



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-17-0065; NOP-17-02]

RIN 0581-AD09

National Organic Program; Strengthening Organic Enforcement

AGENCY: Agricultural Marketing Service, USDA

ACTION: Proposed rule.

SUMMARY: The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) proposes amending the USDA organic regulations to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. The proposed amendments are intended to protect integrity in the organic supply chain and build consumer and industry trust in the USDA organic label by strengthening organic control systems, improving farm to market traceability, and providing robust enforcement of the USDA organic regulations. Topics addressed in this proposed rule include: applicability of the regulations and exemptions from organic certification; National Organic Program Import Certificates; recordkeeping and product traceability; certifying agent personnel qualifications and training; standardized certificates of organic operation; unannounced on-site inspections of certified operations; oversight of certification activities; foreign conformity assessment systems; certification of grower group operations; labeling of nonretail containers; annual update requirements for certified operations; compliance and appeals processes; and calculating organic content of multi-ingredient products.

DATES: Send comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may send comments on this proposed rule to the Federal eRulemaking Portal at <https://www.regulations.gov/>. You can access this proposed rule and instructions for submitting public comments by searching for document number, AMS-NOP-17-0065. Comments may also be sent to Jennifer Tucker, Deputy Administrator, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268; (202) 260-9151 (Fax).

Instructions: All comments received must include the docket number AMS-NOP-17-0065; NOP-17-02, and/or Regulatory Information Number (RIN) 0581-AD09 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers, state your position(s), offer any recommended language change(s), and include relevant information and data to support your position(s) (e.g., scientific, environmental, manufacturing, industry, or industry impact information, etc.). All comments and relevant background documents posted to <https://www.regulations.gov> will include any personal information provided.

In addition to the questions following each topic in the **Overview of Proposed Amendments** section of this proposed rule, AMS is requesting comments on the following general topics:

1. The clarity of the proposed requirements. Can certified operations, handlers, and certifying agents readily determine how to comply with the proposed regulations?
2. The implementation timeframe. AMS is proposing that all requirements in this proposed rule be implemented within ten months of the effective date of the final rule (this is also one year after publication of the final rule).

3. The accuracy of the estimates in the Regulatory Impact Analysis and Regulatory Flexibility Analysis, which describe the expected costs of this proposed rule on all affected entities and on small businesses, respectively.
4. Are there alternatives to regulations, or less stringent requirements, that could achieve the same objectives as this proposed rule?
5. How will certifying agents cover the costs of additional actions required under this rule, such as the required unannounced inspections and the issuing of NOP Import Certificates? Will certifying agents charge fees that are consistent for expanded handlers, brokers, importers and exporters?

FOR FURTHER INFORMATION CONTACT: Jennifer Tucker, Ph.D., Deputy Administrator, National Organic Program. Telephone: 202-720-3252. Email: Jennifer.Tucker@usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Purpose of the Proposed Rule

This proposed rule would amend several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen oversight of the production, handling, certification, marketing, and sale of organic agricultural products as established by the Organic Foods Production Act of 1990 (OFPA, or “the Act”).¹ If implemented, this proposed rule will improve organic integrity across the organic supply chain, and benefit stakeholders throughout the organic industry. The proposed amendments will close gaps in the

¹ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this proposed rule. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>

current regulations to build consistent certification practices to deter and detect organic fraud, and improve transparency and product traceability. In addition, the proposed amendments will assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label.

The need for more consistent oversight to protect organic integrity is a product of the rapidly expanding organic market, increasingly complex organic supply chains, and price premiums for organic products. Total sales of organic agricultural products in the United States grew from \$3.4 billion in 1997 to \$55.1 billion in 2019.² This substantial market growth has allowed many additional types of business to participate in the organic supply chain, and organic agricultural products are now traded on a global scale. Today's global organic marketplace is marked by a multifaceted supply chain with organic products increasingly sold and handled by entities not regulated by the USDA. The absence of direct enforcement authority over some entities in the organic supply chain, in combination with price premiums for organic products, presents the opportunity and incentive for organic fraud, which has been discovered in the organic sector by both the National Organic Program (NOP) and organic stakeholders. The amendments in this proposed rule are designed to mitigate the occurrence of organic fraud.

In response to their experiences in the organic system, stakeholders have repeatedly called for the NOP to take steps to improve oversight of organic systems and enforcement of the USDA organic regulations. Commonly cited areas for improvement include certification of excluded handlers, organic import oversight, fraud prevention, organic trade arrangements, and organic inspector qualifications. In

² Organic Trade Association, Organic Industry Survey, 2018–2020.

addition, public discussions on many proposals included in this action occurred during multiple National Organic Standards Board (NOSB) meetings.³

The NOP identified the need for many of the proposed amendments as part of its direct experience in administering this program, particularly during complaint investigations and audits of certifying agents. Other proposed amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018;⁴ the recommendations of a 2017 Office of Inspector General audit; the recommendations of a federal advisory committee, the NOSB; and industry stakeholder feedback. The amendments in this proposed rule are intended to: (1) strengthen organic control systems; (2) improve organic import oversight; (3) clarify organic certification standards; and (4) enhance supply chain traceability.

B. Summary of Provisions

This proposed rule will strengthen enforcement of the USDA organic regulations through several actions mandated by the Agriculture Improvement Act of 2018:

1. Reduce the types of uncertified entities in the organic supply chain that operate without USDA oversight—including importers, brokers, and traders of organic products. This will safeguard organic product integrity and improve traceability.
2. Require the use of NOP Import Certificates, or equivalent data, for all organic products entering the United States. This proposed change will expand the use of NOP Import

³ The April 2019 NOSB meeting is the most recent example of a public discussion to address fraud concerns in the organic supply chain. A discussion document, meeting transcripts, and public comments are available at: <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>

⁴ The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the “2018 farm bill,” is available at <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>. Organic certification is discussed in Title X, Section 10104.

Certificates to all organic products imported into the United States, improving the oversight and traceability of imported organic products.

3. Clarify the NOP's authority to oversee certification activities, including the authority to act against an agent or office of a certifying agent. Additionally, certifying agents must notify the NOP upon opening a new office, which will allow the NOP to provide more effective and consistent oversight of certifying agents and their activities.

