed product to be sold, labeled, or represented as “100 percent organic,” it must contain 100 percent organically produced ingredients.²⁷² Products in this labeling category may display “on the principal display panel, information panel, and any other panel of the package and on any labeling or market information” pertaining to the product (1) the term “100 percent organic” to modify the name of the product, and (2) the term “organic” to identify the organic ingredients contained in products containing two or more ingredients.²⁷³

The “principal display panel” is “[t]hat part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.”²⁷⁴ “Market information” is “[a]ny written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.”²⁷⁵ The “information panel” is

[t]hat part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g. irregular shape with one usable surface).²⁷⁶

Organic

For a raw or processed product to be sold, labeled, or represented as “organic”— the second labeling category— it “must contain at least 95 percent organically produced raw or processed agricultural products.”²⁷⁷ The remaining ingredients in the product must be organically produced, unless they are either commercially unavailable in organic form or are “nonagricultural substances or nonorganically produced agricultural products produced” in accordance with the National List requirements.²⁷⁸ Products in this labeling category may display “on the principal display panel, information panel, and any other panel of the package and on any labeling or market information” relating to the product (1) the term “organic” to modify the name of the product, and (2) the

²⁶⁹ *Id.* at § 205.302(a)(3).

²⁷⁰ *See id.* at § 205.302(c).

²⁷¹ *See id.*

²⁷² *See id.* at § 205.301(a).

²⁷³ *Id.* at § 205.303(a)(1), (3).

²⁷⁴ *Id.* at § 205.2.

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.* at § 205.301(b). *See supra* text accompanying note 60 (defining “nonagricultural substance”).

²⁷⁸ 7 C.F.R. § 205.301(b).

percentage of organic ingredients contained in the product.²⁷⁹

In addition to the display requirements, products in these two labeling categories may also display “on the principal display panel, information panel, and any other panel of the package and on any labeling or market information” (1) the USDA organic seal,²⁸⁰ and/or (2) “[t]he seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product,” as well as “any other certifying agent which certified production and handling operations producing raw organic product or organic ingredients used in the finished product.”²⁸¹ The identifying mark of the certifying agent(s) may only be displayed, however, if the handler that produced the final product maintains records in accordance with the applicable recordkeeping requirements and if the identifying mark is not displayed more prominently than the USDA seal.²⁸²

Products to be sold, labeled, or represented as either “100 percent organic” or “organic” must identify “each organic ingredient in the ingredient statement with the word ‘organic,’ or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced.”²⁸³ Products in these two labeling categories must also identify the certifying agent that certified the handler of the finished product, with the agent’s name preceded by the statement, “Certified organic by . . .,” or a similar statement.²⁸⁴

Products to be sold, labeled, or represented as “100 percent organic” or “organic” must be produced without the use of excluded methods or sewage sludge and must not be processed with the use of ionizing radiation.²⁸⁵ In addition, these products and the ingredients contained in them that are identified as “organic” in the products’ ingredient statements must be processed without the use of processing aids that are not listed as approved on the National List, except for products labeled as “100 percent organic” that, if processed, must be processed with the use of organically produced processing aids.²⁸⁶ Finally, products in these two labeling categories and the ingredients in them that are identified as “organic” must not (1) “[c]ontain sulfites, nitrates, or nitrites added during the production or handling process”;²⁸⁷ (2) be produced with the use of “nonorganic ingredients when organic ingredients are available”; and (3) “[i]nclude organic and nonorganic forms of the same ingredient.”²⁸⁸

²⁷⁹ See *id.* at § 205.303(a)(1), (2). The size of the percentage statement for products labeled as “organic” cannot exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.” 7 C.F.R. § 205.303(a)(2).

²⁸⁰ The standards governing the USDA seal are discussed below and are located in the regulations at 7 C.F.R. § 205.311.

²⁸¹ 7 C.F.R. § 205.303(4)-(5). The phrase “seal, logo, or other identifying mark” is hereinafter shortened to “identifying mark.”

²⁸² See *id.* at § 205.303(5).

²⁸³ *Id.* at § 205.303(b)(1). Water and salt cannot be identified in the ingredient statement as “organic.”

²⁸⁴ See *id.* § 205.303(b)(2). Although not required, the certifying agent’s business address, Internet address, or telephone number may be included on the label.

²⁸⁵ See *id.* at § 205.303(f)(1)-(3). See also *id.* at § 201.105(e)-(f). See *supra* text accompanying notes 61-76. This requirement also applies to the ingredients identified as “organic” in the products’ ingredient statement.

²⁸⁶ 7 C.F.R. § 205.303(f)(4).

²⁸⁷ This does not include wine that contains added sulfites, which may be labeled “made with organic grapes.” See *id.* at § 205.303(f)(5).

²⁸⁸ 7 C.F.R. § 205.305(f)(4)-(7).

“Made with Organic . . .”

Multiingredient products that are comprised of at least seventy percent but less than ninety-five percent organic ingredients fall with the third labeling category, “made with organic (specified ingredients or food group(s)).”²⁸⁹ No more than three organically produced ingredients or food groups may be specified on the product label.²⁹⁰

The ingredients contained in “made with organic . . .” products must be produced and handled in accordance with the organic production and handling requirements.²⁹¹ The ingredients cannot be produced by using excluded methods or sewage sludge and cannot be processed with the use of ionizing radiation.²⁹² However, a “made with organic . . .” product may contain nonorganic agricultural ingredients that (1) were processed with the use of processing aids not approved on the National List; (2) contain “sulfites, nitrates, or nitrites added during the production or handling process”;²⁹³ (3) were produced using nonorganic ingredients when organic ingredients were available; and (4) can include both organic and nonorganic forms of the same ingredient.²⁹⁴

The package of a product labeled as “made with organic . . .” “may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product, the phrase “made with organic (specified ingredients),” as long as the package does not list more than three organically produced ingredients.²⁹⁵ The package can be labeled with the phrase “made with organic (specified food groups)” as long as it does not list more than three of the following food groups: “beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products.”²⁹⁶ The ingredients for each of the food groups listed on the package must be organically produced.²⁹⁷

For example, a vegetable soup made with eighty-five percent organically produced and handled potatoes, tomatoes, peppers, celery, and onions can be labeled as “soup made with organic potatoes, tomatoes, and peppers,” or it can be labeled as “soup made with organic vegetables.”²⁹⁸ If labeled as “soup made with organic vegetables,” the soup cannot contain any nonorganic vegetables.²⁹⁹

The listing of ingredients or foods groups in the product must appear in letters that are not larger than “one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.”³⁰⁰ The package may contain a statement

²⁸⁹ *Id.* at § 205.301(c). For purposes of this article, the phrase “made with organic (specified ingredients or food group(s))” is hereinafter shortened to “made with organic . . .” when appropriate.

²⁹⁰ *See id.* at § 205.304(a)(1)(i).

²⁹¹ *Id.* at § 205.303(c).

²⁹² *See id.* *See also* 7 C.F.R. § 205.105(d)-(f). *See supra* text accompanying notes 61-76.

²⁹³ This does not include wine that contains added sulfites, which may be labeled “made with organic grapes.” 7 C.F.R. § 205.303(f)(5).

²⁹⁴ *See* 7 C.F.R. § 205.303(c). *See also id.* at § 205.303(f)(4)-(7).

²⁹⁵ *See* 7 C.F.R. § 205.304(a)(1)(i).

²⁹⁶ *Id.* at § 205.304(a)(1)(ii).

²⁹⁷ *See id.*

²⁹⁸ 65 Fed. Reg. 80,547, 80,577 (prefatory comments for final rule with request for comments).

²⁹⁹ *See id.*

³⁰⁰ 7 C.F.R. § 205.304(a)(1)(iii).

identifying the percentage of organic ingredients in the product, as well as the identifying mark of the certifying agent that certified the handler of the finished product.³⁰¹

“Made with organic . . .” product packages must identify each organic ingredient, except for water and salt, listed in the ingredient statement with the word “organic,” “or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced.”³⁰² “Made with organic . . .” product packages are also required to identify the name of the certifying agent that certified the handler of the finished product.³⁰³ The name of the certifying agent must be preceded by the phrase “Certified organic by . . .,” or a similar phrase.³⁰⁴ The agent’s name must be on the information panel of the product and below the information that identifies the handler or distributor of the product.³⁰⁵ “Made with organic . . .” product packages are prohibited from displaying the USDA seal.³⁰⁶

“Products with Less Than 70% Organically Produced Ingredients”

The organic ingredients contained in products falling within the fourth labeling category, “products with less than 70 percent organically produced ingredients,” must have been produced and handled in accordance with the organic production and handling requirements.³⁰⁷ Any nonorganic ingredients contained in the product may be produced without complying with any of the standards set forth in the final rule.³⁰⁸ The packages of products in this labeling category are prohibited from displaying the USDA seal.³⁰⁹ The packages are also prohibited from displaying any identifying mark of a certifying agent that represents that the product or its ingredients have been certified.³¹⁰

The final rule prescribes only two methods in which the organic content of a product with less than seventy percent organic composition may be identified on the package. First, the package may identify “each organically produced ingredient in the ingredient statement with the word, ‘organic,’ or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced.”³¹¹ Second, the package may identify organic content by “displaying the product’s percentage of organic contents on the information panel,” if the ingredients are identified in the ingredient statement.³¹²

3. Livestock Feed

There are only two labeling categories that can be used to indicate that livestock feed has been organically produced: “100 percent organic” and “organic.” Raw or processed livestock feed intended to be sold, labeled, or represented as “100 percent organic” must be composed entirely of organically produced ingredients, excluding water and salt.³¹³ A raw or processed livestock feed to be

³⁰¹ See *id.* at § 205.304(b)(2)-(3). The size of the percentage statement cannot exceed “one-half of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.” 7 C.F.R. § 205.304(b).