Additionally, this proposed rule includes several discretionary actions that work in alignment with the provisions above to further strengthen enforcement of the USDA organic regulations:

4. Clarify the labeling of nonretail containers used to ship or store organic products. Requiring additional information on nonretail containers will clearly identify organic products, reduce the mishandling of organic products, and support traceability. This is needed to maximize the linkage between operation certificates and import certificates and the organic product.
5. Specify the minimum number of unannounced inspections of certified operations that must be conducted annually by accredited certifying agents, and require that supply chain audits be completed during on-site inspections.
6. Require certifying agents to issue standardized certificates of organic operation generated from the USDA's Organic Integrity Database (INTEGRITY) and to keep accurate and current certified operation data in INTEGRITY. Standardization will simplify the verification of valid organic certificates and import certificates. It will also reduce reporting, by eliminating the need to provide notices of approval or denial of certification and annual lists of certified operations to USDA.

7. Clarify that certified operations only need to submit changes to their organic system plan during annual updates, and clarify that certifying agents must conduct annual inspections of certified operations. This will reduce paperwork burden for organic operations and ensure that all organic operations are inspected at least once a year.
8. Establish specific qualification and training requirements for certifying agent personnel, including inspectors and certification reviewers. Requiring that personnel meet minimum education and experience qualifications and requiring continuing education will ensure quality and consistency of certification activities performed by certifying agents.
9. Clarify conditions for establishing, evaluating, and terminating equivalence determinations with foreign government organic programs, based on an evaluation of their organic foreign conformity systems. This will ensure the compliance of organic products imported from countries that have organic equivalence determinations with the United States.
10. Clarify requirements to strengthen and streamline enforcement processes, specifically noting that the NOP may initiate enforcement action against any violator of the OFPA, including responsible parties; defining the term adverse action to clarify what actions may be appealed and by whom; and clarifying NOP's appeal procedures and options for alternative dispute resolution.
11. Specify certification requirements for grower group operations, to provide consistent, enforceable standards and ensure compliance with the USDA organic regulations. Grower group certification would be restricted to crop production and handling only, and would require the use of an internal control system to monitor compliance.
12. Clarify the method of calculating the percentage of organic ingredients in a multi-ingredient product to promote consistent interpretation and application of the regulation.

13. Require certified operations and certifying agents to develop improved recordkeeping, organic fraud prevention, and trace-back audit processes. Information sharing between certifying agents and documented organic fraud prevention procedures are also required.

C. Costs and Benefits

AMS estimates the following costs and benefits of this proposed rule:

| Economic Impact of SOE Proposed Rule | | |
|---|-------------------------------|---------------------------------|
| | Annualized^a | Total^b |
| Costs | \$7,205,815 – \$7,351,910 | \$65,629,941 – \$87,766,628 |
| Benefits | \$83,992,975 – \$86,874,833 | \$765,000,793 – \$1,037,106,112 |

^a Estimated 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

^b Estimated total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent, 15 year

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I. General Information

A. Does this Proposed Action Apply to Me?

You may be affected by this proposed action if you are engaged in the organic industry. Potentially affected entities may include, but are not limited to, the following:

- Individuals or business entities that are considering organic certification;
- Existing production and handling operations that are currently certified organic under the USDA organic regulations;
- Brokers, traders, and importers of organic products that are not currently certified under the USDA organic regulations;
- Operations that use non-retail containers for shipping or storing organic products;
- Retailers that sell organic products;
- Operations that receive or review organic certificates to verify compliance with USDA organic regulations;
- USDA-accredited certifying agents, inspectors, and reviewers;
- Operations that import organic products into the United States; and/or
- Operations that export organic products to the United States.

This listing is not intended to be exhaustive but identifies key entities likely to be affected by this proposed action. Other types of entities may also be affected. To determine whether you or your business may be affected by this proposed action, you should carefully examine the proposed regulatory text.

II. Background

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524), authorizes the Agricultural Marketing Service (AMS) to establish and maintain national standards governing the marketing of organically produced agricultural products. AMS administers these standards through the National Organic Program (NOP). Final regulations implementing the NOP, also referred to as the USDA organic regulations, were published on December 21, 2000 (65 FR 80548) and became effective on October 21, 2002.⁵ Through these regulations, AMS oversees national standards for the production, handling, labeling, and sale of organically produced agricultural products.

Since full implementation of the USDA organic regulations, the organic industry has experienced significant change. Both demand for and sales of organic products have risen steadily; total U.S. sales of organic products reached more than \$55 billion in 2019.⁶ The number of businesses producing, handling, marketing, and selling organic products has also grown to meet consumer demand. Rapid growth has attracted many businesses to the USDA organic label and increased the complexity of the global organic supply chain.

AMS is confident in the integrity and value of the USDA organic seal. Consumers can trust the organic label due to a rigorous oversight system that operates globally. However, the growth and complexity of the modern organic industry has exposed the limitations of the current organic regulations, revealing gaps in oversight and enforcement that the original regulations do not address. A lack of clear and specific standards in portions of the regulations has sometimes led to different interpretations of the regulations, inconsistent practices, and unequal enforcement across the industry. Increasingly complex

⁵ 7 CFR Part 205 National Organic Program; Final Rule. December 21, 2000. Available on the AMS website: <https://www.federalregister.gov/documents/2000/12/21/00-32257/national-organic-program>

⁶ Organic Trade Association, Organic Industry Survey, 2020.

organic supply chains reduce transparency and complicate traceability, yet these elements are essential to trust in the organic label. In addition, businesses that operate in the organic supply chain without oversight from the NOP pose risks to organic integrity. This can lead to mishandling of organic product, loss of organic integrity, and fraud. The provisions in this proposed rule are designed to address these risks.

Complex Organic Supply Chains

The need for this proposed rule is driven partially by the increasing complexity of organic supply chains. When the organic regulations were published in 2000, organic products were marketed mostly locally or regionally, and supply chains tended to be short and transparent; for example, farm to wholesale to retail to consumer. Demand and sales have grown considerably since then. This significant market growth has attracted more producers, handlers, product suppliers, importers, brokers, distributors, and others to the organic market.

Consider the example of an organic egg supply chain in the United States, beginning with the production of certified organic corn and ending with the sale of eggs to the consumer. This demonstrates the typical entities and transactions in an organic supply chain under the existing regulations:

- A certified organic farm produces organic corn.
- The corn is transported via an uncertified truck to a local grain elevator, where it is aggregated with other organic corn from nearby producers.
- An uncertified commodity trader buys the corn.
- The corn is transported via uncertified truck to an uncertified storage facility; both transport and storage are subcontracted and are not owned by the commodity trader.

- The commodity trader sells the corn to a certified organic grain supplier; the two parties remain anonymous because they use an uncertified broker to facilitate the transaction.
- The corn is transported via uncertified rail and river barge to the grain supplier; it is transloaded and stored temporarily several times before being delivered to the certified grain supplier.
- The certified organic grain supplier stores the corn and combines it with imported organic corn purchased from an importer via an uncertified broker.
- The certified grain supplier sells the corn to a certified organic feed processor; the corn is transported via an uncertified truck.
- The certified processor combines the corn with several other ingredients to create organic chicken feed.
- The certified processor sells the feed to a certified organic egg producer and transports it via an uncertified truck.
- The certified organic egg producer sells organic eggs to an uncertified distributor.
- The uncertified distributor sells the organic eggs to a retailer prior to final sale to the consumer.

This is just one example of a complex organic supply chain. It becomes even more complex if one considers that the processor combines several ingredients into the final chicken feed, sourced both domestically and imported. Each ingredient has its own unique supply chain—and together they weave a complex and dense web converging on a single organic product.

Organic Fraud

The risk of organic fraud has grown due to high demand for organic products, the absence of direct enforcement authority over some entities in the organic supply chain, and price premiums for organic

products. Both the NOP and organic stakeholders have uncovered organic fraud in the organic supply chain. The following examples highlight the extent and complexity of organic fraud in organic grain and oilseed supply chains.

Organic Grain and Oilseed Fraud in the United States.

In recent years, the NOP has identified fraud in both domestic and foreign organic grain and oilseed supply chains. These supply chains are generally complex and involve multiple changes in product ownership, creating additional risk and opportunity for fraud. Demand for organic grain and oilseed (especially for organic livestock feed) currently exceeds domestic production. In 2019, a private organic outlook firm predicted a double-digit decline in domestic organic corn and soybean production. The shortage of domestic organic commodities, combined with a projected shrinking supply, increases the incentive for organic fraud. Federal investigations show that organic grain and oilseed fraud can lead to tens of millions of dollars in fraudulent sales within just a few months. Below are several examples which outline the different actors, market complexities, and indicators of an increase in fraud.

In 2019, the U.S. Attorney's office of Northern Iowa sentenced five individuals to prison for their role in an organic grain fraud ring. The lead defendant pled guilty to defrauding customers in a scheme involving at least \$142 million in nonorganic grains sold as organic. The lead defendant sold fraudulent grain to customers over a period of seven years, claiming the product was organically grown in Nebraska and Missouri.

In February 2020, a federal grand jury indicted an individual in South Dakota for allegedly selling \$71 million of nonorganic grains and oilseeds falsely labeled organic over five years. The fraud ring spanned multiple states. After the NOP revoked the organic business' organic certificates, the responsible parties established new brokerage firms to continue their fraud. Under the current organic regulations, these brokerages did not require organic certification; the NOP had no oversight of their activities. This

proposed rule would require the certification and oversight of brokers like those involved in this case. This would allow the NOP to identify and prevent the fraud, minimizing damage to the U.S. market.

In addition to the examples above, the NOP continues to investigate multiple cases of organic grain and oilseed fraud at the production and handling levels. Continuing complaints of organic grain fraud received by the NOP demonstrate an ongoing need for stronger enforcement provisions to ensure integrity in organic supply chains.

Fraud within Complex Supply Chains.

Cases of organic fraud are often compounded by a complex supply chain. Uncertified entities acting within a complex supply chain can create significant oversight and enforcement challenges for both the NOP and accredited certifying agents. Recent fraud investigations have shown that the use of uncertified handlers can decrease the NOP's ability to prevent fraudulent grain sales in the organic market.

Fraudulent actors may obtain organic handler certification solely to take advantage of the regulatory exclusions at 7 C.F.R. 205.101. Investigations have found fraudulent actors using these exclusions to funnel nonorganic feedstuffs through uncertified grain elevators. Because organic certifying agents sometimes consider elevators to be transportation, they are not required to obtain organic certification. In addition, because some grain elevators are not certified, the NOP cannot compel organic certifying agents to investigate the onsite activities at these elevators.

The above examples of actual fraud investigations demonstrate the complexity of organic supply chains, the certification status of the entities involved, and the transactions where fraud occurred. It is also useful to consider the types of entities involved:

- Certified organic farms thought to supply little or none of the feedstuffs later sold as organic.

- Uncertified farms supplying non-GMO feedstuffs to uncertified grain elevators.
- Uncertified grain elevators currently excluded from certification requirements.
- Certified handlers that brokered the sale of nonorganic feedstuffs through an uncertified elevator to certified buyers, falsifying paperwork to represent the products for sale as organic.
- Certified organic handlers that consolidated fraudulent products from previous handlers, thinking the product was organic.
- Certified feed mills that purchased the nonorganic feedstuffs believing the products were organic.
- Livestock and poultry operations that purchased feed rations from the mills and thus unknowingly fed nonorganic feed to their animals, which are required to eat a diet of 100% certified organic feed.

The proposed rule would require the certification of some types of currently uncertified entities, such as the grain elevators in this example. Organic certification would subject these entities to regular, systematic oversight from accredited certifying agents and allow the NOP to monitor these entities' activities through on-site investigations, ensuring faster detection and prevention of millions of dollars in organic fraud.