³⁰² 7 C.F.R. § 205.304(b)(1).

³⁰³ See *id.* at § 205.304(b)(2).

³⁰⁴ See *id.*

³⁰⁵ See *id.*

³⁰⁶ See *id.*

³⁰⁷ See *id.* at § 205.301(c).

³⁰⁸ See *id.*

³⁰⁹ See *id.* at § 205.305(b)(1).

³¹⁰ See *id.* at § 205.305(b)(2).

³¹¹ See *id.* at § 205.305(a)(1).

³¹² See *id.* at § 205.305(a)(2).

³¹³ See *id.* at § 205.301(e)(1).

sold, labeled, or represented as “100 percent organic” or “organic” must be produced in accordance with the organic production and handling requirements for livestock feed.³¹⁴

“100 percent organic” and “organic” livestock feed products may display on any package panel “[t]he statement, ‘100 percent organic’ or ‘organic,’ as applicable, to modify the name of the feed product.”³¹⁵ The package panel may also display the USDA seal and/or the identifying mark of the certifying agent that certified the production and handling operation producing the raw or processed organic ingredients used in the finished product” as long as the certifying agent’s identifying mark is not displayed more prominently than the USDA seal.³¹⁶ Finally, the package may identify ingredients that are organically produced with the word “organic” or an asterisk or other reference mark which is defined on the package” to identify the organic ingredients.³¹⁷

Livestock feed products must display the name of the certifying agent that certified the handler of the finished product.³¹⁸ The agent’s name must be preceded by the phrase “Certified organic by . . .” or another similar phrase, and the package label may include the agent’s telephone number, business address, or internet address.³¹⁹ Livestock feed products must also be labeled, as applicable, with any other labeling requirements created under federal or state law.³²⁰

4. Labeling of Nonretail Containers Used for Shipping and Storage

The labeling requirements discussed so far have related only to the display of written, printed, or graphic material placed on the container or package of an individual agricultural product as it appears for retail sale. Under NOP, there are also requirements for the labeling of nonretail containers used only for shipping or storage of raw or agricultural products labeled as “100 percent organic,” “organic,” or “made with organic”³²¹ The requirements for labeling of nonretail containers are intended to prevent the commingling of organic and nonorganic products and ingredients and to prevent a product from being handled in a way that would destroy the product’s organic status.

Nonretail containers used solely for shipping or storing agricultural products labeled as containing organic ingredients may display (1) the “name and contact information of the certifying agent which certified the handler which assembled the final product”; (2) handling instructions necessary to maintain the product’s organic integrity; (3) terms or marks that identify the product as “organic”; (4) the USDA seal; and (5) the identifying mark “of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.”³²² The containers are also required to display the “production lot number” of the product, if one is available.³²³ The “production lot number” is the “[i]dentification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.”³²⁴

³¹⁴ See *id.* at § 205.305(e)(1)-(2). See also *id.* at § 205.237. The organic and production standards for livestock feed are discussed in Part C of this article.

³¹⁵ 7 C.F.R. § 205.306(a)(1).

³¹⁶ *Id.* at § 205.306(a)(2)-(3).

³¹⁷ *Id.* at § 205.306(a)(4).

³¹⁸ See *id.* at § 205.306(b)(i).

³¹⁹ See *id.* The certifying agent’s name must be placed on the information panel, below the information that identifies the handler or distributor of the product. See *id.*

³²⁰ See *id.* at § 205.306(b)(ii).

³²¹ See *id.* at § 205.307.

³²² *Id.* at § 205.307(a)(1)-(5).

³²³ See *id.* at § 205.307(b).

³²⁴ *Id.* at § 205.2.

Nonretail containers used to export domestically produced products labeled as organic to international markets can be labeled in accordance with the labeling requirements of the country of destination or with the specifications of the foreign contract buyer, if certain conditions are satisfied.³²⁵ The containers and shipping documents must be clearly marked “For Export Only,” and the handler must maintain verification of such marking and export “in accordance with the recordkeeping requirements for exempt and excluded operations under § 205.101.”³²⁶

This requirement states that there are recordkeeping requirements for exempted *and* excluded operations located at § 205.101 of the final rule. According to this provision of the final rule, the AMS indicates its belief that there are recordkeeping requirements for excluded operations set forth at § 205.101. However, as discussed in Part B of this article,³²⁷ there are no recordkeeping requirements specifically applicable to excluded operations located at § 205.101.

5. Products in Other Than Packaged Form at Point of Sale

Products in other than packaged form at the point of retail sale that are to be sold, labeled, or represented as “100 percent organic” or “organic” “may use the term ‘100 percent organic’ or ‘organic,’ as applicable, to modify the name of the product in retail display, labeling, and display containers,” as long as the term “organic” “is used to identify the organic ingredients listed in the ingredient statement.”³²⁸ This requirement applies to “100 percent organic” and “organic” products that are not packaged before sale and are presented in a way that permits consumers to select the amount of the product they want to purchase.

Such products, if prepared in a certified facility, may have the USDA seal placed on the retail display, labeling, and display containers.³²⁹ They may place the identifying mark “of the certifying agent which certified the . . . operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product” on the retail display, labeling, and display containers.³³⁰ The identifying mark cannot be displayed more prominently than the USDA seal.³³¹

Products in other than packaged form at the point of retail sale that are to be sold, labeled, or represented as “made with organic . . .” are allowed to use the term “made with organic . . .” to modify the product name in retail display, labeling, and display containers.³³² The “made with organic . . .” statement cannot list more than three organic ingredients or food groups.³³³ The ingredient statement must identify organic ingredients as “organic.”³³⁴ As long as the product is prepared in a certified facility, it may display the certifying agent’s identifying mark in retail displays, display containers, and market information.³³⁵

³²⁵ See *id.* at § 205.307(c).

³²⁶ See *id.* The prefatory comments state that the records should include documents such as bills of lading and U.S. Customs Service documentation. 65 Fed. Reg. 80,547, 80,581 (prefatory comments to final rule with request for comments).

³²⁷ See *supra* text accompanying notes 40-53.

³²⁸ 7 C.F.R. § 205.308(a).

³²⁹ See *id.* at § 205.308(b)(1).

³³⁰ *Id.* at § 205.308(b)(2).

³³¹ See *id.*

³³² See *id.* at § 205.309.

³³³ See *id.* at § 205.309(a)(1).

³³⁴ See *id.* at § 205.309(a)(2).

³³⁵ See *id.* at § 205.309(b).

6. Labeling of Products Produced on Exempted and Excluded Operations

Excluded or exempted operations must comply with the labeling requirements for exempted and excluded operations.³³⁶ A product that has been produced on an exempted or excluded operation cannot be represented in any way to any buyer that it has been certified as an organically produced product or ingredient.³³⁷ Thus, such products are prohibited from displaying the USDA seal and the identifying mark of a certifying agent that identifies the operation as certified.³³⁸

A product that has been organically produced or handled on an exempt or excluded operation may be identified as an “organic” product or ingredient in a multiingredient product that has been produced by that operation.³³⁹ However, the product or ingredient can only be identified as “organic” if it complies with the applicable labels, labeling, and market information requirements.³⁴⁰ The product or ingredient cannot be identified as “organic” if it has been processed by other persons or if it is used to modify a nonorganic ingredient in the product.³⁴¹

A product that is produced or handled on an exempt or excluded operation cannot be produced by using excluded methods or sewage sludge.³⁴² It must also be processed without the use of ionizing radiation.³⁴³ In addition, the product must be processed without the use of processing aids that are not listed as approved or allowed on the National List, except for products labeled as “100 percent organic” which, if processed, must be processed with the use of organically produced processing aids.³⁴⁴ Finally, products and ingredients produced or handled on an exempt or excluded operation must not (1) “[c]ontain sulfites, nitrates, or nitrites added during the production or handling process”,³⁴⁵ (2) be produced with the use of “nonorganic ingredients when organic ingredients are available”; and (3) “[i]nclude organic and nonorganic forms of the same ingredient.”³⁴⁶

7. The Organic Seal

Only products to be sold, labeled, or represented as “100 percent organic” or “organic,” including livestock feed, may contain the USDA Organic seal.³⁴⁷ The seal indicates to consumers that a product has been certified as organically produced and handled in accordance with all applicable NOP requirements. The USDA seal must “replicate the form and design”³⁴⁸ of the examples provided by the USDA.