Terminology and Objectives

Throughout this proposed rule, AMS refers to four concepts—organic integrity, organic fraud, audit trails, and supply chain traceability—which are integral to the purpose of this proposed rule. AMS is explaining these concepts upfront to assist reader understanding:⁷

1. Organic integrity: The unique attributes that make a product organic, and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.
2. Organic fraud: Intentional deception for illicit economic gain, where nonorganic products are labeled, sold, or represented as organic. This may include substitutions or deliberate mislabeling; falsified records; and/or false statements given in applications or organic system plans, or during inspections, investigations, and audits.
3. Audit trail: Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as “100 percent organic,” the organic ingredients of any agricultural product labeled as “organic” or “made with organic (specified ingredients)” or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement (7 CFR 205.2).
4. Supply chain traceability: The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards” from consumption to source. A supply chain audit assesses supply chain

⁷ These terms are explained only for use in this proposed rule and are not intended to represent any addition to 7 CFR Part 205 or revision to the term *audit trail*.

traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.

The objective of this proposed rule is to strengthen enforcement of the USDA organic regulations and protect the integrity of the organic label by (1) strengthening organic control systems; (2) improving organic import oversight; (3) clarifying organic certification standards; and (4) enhancing supply chain traceability. AMS identified the need for these proposed changes from the following sources:

- Direct experience in administering the NOP, particularly complaint investigations and audits of accredited certifying agents;
- The Agriculture Improvement Act of 2018,⁸ which amended the OFPA.
- Recommendations of a 2017 Office of Inspector General report;⁹
- Recommendations of the NOP's federal advisory committee, the National Organic Standards Board (NOSB); and
- Industry stakeholder and consumer feedback.

If implemented, AMS expects the amendments proposed in this rule will bring more effective oversight and enforcement, improve organic integrity and product traceability, clarify existing standards to ensure fair competition, bolster consumer trust in the organic label, reduce organic fraud, and support continued industry growth. Information about each amendment is described in more detail below.

⁸ The Agriculture Improvement Act of 2018, Public Law No: 115-334, is available at:

<https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

⁹ USDA Office of Inspector General Audit Report 01601-0001-21: National Organic Program International Trade Arrangements and Agreements. September 2017: <https://www.usda.gov/oig/webdocs/01601-0001-21.pdf>

III. Overview of Proposed Amendments

1. Applicability and Exemptions from Certification.

| Section | Action | Proposed Text |
|------------|--------|---|
| 205.2 | Revise | <i>Handle.</i> To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, labeling, combining, containerizing, storing, receiving, or loading. |
| 205.2 | Revise | <i>Handler.</i> Any person engaged in the business of handling agricultural products. |
| 205.2 | Revise | <i>Handling operation.</i> Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification. |
| 205.2 | Revise | <i>Retail operation.</i> An operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions. |
| 205.100(a) | Revise | Except for the exempt operations described in §205.101, each operation, or portion of an operation, that produces or handles agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part. |
| 205.101 | Revise | Exemptions from certification. |
| 205.101 | Revise | The following operations in subparagraphs (a) through (e) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must |

| | | |
|------------|--------|--|
| | | comply with the applicable organic production and handling requirements of subpart C of this part, including the provisions for prevention of contact of organic products with prohibited substances set forth in §205.272, and the specific additional requirements stipulated in §205.101(a) through (f). |
| 205.101(a) | Revise | A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation. Such operations must comply with the labeling provisions of §205.310. |
| 205.101(b) | Revise | A retail operation or a portion of a retail operation that sells, but does not process, organically produced agricultural products. |
| 205.101(c) | Revise | A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer. Such operations must comply with the labeling provisions of §205.310, and must maintain records sufficient to: (1) Prove that agricultural products identified as organic were organically produced and handled; and (2) Verify quantities produced or sold from such agricultural products. |
| 205.101(d) | Add | A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in §205.301(d)), or that only identifies organic ingredients on the |

| | | |
|------------|-----|--|
| | | <p>information panel. Such operations must comply with the labeling provisions of §§205.305 and 205.310 and must maintain records sufficient to:</p> <p>(1) Prove that agricultural products identified as organic were organically produced and handled; and</p> <p>(2) Verify quantities produced or sold from such agricultural products.</p> |
| 205.101(e) | Add | An operation that only stores, receives, and/or loads agricultural products, but does not process or alter such agricultural products. |
| 205.101(f) | Add | Records described in subparagraphs (a)–(d) of this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs’ governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part. |

AMS proposes amending §§ 205.2 and 205.100–101 of the USDA organic regulations to clarify the applicability of the regulations and limit the types of operations excluded from organic certification in the global supply chain. This includes revising the definitions of *handle*, *handler*, *handling operation*, and *retail food establishment*. The proposed amendments would require certification of operations that facilitate the sale or trade of organic products, including but not limited to brokers, importers, and traders.

In general, this proposed rule requires the certification of any handling operation whose activities may affect the organic status of agricultural products they handle or represent after production, as the products move from production source through a supply chain. The amendments also clearly specify which entities and activities are exempt from certification. Most notably, this includes exemptions for

retail operations and entities that only store organic products; the current exclusions at § 205.101(b)(1) would be removed.

Authority.

AMS' authority to modify §§ 205.2, 205.100, and 205.101 of 7 CFR is established in the OFPA. The statute allows AMS to "establish an organic certification program for producers and handlers of agricultural products" (7 U.S.C. 6503(a)) and "require such other terms and conditions as may be determined...necessary" (7 U.S.C. 6506(a)(11)). The OFPA and the USDA organic regulations state that any operation that produces or handles certified organic agricultural products is required to be certified (7 U.S.C. 6503 and 7 CFR 205.100). Additionally, the Agriculture Improvement Act of 2018 (the "2018 farm bill") requires that the USDA "issue regulations to limit the type of organic operations that are excluded from certification under section 205.101" of the organic regulations.¹⁰

This proposed amendment clarifies the terms *handle*, *handler*, and *handling operation* to better align with the OFPA definition of *handle*, "to sell, process, or package agricultural products" (7 U.S.C. 6502(8)). Limiting handler exemptions is necessary to meet the basic purposes delineated in 7 U.S.C. 6501(2)–(3), "to assure consumers that organically produced products meet a consistent standard, and to facilitate interstate commerce in fresh and processed food that is organically produced." As the current exclusions at § 205.101(b)(1) are no longer appropriate, AMS is exercising its authority, as mandated in the 2018 farm bill, to limit those exclusions in order to fully implement the national standards authorized by 7 U.S.C. 6504 and to ensure compliance with the OFPA and the USDA organic regulations.