E. Certification

“Certification” is a certifying agent’s determination that an operation has complied with all

³³⁶ See *id.* at § 205.310.

³³⁷ See *id.* at § 205.310(a)(1)-(2).

³³⁸ See *id.*

³³⁹ See *id.* at § 205.310(b).

³⁴⁰ See *id.* at § 205.310(c). See also 7 C.F.R. § 205.300(a).

³⁴¹ 7 C.F.R. § 205.310(c). See also 7 C.F.R. § 205.300(a).

³⁴² 7 C.F.R. § 205.310(c). See also 7 C.F.R. § 205.301(f)(1)-(2). See *supra* text accompanying notes 61-76.

³⁴³ 7 C.F.R. § 205.310(c). See also 7 C.F.R. § 205.301(f)(3).

³⁴⁴ 7 C.F.R. § 205.310(c). See also 7 C.F.R. § 205.301(f)(4).

³⁴⁵ This does not include wine that contains added sulfites, which may be labeled “made with organic grapes.” See 7 C.F.R. § 205.303(f)(5).

³⁴⁶ 7 C.F.R. § 205.310(c). See also 7 C.F.R. § 205.301(f)(5)-(7).

³⁴⁷ 7 C.F.R. § 205.311(a).

³⁴⁸ *Id.* at § 205.311(b). See also 7 C.F.R. § 205.311(b)(1)(2) & ©). Examples of the USDA seal can be viewed at <http://www.ams.usda.gov/nop/Consumers/Seal.html>.

applicable NOP requirements, which is documented by a certificate of organic operation.³⁴⁹ A “certifying agent” is “[a]ny entity accredited by the Secretary for the purpose of certifying a production or handling operation as a certified production or handling operation.”³⁵⁰

The final rule establishes general requirements for certification, standards for submitting an application for certification, standards for reviewing the application, and requirements governing the on-site inspections that must be conducted by a certifying agent. It also sets forth standards for the granting, denying, and continuing certification.

1. General Certification Requirements

There are six general requirements for certification.³⁵¹ First, any person seeking certification must comply with the OFPA and all applicable organic production and handling standards.³⁵² Second, the producer or handler must also create, implement, and annually update an organic system plan.³⁵³ Third, the producer or handler applying for certification must allow the certifying agent to conduct on-site inspections “with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices.”³⁵⁴ Fourth, the applicant must also maintain all records pertaining to the organic operation for at least five years beyond the creation of the records and allow “authorized representatives of the Secretary, the applicable state organic program’s governing State official, and the certifying agent access” to those records during normal business hours.³⁵⁵ Fifth, the person seeking certification must tender the applicable payments charged by the certifying agent.³⁵⁶ Sixth, the person must notify the certifying agent when there is an application of a prohibited substance to any part of the operation or when there is a change in the operation that could affect the operation’s compliance with NOP.³⁵⁷

2. Application for Certification

A producer or handler of a production or handling operation seeking certification must submit an application for certification to a certifying agent.³⁵⁸ The application must include an organic system plan, the name of the person completing the application, and the applicant’s business name, address, and telephone number.³⁵⁹ If the applicant is a corporate entity, the name, address, and telephone number of the person authorized to act on the entity’s behalf must be provided.³⁶⁰

The application must also include “[t]he name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; [and] the outcome of the application(s) submission.”³⁶¹ If an applicant has previously received either a notice of noncompliance or denial of certification from a certifying agent, a copy of the notice must be included, when available, with the application.³⁶² In the event that an applicant has received a notice of noncompliance or

³⁴⁹ See 7 C.F.R. § 205.2.

³⁵⁰ See *id.* at § 205.2. See also 7 U.S.C. § 6501(3).

³⁵¹ 7 C.F.R. § 205.400.

³⁵² *Id.* at § 205.400(a).

³⁵³ See *id.* at § 205.400(b).

³⁵⁴ *Id.* at § 205.400(c).

³⁵⁵ See *id.* at § 205.400(c)-(d).

³⁵⁶ See *id.* at § 205.400(e).

³⁵⁷ See *id.* at § 205.400(f)(1)-(2).

³⁵⁸ See *id.* at § 205.401.

³⁵⁹ See *id.* at § 205.401(a)-(b).

³⁶⁰ See *id.*

³⁶¹ *Id.* at § 205.401(c).

³⁶² See *id.*

denial of certification, the application should include “a description of the actions taken by the applicant to correct the noncompliances” indicated in the notice, “including evidence of such correction.”³⁶³ Finally, the application must contain any additional information needed to demonstrate compliance with all applicable NOP requirements.³⁶⁴

3. Review of Application

Once an application for certification is submitted, the certifying agent must review the application and determine whether it should be granted, denied, or continued. The final rule sets forth several requirements that certifying agents must follow when making this determination.³⁶⁵

The certifying agent must examine the application to determine whether the applicable requirements for submitting an application for certification have been met.³⁶⁶ Next, the agent must determine whether the applicant “appears to comply or may be able to comply” with the applicable organic production and handling requirements.³⁶⁷ If the agent determines that the applicant may have satisfied the applicable production and handling requirements, then it must schedule an on-site inspection to determine whether the production and handling requirements have been satisfied.³⁶⁸ If the applicant has previously received a notice of noncompliance or denial of certification from another certifying agent, the agent must verify that the applicant has submitted documentation demonstrating that the applicant has corrected the noncompliance(s) indicated in the notice.³⁶⁹

The certifying agent is required to review the application and inform the applicants of its findings within a reasonable time.³⁷⁰ It must provide to the applicant a copy of the inspection report developed from an on-site inspection to the applicant³⁷¹ and a copy of any test results for samples taken by an inspector to detect the presence of a prohibited substance on the operation.³⁷²

An applicant is allowed to withdraw its application at any time but must pay costs of services provided up to the time of withdrawal.³⁷³ A notice of noncompliance or denial of certification will not be issued to an applicant if the applicant voluntarily withdrew its application before such notice was issued.³⁷⁴

4. On-site Inspections

Certifying agents are required to “conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested.”³⁷⁵ Following the initial on-site inspection, annual inspections must be

³⁶³ *Id.*

³⁶⁴ *See id.* at § 205.401(d).

³⁶⁵ *See id.* at § 205.402.

³⁶⁶ *See id.* at § 205.402(a)(1). *See supra* text accompanying notes 336-42.

³⁶⁷ 7 C.F.R. § 205.402(a)(2).

³⁶⁸ *See id.* at § 205.402(a)(4).

³⁶⁹ *See id.* at § 205.402(a)(3).

³⁷⁰ *See id.* at § 205.402(b)(1).

³⁷¹ *See id.* at § 205.402(b)(2).

³⁷² *See id.* at § 205.402(b)(3). *See also* 7 C.F.R. § 205.2 (defining an “inspector” as “[a]ny person retained or used by a certifying agent to conduct inspections of certification applicants or certified production and handling operations”). *See also* 7 C.F.R. § 205.670 (establishing requirements for inspection and testing of agricultural products to be sold or labeled as “organic”).

³⁷³ 7 C.F.R. § 205.402(c).

³⁷⁴ *See id.*

³⁷⁵ *See id.* at § 205.403(a)(1).

conducted for certified operations to determine whether a request for certification should be approved or whether certification for the operation should continue.³⁷⁶

In addition to the initial and subsequent annual inspections, certifying agents may conduct additional inspections to determine whether an applicant or an already certified operation is in compliance with NOP requirements.³⁷⁷ The AMS Administrator, the representative delegated responsibility to act on behalf of the Administrator, or the governing official of a State organic program may require a certifying agent to conduct additional inspections “for the purpose of determining compliance” with the OFPA and the final rule.³⁷⁸ At the discretion of the Administrator, its representative, or the governing official of a state organic program, additional inspections may be announced or unannounced.³⁷⁹

The initial inspection must be conducted within a reasonable time after the certifying agent has determined that the applicant “appears or may be able to comply” with the organic production and handling requirements.³⁸⁰ An initial inspection can be delayed for up to six months, however, “to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.”³⁸¹

All inspections, whether initial, annual, or additional must occur when an authorized representative of the operation is present and “at a time when land, facilities, and activities that demonstrate the operation’s compliance with or capability to comply” with the applicable organic production and handling requirements can be observed.³⁸² This requirement does not apply to unannounced inspections.

An inspection must verify an “operation’s compliance or capability to comply” with OFPA and the final rule and confirm that the information provided in the application including the organic system plan, “accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”³⁸³ On-site inspections must also verify that no prohibited substances have been applied or are currently being applied to the production or handling operation.³⁸⁴ Such verification may, at the discretion of the certifying agent, include “the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.”³⁸⁵ If samples are taken, the inspector must provide the operation’s authorized representative with a receipt if samples are taken.³⁸⁶

³⁷⁶ See *id.*

³⁷⁷ See *id.* at § 205.403(a)(2)(i). See also 65 Fed. Reg. 80,547, 80,590 (prefatory comments to the final rule with request for comments) (stating that a certifying agent’s misuse of its authority to conduct additional inspections “would be subject to review by USDA during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints” and that “[c]ertified production and handling operations can file complaints with USDA at any time should they believe a certifying agent abuses its authority to perform additional inspections”).