¹⁰ See section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

History and justification for amendments.

In addition to the 2018 farm bill, several factors compel regulatory changes to require the certification of many currently excluded operations. The present need for expanded oversight to protect organic integrity is primarily due to the emergence of complex global supply chains and business relationships, and price premiums for organic products. These factors present the opportunity and incentive for organic fraud, which has materialized in the organic sector, and which would be mitigated by reducing the types of entities excluded from certification.

Following full implementation of the NOP in 2002, AMS believed that organic product integrity would not be compromised or altered when handled by entities such as brokers, distributors, traders, storage professionals, receivers, and loaders. As such, these handlers were not required to be certified. At that time, marketing was mostly local or regional, and organic market sales totaled a fraction of today's figures. Additionally, the percentage of organic product handled by excluded entities was relatively low.

The organic market has grown considerably since the USDA organic regulations took effect in 2002. The Organic Trade Association reports that total U.S. organic sales grew from \$3.4 billion in 1997 to \$55.1 billion in 2019.¹¹ This significant market growth has created the opportunity for additional domestic and international producers, handlers, product suppliers, importers, brokers, distributors, and others to participate in the organic market. Interpretation of the current regulations has allowed many of these operations to remain uncertified. This has resulted in increased complexity of organic supply chains. Today's organic marketplace is marked by multifaceted supply chains with organic products increasingly coordinated by entities not regulated by the USDA, creating risks that could impact the integrity of organic products.

¹¹ Organic Trade Association, Organic Industry Survey, 2018–2020.

Other contributors to risk include entities in the middle of supply chains that facilitate the sale or trade of organic products. These include domestic importers of products, brokers/traders, distributors, and other handlers who represent a link between certified parties. Although some of these handlers voluntarily seek certification, the current organic regulations do not require their certification. Handlers are responsible for the integrity of the organic products they handle, even if they never take ownership or possession of a product, because they frequently make decisions impacting the integrity of organic products. For example, they may file import and export permits; arrange sales to both certified and uncertified entities; and comply with mandatory import conditions such as fumigation or irradiation. The current lack of certification requirements for excluded handlers can negatively affect the organic status of products, and reduce the availability of auditable records needed to assess organic status.

The evolution of the organic industry has made clear that the current terms *handle*, *handler*, and *handling operation*, as defined at § 205.2 of the organic regulations, no longer adequately represent the full scope of organic supply chains. The allowance of uncertified handlers creates gaps in the organic supply chain, breaking chains of custody and complicating the verification of product origin. Expanding organic certification to cover a wider range of handling operations is critical to supply chain traceability. It would make more parties visible and accountable, require the generation and maintenance of auditable records, and improve the usefulness of audit trails and product verification. The NOP believes improved supply chain traceability is critical to the continuing success of the program and its ability to ensure the integrity of organic products. Supply chain traceability is discussed in more detail later in this proposed rule.

Previous actions by AMS, the NOSB, and stakeholders.

In 2010, the NOSB provided AMS recommendations to address the risks to organic integrity created by handler exclusions.¹² The NOSB determined that handlers of unpackaged bulk agricultural products should not be excluded from certification and requested that the NOP define the scope of handling activities addressed by § 205.101(b) of the organic regulations. In 2014, the NOP issued guidance on the certification requirements for handling unpackaged organic products (NOP 5031)¹³ and provided clarification about the circumstances under which a handling operation is excluded from certification requirements. This guidance was based upon both the 2010 NOSB recommendations and the findings of two Office of Inspector General audits of the NOP's oversight of organic milk.¹⁴ Because the guidance in NOP 5031 only addresses handlers of unpackaged organic products, it has not eliminated the audit trail gaps that prevent full product traceability from farm gate to consumer. Furthermore, NOP 5031 has not been consistently implemented by certifying agents, particularly with respect to less-typical handling activities (e.g., auguring commodities from vessels to rail cars at ports).

Clarification of applicability.

The proposed rule clarifies the applicability of the regulations by revising § 205.100 and the definitions of *handle*, *handler*, and *handling operation*. These proposed revisions clearly state which entities, operations, and activities require certification under the USDA organic regulations. Specifically, the proposed rule revises the definition of *handle* by including additional activities, most notably trading, brokering, and facilitating sale or trade. The revised definition of *handle* reflects the broad range of

¹² NOSB Formal Recommendation: Clarifying the Limits of 205.101(b), October 28, 2010: <https://www.ams.usda.gov/sites/default/files/media/NOP%20CACC%20Final%20Rec%20Clarifying%20the%20Limitations.pdf>

¹³ NOP 5031—Guidance, Certification Requirements for Handling Unpackaged Organic Products, January 22, 2014: <https://www.ams.usda.gov/sites/default/files/media/5031.pdf>

¹⁴ USDA Office of Inspector General Audit Report 01601-0001-Te: National Organic Program—Organic Milk, February 2012: <https://www.usda.gov/oig/webdocs/01601-0001-Te.pdf>

handling activities that take place in the modern organic industry, and can be generally described to include activities that affect the organic status or ownership of an agricultural product after production as it moves from production source through a supply chain.

Unless specifically exempted from certification, as discussed in a later section, any person or operation that conducts activities described in the revised definition of *handle* would need to be certified and comply with all applicable requirements for handlers. This would require the certification of certain types of excluded handlers that currently operate without regular systematic oversight from the USDA, most notably intermediate market actors such as brokers, traders, and importers. Certified organic products that are handled by an uncertified, non-exempt operation at any point in the supply chain will lose their certified organic status and may no longer be sold, labeled, or represented as organic. In turn, certified organic operations that receive products from uncertified, non-exempt handlers and subsequently label the products as organic, use as feed for organic livestock, or use as ingredients for organic products are in violation of USDA organic regulations, and may be subject to proposed suspension or revocation of certification and possible civil penalties.