³⁷⁸ *Id.* at § 205.403(a)(2)(ii).

³⁷⁹ See *id.* at § 205.403(a)(2)(iii).

³⁸⁰ *Id.* at § 205.403(a)(2)(iii).

³⁸¹ *Id.* at § 205.403(b)(1). See also 65 Fed. Reg. 80,547, 80,592 (prefatory comments to the final rule with request for comments) (stating that “[a]pplicants who believe that the certifying agent is abusing its authority to delay the on-site inspection may file a complaint with the Administrator”).

³⁸² See 7 C.F.R. § 205.403(b)(2).

³⁸³ *Id.* at § 205.403(c)(1)-(2).

³⁸⁴ See *id.* at § 205.403(c)(3).

³⁸⁵ *Id.*

³⁸⁶ See *id.* at § 205.403(e).

An exit interview must be conducted “with an authorized representative of the operation who is knowledgeable about the inspected operation” to verify that observations and information gathered during the inspection are accurate and complete.³⁸⁷ During the interview, the inspector must inform the authorized representative if additional information is needed and if there are any issues of concern.³⁸⁸ The prefatory comments to the final rule state that the main purpose of the exit interview “is to present the inspection observations to those in charge of the firm in such a manner so as to ensure they clearly understand the results of the inspection.”³⁸⁹

5. Granting Certification

Once the initial inspection has been conducted, the certifying agent must review the initial inspection report, the results from any tests conducted to detect the presence of prohibited substances, any information supplied by or requested from the applicant, the organic system plan, and all procedures and activities used in the applicant’s operation.³⁹⁰ Based upon this review, the certifying agent must grant certification if it determines that the applicant’s operation complies with the applicable NOP requirements and that the operation will be able to conduct its operation in accordance with its organic system plan.³⁹¹ The certifying agent may require the operation to correct minor noncompliances “within a specified time period as a condition of continued certification.”³⁹²

In 2008, consumer plaintiffs filed a class action suit against a certified organic dairy producer, claiming the labeling of its products as organic, when, allegedly, the producer failed to comply with NOP standards, violated various state laws.³⁹³ The district court held that the plaintiffs’ state law claims were preempted by OFPA and NOP.³⁹⁴ Furthermore, the court, citing 7 C.F.R. § 205.404(c), stated that regardless of whether the producer was meeting the standards of the NOP, the producer, as a certified operation, was entitled to market its products as organic unless its certification had been suspended, revoked, or surrendered.³⁹⁵

If certification is granted, the certifying agent must issue a certificate of organic operation to the certified operation.³⁹⁶ The certificate must specify (1) the name and address of the certified operation; (2) the effective date of certification; (3) the name, address, and telephone number of the certifying agent, and (4) the “[c]ategories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”³⁹⁷ An operation’s certification is effective until it is surrendered by the operation, or suspended or revoked by either the certifying agent, the governing official for a State’s organic program, or the Administrator.³⁹⁸

³⁸⁷ *Id.* at § 205.403(d).

³⁸⁸ *See id.*

³⁸⁹ 65 Fed. Reg. 80,547, 80,589 (prefatory comments to final rule with request for comments).

³⁹⁰ *See* 7 C.F.R. § 205.404(a).

³⁹¹ *See id.*

³⁹² *Id.*

³⁹³ *See In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practice Litig.*, Nos. 4:08MD01907 ERW, 4:07CV01701 ERW, 4:08CV00254 ERW, 4:08CV00280 ERW, 4:08CV00303 ERW, 4:08CV00305 ERW, 4:08CV00371 ERW, 4:08CV00374 ERW, 4:08CV00382 ERW, 4:08CV00384 ERW, 4:08CV00385 ERW, 4:08CV00386 ERW, 4:08CV00387 ERW, 4:08CV00391 ERW, 4:08CV00444 ERW, 4:08CV00466 ERW, 4:08CV00526 ERW, 4:08CV01460 ERW, 4:08CV01462 ERW, 4:08CV01464 ERW, 2009 WL 1576928 (E.D.Mo. June 3, 2009).

³⁹⁴ *Id.* at *9

³⁹⁵ *Id.*

³⁹⁶ *See id.* at § 205.404(b).

³⁹⁷ *Id.* at § 205.404(b)(1)-(4).

³⁹⁸ *See id.* at § 205.404(c).

6. Denial of Certification

If a certifying agent has reason to believe that an applicant “is not able to comply or is not in compliance with the requirements” set forth in the final rule, it must provide a written notice of noncompliance to the applicant.³⁹⁹ When an operation’s noncompliance is such that it would be impossible to correct, the certifying agent may combine a written notification of noncompliance and denial in one notice.⁴⁰⁰

A notice of noncompliance must describe each noncompliance, the factual basis for the noncompliance, and the “date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.”⁴⁰¹ If a certifying agent determines that an applicant has willfully provided a false statement or purposefully misrepresented its operation or compliance, the agent may issue a denial of certification without first issuing a notice of noncompliance.⁴⁰²

An applicant that has received a notice of noncompliance may exercise one of three options. First, it may correct the noncompliances and explain to the certifying agent in supporting documentation the corrective actions that it implemented.⁴⁰³ Second, the applicant may also correct the noncompliance(s) and submit a new application for certification to another certifying agent.⁴⁰⁴ If an applicant exercises this second option, it must submit a complete application for certification to the new certifying agent that includes a copy of “the notification of noncompliance received from the first certifying agent,” a description of the corrective measures that it implemented to remedy the noncompliance, and documentation that evidences the corrective measures that were taken.⁴⁰⁵ Finally, the applicant may challenge the certifying agent’s determination with written information that rebuts the noncompliance(s) described in the notice of noncompliance.⁴⁰⁶

After issuing a notice of noncompliance, the certifying agent must examine the corrective measures taken by an applicant, the documentation evidencing those corrective actions, or the applicant’s written rebuttal.⁴⁰⁷ If necessary, the certifying agent must also conduct an on-site inspection.⁴⁰⁸ The certifying agent must issue an approval of certification to the applicant if it determines that either the corrective measures implemented by the applicant or the applicant’s rebuttal are sufficient to qualify the applicant for certification.⁴⁰⁹ The certifying agent must provide a written notice of denial of certification to the applicant if it determines that the corrective measures or the rebuttal are not sufficient to qualify the applicant for certification.⁴¹⁰ A certifying agent must also send a written notice of a denial of certification if the applicant fails to respond to a notice of noncompliance.⁴¹¹ Notice of either approval or denial must also be sent by the certifying agent to the Administrator.⁴¹²

³⁹⁹ *Id.* at § 205.405(a).

⁴⁰⁰ *See id.*

⁴⁰¹ *Id.* at § 205.405(a)(1)-(3).

⁴⁰² *See id.* at § 205.405(g).

⁴⁰³ *See id.* at § 205.405(b)(1).

⁴⁰⁴ *See id.* at § 205.405(b)(2).

⁴⁰⁵ *Id.*

⁴⁰⁶ *See id.* at § 205.405(b)(3).

⁴⁰⁷ *See id.* at § 205.405(c)(1).

⁴⁰⁸ *See id.*

⁴⁰⁹ *See id.* at § 205.405(c)(1)(i).

⁴¹⁰ *See id.* at § 205.405(c)(1)(ii).

⁴¹¹ *See id.* at § 205.405(c)(2).

⁴¹² *See id.* at § 205.405(c)(3).

Any notice of denial must state the reason(s) for the denial.⁴¹³ It must also state that the applicant has a right to reapply for certification, to request mediation, or file an appeal challenging the denial of certification.⁴¹⁴ When a certifying agent receives a new application for certification that includes a notice of noncompliance or notice of denial, it must review the application as if it were a new application and begin an entirely new application process.⁴¹⁵

7. Continuation of Certification

To maintain its certification status, a certified operation must annually update its organic system plan, submit the updated information to its certifying agent, and pay the necessary fees.⁴¹⁶ The updated organic system plan must contain a summary statement and supporting documentation describing any changes or modifications to the previous year's organic system plan.⁴¹⁷ The updated plan must also describe any deletions or additions to the previous year's organic system plan that are expected to be implemented in the upcoming year.⁴¹⁸

Any changes in the applicant's business name, address, telephone number, or the name, address, or telephone number of its authorized representative must also be provided to the certifying agent as part of the annual update.⁴¹⁹ If the certifying agent notified the operation that minor noncompliances would need to be corrected when it granted certification, the operation must provide an update on the corrective measures it implemented.⁴²⁰ Finally, the operation must provide any information requested by the certifying agent to demonstrate compliance with NOP requirements.⁴²¹

Once the certifying agent has received the required updated information, it must arrange for and conduct an on-site inspection of the operation.⁴²² When such an inspection is not possible, however, the certifying agent "may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months."⁴²³ If an operation's certification is continued in this manner, the required annual on-site inspection must be conducted in the first six months after the operation's scheduled date of annual update.⁴²⁴

The certifying agent must issue a written notice of noncompliance to an operation if the on-site inspection and review of an operation's updated information causes the certifying agent to determine that the operation is not in compliance with NOP requirements.⁴²⁵ On the other hand, if the inspection and review of information demonstrates an operation's compliance with NOP requirements, the certifying agent must issue an updated certificate of organic operation.⁴²⁶

⁴¹³ See *id.* at § 205.405(d).

⁴¹⁴ See *id.* at § 205.405(d)(1)-(3).

⁴¹⁵ See *id.* at § 205.405(f).

⁴¹⁶ See *id.* at § 205.406(a).

⁴¹⁷ See *id.* at § 205.406(a)(1)(i).

⁴¹⁸ See *id.* at § 205.406(a)(1)(ii).

⁴¹⁹ See *id.* at § 205.406(a)(2).

⁴²⁰ See *id.* at § 205.406(a)(3).

⁴²¹ See *id.* at § 205.406(a)(4).

⁴²² See *id.* at § 205.406(b).

⁴²³ *Id.*

⁴²⁴ See *id.*

⁴²⁵ See *id.* at § 205.406(c).

⁴²⁶ See *id.* at § 205.406(d).

F. Accreditation of Certifying Agents

“Accreditation” is a “determination by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent” in accordance with NOP requirements.⁴²⁷ An entity must comply with several requirements in order to receive accreditation to operate as a certifying agent.⁴²⁸

An entity can be granted accreditation by the Administrator in the areas of crops, livestock, wild crops, or handling, or any combination of these areas.⁴²⁹ For example, an accredited certifying agent may be accredited to conduct certification activities with respect to crop production and wild crops but not for livestock production. Accreditation is effective for five years from the date in which the Secretary grants an application for accreditation.⁴³⁰

A foreign entity’s accreditation can be accepted by the Secretary if the Secretary determines that the standards under which the foreign entity’s accreditation was granted satisfies the NOP accreditation requirements, or if the foreign government that granted accreditation to the agent acted under an equivalency agreement negotiated between it and the United States.⁴³¹

The final rule sets forth numerous general requirements that an entity must satisfy to become accredited or, in some instances, maintain its accreditation.⁴³² For example, an entity must have the expertise, ability, and a sufficient number of personnel to allow it to fully comply with all applicable NOP requirements, in particular the requirements for certification and accreditation.⁴³³ It must demonstrate that its “responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise” with respect to production and handling practices to allow them to successfully perform their respective duties.⁴³⁴ The entity must conduct an annual evaluation of all members of its personnel involved in making certification determinations so that any deficiencies in the entity’s certification services can be corrected.⁴³⁵ It must also have an annual review of its certification activities performed by its staff, an outside auditor, or a consultant with sufficient expertise to conduct the reviews and must implement measures to correct any deficiencies revealed in the evaluation.⁴³⁶

The entity must provide to persons interested in being certified information that is sufficient to allow that person to comply with all applicable NOP requirements, and it must maintain records in accordance with the recordkeeping requirements for certifying agents.⁴³⁷ In addition, the entity must maintain strict confidentiality with respect to its clients and must refrain from disclosing to third parties any business-related information that it collected while carrying out its duties under the NOP.⁴³⁸ It

⁴²⁷ *Id.* at § 205.2.

⁴²⁸ *See id.* at §§ 205.500-.510. The requirements for accreditation of certifying agents are summarized below and are not discussed in detail in this article.

⁴²⁹ *See id.* at § 205.500(a).

⁴³⁰ *See id.* at § 205.500(b).

⁴³¹ *See id.* at 205.500(c)(1)-(2).

⁴³² This article does not describe all of the general requirements for accreditation. For a full listing of these requirements consult 7 C.F.R. § 205.501.

⁴³³ 7 C.F.R. § 205.501(a)(1)-(4).

⁴³⁴ *See id.* at § 205.500(a)(5). *See also* 7 C.F.R. § 205.2 (defining “responsibly connected”).

⁴³⁵ 7 C.F.R. § 205.501(a)(6).

⁴³⁶ *See id.* at § 205.501(a)(7).

⁴³⁷ *See id.* at § 205.501(a)(8)-(9). *See also* 7 C.F.R. § 205.510(b) (describing the recordkeeping requirements for certifying agents).

⁴³⁸ 7 C.F.R. § 205.501(a)(10).

must also prevent conflicts of interest in accordance with the measures set forth in the final rule.⁴³⁹

An entity seeking accreditation as a certifying agent must submit, along with the applicable fees, an application to the Secretary, that contains (1) the required applicant information; (2) evidence of expertise and ability; (3) and a statement of agreement.⁴⁴⁰ The Administrator must review this information and, if necessary, information derived from an on-site inspection to determine whether the entity has satisfied the general requirements for accreditation.⁴⁴¹

If based on this review the Administrator concludes that the entity has satisfied the general requirements for accreditation, it must provide written notification to the applicant that accreditation has been granted.⁴⁴² This notice must state what area(s)— crop production, handling, wild crops, or livestock— for which the entity is being accredited, the effective date of accreditation, and, if applicable, the terms and conditions for the correction of minor noncompliances.⁴⁴³ For a certifying agent that is a private entity, the notice must state what “the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.”⁴⁴⁴

If the Administrator⁴⁴⁵ reviews this information and determines that an entity is not able to comply or is not in compliance with all applicable NOP accreditation requirements, it must provide a written notification of noncompliance to the applicant.⁴⁴⁶ This notice must describe the noncompliance(s), the factual basis for the noncompliance(s), the date by which the noncompliance must be rebutted or corrected, and the date by which supporting documentation of the correction must be submitted.⁴⁴⁷ The Administrator must send a written notice of noncompliance resolution and continue processing the application for accreditation when the noncompliance(s) have been resolved.⁴⁴⁸

The Administrator must provide a notice of accreditation denial if the applicant does not correct the noncompliance(s), report the corrections by the date specified in the notice of noncompliance, rebut the notification of noncompliance by the date specified in the notice, or succeed in its rebuttal of the notice of noncompliance.⁴⁴⁹ If an applicant receives a notice of accreditation denial, it may submit another application at any time or appeal the denial by the date specified in the notice of accreditation denial.⁴⁵⁰

⁴³⁹ See *id.* at § 205.501(a)(11). See also 7 C.F.R. § 205.501(a)(11)(i)-(vi) (describing the methods in which the entity must prevent conflicts of interest). See also 7 C.F.R. § 205.501(12)(i)-(ii) (describing process for reconsidering an operation’s application for certification when it is determined that a conflict of interest existed within a year of granting certification).

⁴⁴⁰ See *id.* at § 205.502(a). See also 7 C.F.R. § 205.640-.642 (describing fees and other charges for accreditation).

⁴⁴¹ 7 C.F.R. § 205.502(b).

⁴⁴² See *id.* at § 205.506(b).

⁴⁴³ See *id.* at § 205.506(b)(1)-(3).

⁴⁴⁴ *Id.* at § 205.506(b)(4).

⁴⁴⁵ In the requirements for granting accreditation, § 205.506, the final rule states that the decision to grant accreditation is left to the Administrator. In the requirements for denying accreditation, § 205.507, the final rule states that decision to deny accreditation is left to the “Program Manager.” The term “Administrator” is used here for consistency and because “Program Manager” is not defined in either the OFPA or the final rule.

⁴⁴⁶ See 7 C.F.R. § 205.507(a).

⁴⁴⁷ See *id.* at § 205.507(a)(1)-(3).

⁴⁴⁸ See *id.* at § 205.507(b).

⁴⁴⁹ See *id.* at § 205.507(c).

⁴⁵⁰ See *id.*

The Administrator must commence proceedings to suspend or revoke an already accredited certifying agent's accreditation if the agent fails to correct its noncompliances, "fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification on noncompliance by the date specified."⁴⁵¹ If a certifying agent's accreditation is suspended, it may submit a request to the Secretary at any time to have its accreditation reinstated, unless the notice of suspension states otherwise.⁴⁵² A certifying agent whose accreditation is revoked cannot be eligible for accreditation for at least three years following the revocation.⁴⁵³

Once an entity has been granted accreditation, site evaluations must be conducted by either the Administrator or the Administrator's representative(s), for the purpose of examining the certifying agent's operations and evaluating its compliance with NOP requirements.⁴⁵⁴ Site evaluations must "include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production and handling operations certified by the certifying agent."⁴⁵⁵ Accredited certifying agents must provide an annual report to the Administrator, "on or before the date of the issuance of the notification of accreditation" along with the required accreditation fees.⁴⁵⁶

G. National List

The use of synthetic substances in the production and handling of organically produced agricultural products is prohibited, unless the substance is listed as an allowed substance on the National List.⁴⁵⁷ The National List also includes nonsynthetic substances prohibited in the production and handling of organically produced agricultural products.⁴⁵⁸ A "nonsynthetic substance," also referred to as a "natural substance," is a substance that "is derived from mineral, plant, or animal matter and does not undergo a synthetic process."⁴⁵⁹

The National List contains "an itemization, by specific use or application, of each synthetic substance permitted . . . or each natural substance prohibited" under the NOP.⁴⁶⁰ More specifically, it lists the (1) synthetic substances allowed for use in organic crop production; (2) nonsynthetic substances prohibited for use in organic crop production; (3) synthetic substances allowed for use in organic livestock production; (4) nonsynthetic substances prohibited for use in organic livestock production; (5) nonagricultural substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic . . ."; and (6) nonorganically produced agricultural products⁴⁶¹ allowed as ingredients in or on processed products labeled as "organic" or "made with organic"

⁴⁵¹ *Id.*

⁴⁵² *See id.* at § 205.507(d).