The proposed rule also modifies the definitions of *handler* and *handling operation* to include any person or operation that handles agricultural products. This includes handling operations such as importers, brokers, and traders. Accountability from these operations is required to maintain the integrity of organic products. Even if these operations do not take physical possession or ownership of the product they represent, their decisions affect the status of organic products; the operation's records are essential to demonstrate a product's compliance at that point in the supply chain. For example, uncertified brokers may receive notices of organic products being treated with substances prohibited for use on organic products, but might not provide those notices to certified importers or accredited certifying agents. Such critical breaks in the audit trail could allow products to be sold as organic, after being treated with substances prohibited for use on organic products.

Similarly, uncertified storage facilities may store and split or combine lots and loads. Certifying agents and certified importers may not be informed of the full range of activities conducted at such facilities; however, handlers at these locations have a critical role in maintaining the integrity and traceability of organic products. For this reason, the proposed rule would require the certification of these types of handlers.

Finally, because uncertified handlers are not required to maintain auditable records for five years, sales or transit records might not be available for inspection by the USDA or certifying agents. The U.S. Government has limited ability to obtain records from foreign businesses who are not certified to the USDA regulations. The current exclusion of these brokers from organic certification creates risks for organic integrity when they facilitate the sale of USDA-organic products produced overseas, prior to export to the United States.

Clarification of exemptions from certification.

In addition to clearly stating who requires organic certification, the proposed rule also describes the activities that would not require certification to produce, handle, or sell organic agricultural products. The proposed rule modifies § 205.101 by renaming the section “Exemptions from certification,” eliminating the exclusions currently listed at § 205.101(b), and listing in revised § 205.101 all operations that are exempt from organic certification. Eliminating reference to exclusion and excluded operations, and categorizing as exempt those operations that do not require organic certification, will reduce confusion and misinterpretation about who needs to be certified.

Although they do not require certification, exempt operations must comply with portions of the organic regulations. Exempt operations that are producing or handling organic products are responsible for maintaining organic integrity and must follow the production and handling requirements of the organic regulations that relate to their activities. Stakeholders have expressed concern about the clarity and

consistent implementation of these requirements. The proposed rule addresses this concern by clearly stating what requirements each exempt operation must follow. In general, all exempt operations must follow the applicable organic production and handling requirements of subpart C of the regulations, including the provisions for prevention of contact of organic products with prohibited substances (§ 205.272). In addition, specific additional requirements are included for some exemptions, and recordkeeping requirements are explained in revised § 205.101.

Exemptions retained by the proposed rule.

The current exemption for operations with \$5,000 or less in annual income from organic sales is retained at revised § 205.101(a). To ensure the integrity of organic products, these operations are required to comply with the provisions for the prevention of contact of organic products with prohibited substances (§ 205.272) and the labeling provisions of § 205.310. The current exemptions for operations that handle products with less than 70 percent organic ingredients and operations that only identify organic ingredients on product labels are also retained at new § 205.101(d). These exempt handlers are required to comply with the labeling requirements of §§ 205.305 and 205.310, the comingling requirements of § 205.272, and must maintain records that (1) prove that agricultural products identified as organic were organically produced and handled, and (2) verify quantities produced or sold from such agricultural products.

Exclusions removed from the proposed rule.

The current exclusion at § 205.101(b)(1), for operations that only handle packaged organic products, is omitted from the proposed rule. This amendment will improve traceability of organic products through the supply chain and reduce the potential mishandling of packaged organic products by uncertified operations. This modification also addresses many stakeholders' request that everyone in the supply chain producing or handling organic products must be certified, with very limited exceptions. Requiring

certification of additional types of handling operations, including those previously excluded by the “packaged product” condition, would substantially enhance the integrity of organic products by eliminating record gaps in the supply chain and enabling more complete audit trails. Expanded certification also would reduce the risk of exposure of packaged organic products to prohibited methods such as ionizing radiation and fumigation with prohibited materials, processes that may compromise the product’s organic status.

Clarification of the retail operation exemption.

The proposed rule renames the term *retail food establishment* as *retail operation* and expands the definition to include current modes of direct-to-consumer sales that commonly occur in the modern marketplace. The term *retail operation* is defined as an operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions. This amended term is required to capture the full range of direct-to-consumer sales that may occur in the current era of electronic and internet commerce. “Virtual transaction” is used to describe any form of transaction that does not occur in person (e.g., telephone, mail-order, and/or online sales). Additionally, expanding the term to include food and other agricultural products is necessary to reflect the full range of certified organic products that may be sold directly to consumers in today’s retail marketplace. Examples of retail operations include but are not limited to restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service stations (e.g., grains, nuts), or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.

The OFPA excludes final retailers that do not process agricultural products from the definition of “handler” and “handling operation.” (7 U.S.C. 6502). Therefore, these types of retailers are not required to be certified in order to sell organic products. In the proposed rule, AMS is modifying and expanding the current provision in the USDA organic regulations which permits retailers that process raw and

ready-to-eat agricultural products to sell, label, or represent these products as organic. In the future, under its existing authority, AMS could consider requirements for the certification of retailers that process agricultural products intended to be sold, labeled, or represented as organic. We are retaining the exemption from certification for retailers that process unless and until we have more input from stakeholders on the need for and impact of removing this exemption and recommended standards for retailers.

The proposed rule would exempt retail operations from certification, including retail operations that sell, but do not process, organic agricultural products (proposed § 205.101(b)), and retail operations that process agricultural products previously labeled for retail sale as organic (proposed § 205.101(c)). These exemptions are very similar to the current exemption and exclusion for retail food establishments at current §§ 205.101(a)(2) and (b)(2). To qualify for the exemption at proposed § 205.101(c), any processing of organic products performed by a retail operation must occur in connection with the direct sale to the final consumer. This means that the products must be processed and sold in the same physical location. An operation processing a product for sale at another site would require certification. This would include retailers that sell virtually; the organic products which they sell, label or represent as organic must have been produced and processed by certified operations.