⁴⁵³ *See id.*

⁴⁵⁴ *See id.* at § 205.508(a).

⁴⁵⁵ *Id.* *See also* 7 C.F.R. § 205.508(b) (describing when on site evaluations must be conducted).

⁴⁵⁶ *See* 7 C.F.R. § 205.510(a). *See also* 7 C.F.R. § 205.510(a)(1)-(4) (describing the information that the certifying agent is required to submit in its annual report).

⁴⁵⁷ *See* 7 U.S.C. §§ 6504, 6510, 6517, & 6518. A "synthetic" is "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources," but does not include substances created by a naturally occurring biological process." 7 U.S.C. § 6502(21).

⁴⁵⁸ *See id.*

⁴⁵⁹ 7 C.F.R. § 205.2.

⁴⁶⁰ 7 U.S.C. § 6502(12). This itemized listing is found at 7 C.F.R. §§ 205.601-.606 and is not reprinted in this article.

⁴⁶¹ *See supra* text accompanying note 60 (defining "nonagricultural substance"). *See supra* text accompanying note 59 (defining "nonagricultural substance").

The National List is based upon recommendations submitted to the Secretary by the National Organic Standards Board (“NOSB”). The NOSB is the entity established by OFPA to assist the Secretary in all aspects of NOP, including developing and amending the National List.⁴⁶² The NOSB is comprised of fifteen members who serve five-year staggered terms.⁴⁶³ These fifteen members must include four individuals who own or operate an organic farming operation, two individuals that own or operate an organic handling operation, one individual who owns or operates a retail establishment having significant trade in organic products, and three individuals possessing an expertise in environmental protection and resource conservation.⁴⁶⁴ The NOSB also includes an individual with expertise in toxicology, ecology, or biochemistry, and one individual who is a certifying agent.⁴⁶⁵

The creation of the National List was a two-part process in which the NOSB developed and submitted recommendations to the Secretary and the Secretary used those recommendations to make a final determination about the content of the National List. Amendments to the National List follow this same two-part developmental process. The Secretary is not required to adopt recommendations submitted to it by NOSB.

1. National List Requirements Under OFPA

In developing its recommendations, NOSB must “convene technical advisory panels to provide scientific evaluation of the materials considered for including in the National List,” and it must review information available from the EPA, the National Institute of Environmental Health Studies, and any other appropriate information sources “concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List.”⁴⁶⁶ NOSB must also consult with the manufacturers of substances to determine whether those substances contain inert materials that are synthetically produced.⁴⁶⁷ The results of these evaluations must be submitted to the Secretary along with NOSB’s proposal.⁴⁶⁸

NOSB is required to consider the potential for detrimental chemical interactions between the considered substance and other substances commonly used in organic production, “the toxicity and mode of action of the substance and of its breakdown products or contaminants, and their persistence and areas of concentration in the environment,” and the likelihood of environmental contamination “during manufacture, use, misuse or disposal of . . . [the] substance.”⁴⁶⁹ NOSB must also consider the effects that the substance has on “biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms . . . , crops and livestock;” and on human health.⁴⁷⁰ Finally, the NOSB must consider alternatives to using the substance and the substance’s compatibility with a system of sustainable agriculture.⁴⁷¹

The Secretary may list a prohibited substance as allowed only if it determines, in consultation with the Secretary of Health and Human Services and the EPA Administrator, that use of the substance “would not be harmful to human health or the environment . . . , is necessary to the production and handling of the agricultural product because of unavailability of wholly natural

⁴⁶² See 7 U.S.C. § 6518.

⁴⁶³ See *id.* at § 6518(b),(d).

⁴⁶⁴ See *id.* at § 6518(b)(1)-(4).

⁴⁶⁵ See *id.* at § 6518(b)(6).

⁴⁶⁶ *Id.* at § 6518(k)(3),(l)(1).

⁴⁶⁷ See *id.* at § 6518(l)(2).

⁴⁶⁸ See *id.* at § 6518(l)(3).

⁴⁶⁹ *Id.* at § 6518(m)(1)-(3).

⁴⁷⁰ *Id.* at § 6518(m)(4)-(5).

⁴⁷¹ See *id.* at § 6518(m)(6)-(7).

substitute products . . . , and is consistent with organic farming and handling.⁴⁷²

For an otherwise prohibited substance to be listed as allowed on the National List, it must also satisfy one of three requirements. First, the substance must be only used in production and contain an active synthetic ingredient that falls within one of the following categories: “copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers.”⁴⁷³ Second, the substance must be only used in production and contain “synthetic inert ingredients that are not classified by the Administrator of the [EPA] as inerts of toxicological concern.”⁴⁷⁴ Finally, the substance must be used in handling and be nonsynthetic, but not organically produced.⁴⁷⁵

The Secretary may prohibit the use of a specific natural substance only if it determines, in consultation with the Secretary of Health and Human Services and the EPA Administrator, that use of the substance “would be harmful to human health or the environment” and inconsistent with organic farming and handling and the purposes of the OFPA.⁴⁷⁶

The Secretary is prohibited from including “exemptions for the use of specific synthetic substances in the National List other than those exemptions contained” in the NOSB’s proposal.⁴⁷⁷ Under no circumstances can a substance whose presence in food is prohibited by any federal regulatory action be included on the National List.⁴⁷⁸

The Secretary is required to publish in the Federal Register any proposal it receives from NOSB and any changes it recommends to the NOSB’s proposal.⁴⁷⁹ All exemptions and prohibitions contained in the National List are valid only if NOSB reviews them within five years of being adopted or reviewed and the Secretary renews the exemption or prohibition.⁴⁸⁰

2. National List Requirements Under the Final Rule

The final rule incorporates the OFPA requirements for determining whether a substance should be listed as allowed or prohibited on the National List.⁴⁸¹ It also sets forth several requirements— which are authorized by, but not included in the OFPA— for determining whether a synthetic substance that is used as a processing aid or adjuvant should be listed as allowed or prohibited on the National List.⁴⁸² The final rule defines the term “processing aid” as the following:

(a) [A] substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (c) a substance that is added to a food for

⁴⁷² *Id.* at § 6517(c)(1)(A)(i)-(iii).

⁴⁷³ *Id.* at § 6517(c)(1)(B)(i).

⁴⁷⁴ *Id.* at § 6517(c)(1)(B)(ii).

⁴⁷⁵ *See id.* at § 6517(c)(1)(B)(iii).

⁴⁷⁶ *Id.* at § 6517(c)(2)(A)(i)-(ii).

⁴⁷⁷ *Id.* at § 6517(d)(2).

⁴⁷⁸ *See id.* at § 6517(d)(3).

⁴⁷⁹ *See id.* at § 6517(d)(4).

⁴⁸⁰ *See id.* at § 6517(d)(5).

⁴⁸¹ *See* 7 C.F.R. § 205.600(a).

⁴⁸² *See id.* at § 205.600(b) & (c).

its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.⁴⁸³

There are six criteria for making this determination. First, the processing aid or adjuvant must not be a substance that was produced from a natural source and must not have any organic substitutes.⁴⁸⁴ Second, the manufacture, use, and disposal of the substance must not have adverse effects on the environment and must be conducted in a manner compatible with organic handling.⁴⁸⁵ Third, the nutritional quality of the food must be maintained “when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal Regulations.”⁴⁸⁶ Fourth, the primary use of the substance cannot be as a preservative “or to recreate or improve flavors, colors, textures, or nutritive value lost during processing,” unless the replacement of nutrients is required by law.⁴⁸⁷ Fifth, the substance must be listed as “generally recognized as safe” by the Food and Drug Administration (FDA) when used in accordance the FDA’s good manufacturing practices and must not contain any “residues of heavy materials or other contaminants in excess of tolerance” established by the FDA.⁴⁸⁸ Finally, the substance must be “essential for the handling of organically produced agricultural products.”⁴⁸⁹

3. Amending the National List

Any person may petition NOSB to evaluate a substance for recommendation to the Secretary that the substance be listed as allowed or prohibited on the National List.⁴⁹⁰ A copy of the petition procedures can be obtained from the USDA by sending the request for petition procedures to the following address:

Program Manager, USDA/AMS/TMP/NOP
Room 2945, South Building
P.O. Box 96456
Washington, D.C. 20090-6456.⁴⁹¹

H. State Organic Programs

Any state is allowed, subject to certain conditions, to create a state organic program (“SOP”) for production and handling operations within that state.⁴⁹² The SOP must comply with all NOP requirements, although it may contain additional requirements that are more restrictive than NOP requirements “because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.”⁴⁹³ The additional requirements must further the purposes of NOP, must not be inconsistent with NOP, and must not be “discriminatory towards agricultural commodities organically produced in other States” that are produced in

⁴⁸³ 7 C.F.R. § 205.2.

⁴⁸⁴ See *id.* at § 205.600(b)(1).

⁴⁸⁵ See *id.* at § 205.600(b)(2).

⁴⁸⁶ *Id.* at § 205.600(b)(3).

⁴⁸⁷ See *id.* at § 205.600(b)(4).

⁴⁸⁸ See *id.* at § 205.600(b)(5).

⁴⁸⁹ *Id.* at § 205.600(b)(6).

⁴⁹⁰ See *id.* at § 205.607(a)(1).

⁴⁹¹ See *id.* at § 205.607(b)-(c).

⁴⁹² See 7 U.S.C. § 6503(b). See also 7 C.F.R. § 605.620(a).

⁴⁹³ See 7 U.S.C. § 6507(a), (b)(1). See also 7 C.F.R. § 205.620(c).

accordance with NOP.⁴⁹⁴ A SOP and any amendments to it must be approved by the Secretary before being implemented by the state.⁴⁹⁵

The SOP submitted for the Secretary's approval "must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State" that require more restrictive requirements than NOP requirements, and any other information requested by the Secretary.⁴⁹⁶ If an amendment to an approved SOP is requested, the request "must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment."⁴⁹⁷ The submission must also describe how the amendment would further the purposes of NOP and how it is consistent with NOP.⁴⁹⁸

The Secretary must approve or reject a proposed SOP or an amendment to the SOP within six months of receiving submission of the plan or amendment.⁴⁹⁹ Once an SOP is approved, the Secretary must review the SOP at least once for every five years following the date of the plan's approval.⁵⁰⁰ If an SOP is not approved, the SOP's governing State official may at any time submit a revised plan or amendment thereto.⁵⁰¹

I. Compliance

OFPA mandates that the Secretary establish appropriate and adequate procedures for enforcing the NOP.⁵⁰² The enforcement procedures implemented by the Secretary include (1) general compliance requirements; (2) requirements for the investigation of certified operations; (3) procedures that must be followed when a certified operation, certifying agent, or a SOP receives a notice of noncompliance; and (4) requirements for mediation.

1. General Requirements

The Secretary may inspect and review certified operations and accredited certifying agents to determine if the operations and agents have complied with all applicable NOP requirements.⁵⁰³ The Secretary may initiate suspension or revocation proceedings against certified operations when it believes that the operation has violated or is not in compliance with NOP requirements⁵⁰⁴ and when a certifying agent or state official governing a SOP fails to take appropriate action to enforce NOP requirements.⁵⁰⁵ The Secretary may initiate suspension or revocation proceedings against an agent's

⁴⁹⁴ 7 U.S.C. § 6507(b)(2)(A)-(c).

⁴⁹⁵ See *id.* at § 6507(a), (b)(2)(D), & (c)(2). See also 7 C.F.R. § 205.620(e).

⁴⁹⁶ 7 C.F.R. § 205.621(a)(1).

⁴⁹⁷ *Id.* at § 205.621(a)(2).

⁴⁹⁸ See *id.*

⁴⁹⁹ 7 U.S.C. § 6507(c)(3). See also 7 C.F.R. § 205.621(b).

⁵⁰⁰ See 7 U.S.C. § 6507(c)(1). See also 7 C.F.R. § 205.622.

⁵⁰¹ 7 C.F.R. § 205.621(c).

⁵⁰² 7 U.S.C. § 6506(7).

⁵⁰³ See 7 C.F.R. § 205.660. The final rule actually states that the "National Organic Program's Program Manager, on behalf of the Secretary," may inspect and review operations and certifying agents for compliance with the NOP. The term "Secretary" is used in the text of this article, rather than the term "National Organic Program Program Manager," for consistency and because "National Organic Program Program Manager" is not defined in either the OFPA or the final rule.

⁵⁰⁴ See *id.* at § 205.660(b)(1).

⁵⁰⁵ See *id.* at § 205.660(b)(2).

accreditation status if the agent “fails to meet, conduct, or maintain accreditation requirements” in accordance with the NOP requirements.⁵⁰⁶

2. Investigation and Noncompliance Procedures for Certified Operations

A certifying agent may investigate complaints that a certified operation is not in compliance with NOP requirements when the complaints are made against an operation that the agent has certified.⁵⁰⁷ The certifying agent must notify the Secretary of all compliance proceedings and actions that it has taken against the certified operation.⁵⁰⁸ For states that have established a SOP, the SOP governing official may investigate complaints of noncompliance operations operating by that State.⁵⁰⁹

When an investigation confirms any noncompliance with the NOP requirements, the certifying agent or SOP governing official must send a written notification of noncompliance to the operation.⁵¹⁰ The notification must describe the operation’s noncompliance(s), the facts supporting the finding of noncompliance, the date by which the operation must challenge or correct the noncompliance(s) and “supporting documentation of each such correction when correction is possible.”⁵¹¹ Once the operation demonstrates that the noncompliance has been corrected, the agent or SOP governing official must send the operation a written notification of noncompliance resolution.⁵¹² Notwithstanding any of these requirements, if the certifying agent or SOP governing official has reason to believe that the operation willfully violated NOP requirements, it must send the operation “a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”⁵¹³

If the operation’s challenge to the notice of noncompliance is unsuccessful or the operation fails to correct the noncompliance within the time specified in the written notice of noncompliance, the certifying agent or SOP governing official must send the operation “a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”⁵¹⁴ If the noncompliance is one that is impossible to correct, the notice of noncompliance and the notice of suspension or revocation can be combined into a single written notification.⁵¹⁵ The notice of suspension or revocation must describe the reasons for the proposed suspension or revocation, the proposed effective date of the suspension or revocation, and the consequence that the suspension or revocation will have on the operation’s eligibility for certification in the future. It must also state that the operation has a right to request mediation or to file an appeal.⁵¹⁶

If an operation requests mediation or files an appeal, the certifying agent or SOP governing official cannot send a notice of suspension or revocation while a final resolution of either the mediation or the appeal is pending.⁵¹⁷ If the operation does not correct the noncompliance, successfully challenge or mediate the noncompliance issue, or file an appeal of the proposed

⁵⁰⁶ *Id.* at § 205.660(c).

⁵⁰⁷ *See id.* at § 205.661(a).

⁵⁰⁸ *See id.*

⁵⁰⁹ *See id.* at § 205.661(b).

⁵¹⁰ *See id.* at § 205.662(a).

⁵¹¹ *Id.* at § 205.662(a)(1)-(3).

⁵¹² *See id.* at § 205.662(b).

⁵¹³ *Id.* at § 205.662(d).

⁵¹⁴ *Id.* at § 205.662(c).

⁵¹⁵ *See id.*

⁵¹⁶ *See id.* at § 205.662(c)(1)-(4).

⁵¹⁷ *See id.* at § 205.662(e)(2).

suspension or revocation of certification, the certifying agent or SOP governing official must send the operation a written notification of suspension or revocation.⁵¹⁸

Unless otherwise stated in the notice of suspension, an operation may at any time submit a request to the Secretary that its certification be reinstated.⁵¹⁹ The operation must submit evidence demonstrating correction of the noncompliance and the corrective measures it has taken to remain in compliance with the NOP requirements.⁵²⁰ The option to request reinstatement of certification does not apply to operations that have received a notice of revocation.⁵²¹ An operation, as well as any person “responsibly connected” with the operation, that receives a notice of revocation is ineligible for certification for five years from the date of revocation.⁵²² The five-year period of ineligibility can be reduced or eliminated by the Secretary, however, if such action is “in the best interest of the certification program.”⁵²³

3. Violations of OFPA

In addition to suspension or revocation, a certified operation that “[k]nowingly sells or labels a product as organic, except in accordance with” OFPA, shall be subject to a civil penalty of up to \$10,000.00 for each violation.⁵²⁴ Further, any certified operation that makes a false statement under OFPA to the Secretary, a SOP governing official, or an accredited certifying agent is subject to the provisions of 18 U.S.C. § 1001.⁵²⁵ 18 U.S.C. § 1001 provides, in part, that

[e]xcept as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully . . . falsifies, conceals, or covers up any trick, scheme, or device a material fact; [or] . . . makes any materially false, fictitious, fraudulent statement or representation; [or] . . . makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; . . . shall be fined . . . or imprisoned not more than 5 years, or both.⁵²⁶

4. Mediation

An applicant for certification or a certified operation may choose to mediate any dispute involving the denial of certification or proposed suspension or revocation of certification.⁵²⁷ The applicant or operation must request mediation in writing and the request must be accepted by the applicable certifying agent.⁵²⁸ If the request is rejected by the certifying agent, it must provide a written notification to the applicant or certified operation.⁵²⁹ The notification must explain to the applicant or operation that it has a right to request an appeal within thirty days of the written notification.⁵³⁰

⁵¹⁸ See *id.* at § 205.662(e)(1).

⁵¹⁹ See *id.* at § 205.662(f)(1).

⁵²⁰ See *id.*

⁵²¹ See *id.* at § 205.662(f)(2).