Retail operations may present risks to organic integrity. For example, a grocery store may accidentally mix or combine organic and nonorganic produce of the same type, or they may unintentionally place an organic label on a shelf that holds nonorganic products. Further, storing organic produce in a container that was previously used for nonorganic produce without first cleaning the container may expose the organic produce to a prohibited pesticide. Therefore, all exempt retail operations must comply with the requirements of § 205.272, which describe handling requirements to prevent comingling and contact with prohibited substances. Additionally, exempt retail operations that process organic products must follow the labeling provisions of § 205.310, and maintain records to (1) demonstrate that agricultural

products identified as organic were organically produced and handled; and (2) verify quantities received, sold, or produced from such agricultural products. Following these requirements will help maintain organic integrity, even in the absence of certification.

Exemption for storage of organic agricultural products.

There are many operations that store organic products; however, these operations are generally considered low-risk because of the type of activities they perform and because they may be identified in the organic system plan of a certified operation. Given that these operations are lower-risk and are subject to oversight by certified handlers in adjacent segments of the supply chain, AMS proposes exempting from organic certification operations that only store agricultural products, but do not process or alter such agricultural products (proposed § 205.101(e)).¹⁵ This approach is consistent with risk-based oversight models.

This exemption would apply to warehouses, storage facilities, and other operations whose only function is the temporary holding or storage of organic products, and the associated receiving and loading of organic products. An operation that processes or alters the organic products they store would not qualify for the exemption and must be certified. Storage operations claiming this exemption must not label/relabel, combine, split, containerize, pack/repack, treat, sort, open, enclose, or otherwise alter the organic products they handle. Like other exempt operations, the proposed rule would require storage operations exempted at proposed § 205.101(e) to comply with the requirements of § 205.272 for the prevention of commingling and contact with prohibited substances.

¹⁵ *Processing*, as defined by 7 CFR 205.2, includes “packaging...or otherwise enclosing food in a container.”

Transport of organic agricultural products.

Like storage, transport also qualifies as a low-risk activity and may be identified in the organic system plan of a certified handler. Because transport alone is not a handling activity (see 7 U.S.C. 6502(8) and 7 CFR 205.2), operations that only transport organic products are not required to be certified. Certifying agents have expressed confusion about which activities constitute transport versus which activities qualify as handling and, thus, require certification. Transport commonly refers to the movement of products in commerce; any activity that alters an agricultural product during transport would qualify as handling, and would require certification. Other activities that could occur adjacent to transport include, for example, combining, splitting, containerizing, packing/repacking, treating, sorting, opening, enclosing, or labeling/relabeling. These activities are handling and would require certification. Permitted activity that does not require certification would be restricted to movement of agricultural products only.

Certified operations' verification and recordkeeping responsibilities.

The exempt activities described in this proposed rule present relatively low risk to organic integrity; however, exempted operations are not without risk. To address this risk, AMS proposes that certified operations include in their organic system plans monitoring practices and procedures to verify their supply chains and the organic status of products they receive (see proposed amendments to § 205.201 and discussion on Supply Chain Traceability and Fraud Prevention later in this proposed rule). This includes verifying the organic status of products that are handled by exempt operations in a supply chain. Certified operations should carefully review the practices and records of operations in their supply chain, including transportation and storage operations. Certified operations that load/sell/export organic products and certified operations that receive/purchase/import organic products are ultimately responsible for verifying that organic status has not been compromised during transport or storage.

In addition to procedures in an organic system plan, certified operations must also maintain records to support the verification of organic integrity and facilitate supply chain audits. The current organic regulations at § 205.103 state that certified operations “must maintain records concerning the production, harvesting, and handling” of their products. Certified operations must keep records of these activities to “Fully disclose all activities and transactions of the certified operation in sufficient detail” to “demonstrate compliance with the Act and the regulations.” Therefore, to demonstrate compliance, certified operations must maintain records of products that were handled by operations in their supply chain, including transportation and storage operations.¹⁶

As a best practice, records covering these types of handling activities should (1) demonstrate that the organic integrity of the product is maintained during transport and/or storage, and (2) verify both the quantities and the organic status of the product being transported and/or stored. Records could include clean truck affidavits; records of cleaning and sanitizing materials, and procedures used to clean trucks; bills of lading, manifests, transaction certificates, shipping records, delivery records, invoices, lot numbers, and other audit trail documents; and records documenting the audit trail, chain of custody, tanker seals, wash tags, truck and trailer numbers. Records such as these can be used by a certified operation to verify that organic products are properly handled by exempt transport or storage operations. Records can also be used for traceability, both by certified operations to verify the source of a product they receive, and by certifying agents to verify the origin of a product during a trace-back audit.

These recordkeeping requirements will ensure that certified operations maintain documents to demonstrate that the organic integrity of products is not compromised during transport and/or storage.

¹⁶ 7 U.S.C. 6519(a)(1) “...each person who sells, labels, or represents any agricultural product as having been produced or handled using organic methods shall make available...all records associated with the agricultural product.”

Additionally, records will show the quantities of organic products transported and/or stored, and facilitate certifying agents in performing trace-back and mass-balance audits through a supply chain.

Clarifying what activities that are exempt from certification—and clarifying recordkeeping responsibility—will enhance accountability for the integrity of both domestic and imported organic products by bolstering the NOP’s oversight of handlers that affect the status of organic products.

Request for comment.

AMS seeks comment regarding the proposed amendments to §§ 205.2 and 205.100–101 discussed above, including answers to the following questions:

1. Are there additional activities that should be included in the proposed definition of *handle* (i.e., are there additional activities that require certification)? Are there any activities in the proposed definition of *handle* that should be exempt from certification?
2. Are there specific activities not included in the proposed rule that you believe should be exempt from organic certification?
3. Are there additional requirements that exempt handlers described in this proposed rule should follow?
4. Activities at ports may present a threat to the integrity of organic products due to the multiple types of handling activities performed in these locations. It is common for independent operations to perform specific physical handling activities within a port (e.g., loading, unloading, or transfer of packaged, unpackaged, or bulk organic product). The proposed rule would require certification of these operations, who are often contractors. What other activities performed at ports should require certification and why?