⁵²² See *id.* See also 7 C.F.R. § 205.2 (defining “responsibly connected”).

⁵²³ 7 C.F.R. § 205.662(f)(2).

⁵²⁴ See *id.* at § 205.662(g). See also 7 C.F.R. § 205.100(b).

⁵²⁵ 7 C.F.R. § 205.662(g).

⁵²⁶ 18 U.S.C. § 1001(a).

⁵²⁷ 7 C.F.R. § 205.663.

⁵²⁸ See *id.*

⁵²⁹ See *id.*

⁵³⁰ See *id.*

If the certifying agent accepts the request for mediation, the mediation proceeding are to be conducted by a qualified mediator agreeable to the parties.⁵³¹ The parties have up to thirty days to reach an agreement following a mediation session.⁵³² If the parties cannot reach an agreement, the applicant or operation has thirty days from the termination of mediation to appeal the certifying agent's decision.⁵³³ All agreements reached by the parties must be in accordance with NOP requirements, and is subject to review by the Secretary.⁵³⁴ The Secretary may reject any agreement or part of an agreement that it determines violates NOP requirements.⁵³⁵ If a dispute involves a SOP, the parties must use the mediation procedures for that state.⁵³⁶

5. Noncompliance Procedure for Certifying Agents

When the Secretary determines that an accredited certifying agent is not complying with NOP requirements, the Secretary must provide a written notification of noncompliance.⁵³⁷ The notification must describe the noncompliance(s), the factual basis for the notice of noncompliance, and "[t]he date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction."⁵³⁸ Once the certifying agent has demonstrated resolution of the noncompliance(s), the Secretary shall send the agent a written notification of compliance resolution.⁵³⁹ If the Secretary believes that the noncompliance(s) is willful, it must forgo sending a notice of noncompliance and shall send a notice of revocation or suspension instead.⁵⁴⁰

The Secretary must send a written notification of suspension or revocation if the certifying agent's rebuttal fails or if the agent fails to correct the noncompliance within the time period given in the notice of noncompliance.⁵⁴¹ This notice must state whether the certifying agent's entire accreditation or parts thereof are suspended or revoked.⁵⁴² If the noncompliance cannot be corrected, the Secretary's notice of noncompliance and the proposed suspension or revocation can be combined into one notification.⁵⁴³ A notice of proposed suspension or revocation must describe the reasons for the proposed action, the proposed effective date of the suspension or revocation, and the consequences that the proposed suspension or revocation will have on eligibility for accreditation in the future.⁵⁴⁴ It must also state that the certifying agent has a right to file an appeal.⁵⁴⁵

In the event that the certifying agent does not file an appeal, the Secretary must provide a written notice of suspension or revocation of accreditation to the certifying agent.⁵⁴⁶ When its accreditation has been suspended or revoked, the certifying agent shall terminate all of its certification activities.⁵⁴⁷ It must also provide the Secretary all of the records pertaining to its suspended or

⁵³¹ See *id.*

⁵³² See *id.*

⁵³³ See *id.*

⁵³⁴ See *id.*

⁵³⁵ See *id.*

⁵³⁶ See *id.*

⁵³⁷ See *id.* at § 205.665(a).

⁵³⁸ *Id.* at § 205.665(a)(1)-(3).

⁵³⁹ See *id.* at § 205.665(b).

⁵⁴⁰ See *id.* at § 205.665(d).

⁵⁴¹ See *id.* at § 205.665(c).

⁵⁴² See *id.*

⁵⁴³ See *id.*

⁵⁴⁴ See *id.* at § 205.665(c)(1)-(3).

⁵⁴⁵ See *id.* at § 205.665(c)(4).

⁵⁴⁶ See *id.* at § 205.665(e).

⁵⁴⁷ See *id.* at § 205.665(f)(1).

revoked certification activities and make the records available to the SOP governing official, as applicable.⁵⁴⁸

Unless otherwise specified in the notice of suspension, a certifying agent whose accreditation has been suspended at any time may request the Secretary to reinstate its accreditation.⁵⁴⁹ The request must include evidence demonstrating that the noncompliance has been corrected with a description of the corrective measures being implemented to maintain compliance with the NOP requirements.⁵⁵⁰ The certifying agent may not, however, request reinstatement for at least three years.⁵⁵¹ Unlike the ineligibility requirements pertaining to a notice of revocation of certification issued to a certified production or handling operation, the final rule does not allow the Secretary to shorten or eliminate the three-year time period of ineligibility for a certifying agent that has received a notice of revocation of accreditation.

6. Noncompliance Procedures Under SOPs

The governing official for a SOP must provide prompt notice to the Secretary whenever it commences a noncompliance proceeding against a certified operation.⁵⁵² The governing official must also provide a copy of each notice of noncompliance issued to an operation.⁵⁵³ Any appeal of a noncompliance proceeding must be appealed in accordance with the appeal procedures established for the SOP, which are discussed below.⁵⁵⁴ Final decisions rendered in SOP noncompliance proceedings may be appealed to the United States District Court for the district in which the operation is located.⁵⁵⁵ There are no subsequent appeal rights to the Secretary.⁵⁵⁶

The governing official may also review and investigate noncompliance complaints concerning accreditation of certifying agents within the state.⁵⁵⁷ ⁵⁵⁸ If the official discovers any noncompliance in the course of its review or investigation, it must send a written report of noncompliance to the Secretary that describes the noncompliance(s) and the factual basis for issuing the notice.⁵⁵⁹

J. Adverse Action Appeals Process

Producers and handlers may appeal to the Administrator a certifying agent's decision to deny an application for certification, as well as a certifying agent's decision to issue the operation a notice of proposed suspension or revocation of certification.⁵⁶⁰ However, if the operation is subject to an approved SOP, the appeal must be made to the SOP and must be carried out in accordance with the

⁵⁴⁸ See *id.* at § 205.665(f)(2).

⁵⁴⁹ See *id.* at § 205.665(g)(1).

⁵⁵⁰ See *id.*

⁵⁵¹ See *id.* at § 205.665(g)(2).

⁵⁵² See *id.* at § 205.668(a).

⁵⁵³ See *id.*

⁵⁵⁴ See *id.* at § 205.668(b).

⁵⁵⁵ See *id.*

⁵⁵⁶ See *id.*

⁵⁵⁷ See *id.* at § 205.668(c).

⁵⁵⁸ In 2003, Massachusetts Independent Certification, Inc. (MICI), an independent certifier, sought to have a decision issued by the Administrator reversed; the Administrator had sustained an appeal brought by a producer who had been denied certification by MICI. *In re Mass. Indep. Certification, Inc.*, OFPA Docket No. 03-0001, 2004 WL 909533, at *1 (USDA Apr. 27, 2004). The case was dismissed for lack of jurisdiction. *Id.* at *2. On appeal, the United States District Court for the District of Massachusetts dismissed MICI's appeal, stating that the regulations denying certifiers the right to appeal did not violate OFPA. *Mass. Indep. Certification, Inc. v. Johanns*, 486 F.Supp. 2d 105, 118-20 (D.Mass 2007).

⁵⁵⁹ See *id.*

⁵⁶⁰ See *id.* at §§ 205.680 & 205.681.

SOP appeal procedures.⁵⁶¹ The Administrator or SOP has the responsibility to either sustain or deny the appeal.⁵⁶²

A decision by the Administrator or SOP to sustain the appeal shall not be subject to appeal by the affected certifying agent.⁵⁶³ If the appeal is denied, “a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification” and “shall be conducted pursuant to the U.S. Department of Agriculture’s Uniform Rules of Practice or the State Organic Program’s rules of procedure.”⁵⁶⁴

Certifying agents may appeal to the Administrator a decision by the Secretary to deny an application for accreditation, as well as a decision by the Secretary to issue a proposed notice of suspension or revocation of accreditation.⁵⁶⁵ As with certification appeals, the Administrator will sustain or deny the appeal.⁵⁶⁶ If it is sustained, the applicant will be issued accreditation or the certifying agent will continue its accreditation.⁵⁶⁷ If the appeal is denied, “a formal adjudicative proceeding to deny, suspend, or revoke the accreditation will be initiated” and such proceeding “shall be conducted pursuant to the U.S. Department of Agriculture’s Uniform Rules of Practice”⁵⁶⁸

An appeal of a noncompliance determination must be filed within either the time period provided in the letter of notification or within thirty days from the receipt of the notification, whichever occurs later.⁵⁶⁹ If not filed in a timely manner, a decision to deny, revoke, or suspend certification or accreditation will become final and nonappealable.⁵⁷⁰

⁵⁶¹ *See id.*

⁵⁶² *See id.*

⁵⁶³ *See id.*

⁵⁶⁴ *Id.* at § 205.681(a)(2).

⁵⁶⁵ *See id.* at § 205.681(b).

⁵⁶⁶ *See id.*

⁵⁶⁷ *See id.* at § 205.681(b)(1).

⁵⁶⁸ *See id.* at § 205.681(b)(2).

⁵⁶⁹ *See id.* at § 205.681(c).

⁵⁷⁰ *See id.*