2. Imports to the United States.

| Section | Action | Proposed Text |
|------------|-----------------|---|
| 205.2 | Add new term | <i>Organic exporter.</i> The owner or final exporter of the organic product who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic product from a foreign country. |
| 205.2 | Add new term | <i>Organic importer of record.</i> The operation responsible for accepting imported organic products within the United States. |
| 205.273 | Add new section | Imports to the United States. |
| 205.273 | Add | Each shipment of organic products imported into the United States through U.S. Ports of Entry must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with a valid NOP Import Certificate (Form NOP 2110-1) or equivalent data source. |
| 205.273(a) | Add | Persons exporting organic products to the United States must request an NOP Import Certificate, or provide data through an equivalent data source, from a certifying agent, for each physical shipment of certified organic products prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement may issue an NOP Import Certificate or approve a listing in an equivalent data source (e.g., a third-party export system). |
| 205.273(b) | Add | The certifying agent must review an NOP Import Certificate request, determine whether the shipment complies with the USDA organic |

| | | |
|------------|--------|--|
| | | regulations, and issue the NOP Import Certificate or equivalent within 30 calendar days of receipt if the shipment complies with the USDA organic regulations. |
| 205.273(c) | Add | Each compliant organic shipment must be declared as organic to U.S. Customs and Border Protection through a U.S. Port of Entry by uploading the unique NOP Import Certificate, or equivalent electronic data entry, into the U.S. Customs and Border Protection’s Automated Commercial Environment system. |
| 205.273(d) | Add | Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to § 205.272 or exposure to ionizing radiation pursuant to § 205.105, since export. |
| 205.273(e) | Add | The use of the term equivalent in this section refers to electronic data, documents, identification numbers, databases, or other systems verified as an equivalent data source to the NOP Import Certificate. |
| 205.300(c) | Revise | Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply with the requirements in §205.273, Imports to the United States. |

AMS proposes amending the USDA organic regulations by adding a new section (205.273) discussing the use of the National Organic Program Import Certificate (“NOP Import Certificate”). Currently, NOP

Import Certificates are only required for organic products imported from a country that the NOP has determined uses an equivalent system of organic certification, e.g., NOP Import Certificates are currently used for imports from the European Union, Switzerland, Japan, and South Korea. This proposed rule would require that any organic agricultural product imported to the United States be associated with a valid NOP Import Certificate or equivalent data source. The use of the term “equivalent” in this section refers to data and systems that are created, issued, or used by the United States or foreign governments to share trade-related information. Allowing for equivalent data and systems that harmonize with U.S. Government trade systems allows for the future development of interoperable import and export systems that facilitate information exchange between governments or authorized entities.

What is an NOP Import Certificate?

The NOP Import Certificate, or equivalent, is a type of transaction certificate, or equivalent data source, that contains detailed information about the quantity and origin of organic product being imported into the United States. The purpose of the NOP Import Certificate is to document the organic status and quantity of a specific physical shipment of imported organic products. The NOP Import Certificate is associated with a specific shipment of imported organic products as it travels from a certified organic exporter in a foreign country to a certified organic importer in the United States. The NOP Import Certificate is used to ensure a smooth, auditable business transaction by documenting that the products in the shipment are organic and may be sold, represented, and distributed as organic within the United States.

NOP Import Certificates are currently used for organic products imported from countries that the NOP has determined to be equivalent (OMB Approval No. 1651-0022). The USDA has established equivalency

with Canada, the European Union, Switzerland, Japan, South Korea, Taiwan, and the United Kingdom.¹⁷

Organic imports from Canada are accompanied by an attestation statement that the products comply with the terms of the United States-Canada Organic Equivalency Arrangement. Organic imports from the European Union, Switzerland, Japan, South Korea, Taiwan, and the United Kingdom are accompanied by an NOP Import Certificate. The certifying agent evaluates the request for an NOP Import Certificate, and upon verification of the organic shipment, completes and issues an NOP Import Certificate. Form NOP 2110-1 (OMB Control Number 0581-0191) is currently used for this purpose.

AMS does not currently require NOP Import Certificates for organic imports from countries that the United States does not have organic equivalency with. This proposed rule would expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin. Specifically, this proposed rule would require that all imported products intended to be sold, represented, or labeled as organic in the United States must be declared as organic to U.S. Customs and Border Protection (CBP), and that each physical shipment passing through a U.S. Port of Entry must be associated with an NOP Import Certificate, or equivalent data source. Requiring an NOP Import Certificate provides trackable and auditable verification that a specific shipment of imported organic products complies with the USDA organic regulations. It will also support investigations if noncompliant products are exported and misrepresented as organic for sale in the United States.

Authority and justification for the mandatory use of NOP Import Certificates.

The mandatory use of NOP Import Certificates is authorized by the OFPA, as amended by the Agriculture Improvement Act of 2018.¹⁸ The OFPA specifies what information an NOP Import Certificate must

¹⁷ The United States–United Kingdom equivalency will be effective in January 2021.

¹⁸ See sections 10104(b)(3) and 10104(c) of the Agriculture Improvement Act of 2018, Public Law No: 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

include (7 U.S.C. 6502(13)), and also stipulates that the NOP Import Certificate must “be available as an electronic record” and captured in a tracking system maintained by the U.S. Government (7 U.S.C. 6514(d)). The OFPA also provides the Secretary with broad authority to establish appropriate and adequate enforcement procedures and any other requirements that the Secretary may determine to be necessary (7 U.S.C. 6506).

Both the OFPA and the USDA organic regulations require certified operations to maintain and make available to the Secretary records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as organic (7 U.S.C. 6519, 7 CFR 205.103, and 7 CFR 205.400(d)). This includes sufficient records to provide an audit trail to determine the source, type and quantity, transfer of ownership, and transportation of any agricultural product labeled as organic (7 CFR 205.2). Likewise, both the OFPA and the USDA organic regulations require certifying agents to maintain and make available to the Secretary records concerning its activities (7 U.S.C. 6519, 7 CFR 205.501(a)(9), 7 CFR 205.510(b)).

NOP Import Certificate format and tracking system.

AMS proposes that NOP Import Certificates must be provided in a standardized electronic format to ensure consistency. AMS anticipates that Form NOP 2110-1, or an electronic equivalent that provides the same data, will serve this purpose, because it includes fields for the information needed to meet the requirements of an NOP Import Certificate as defined in the OFPA: origin; destination; the certifying agent issuing the NOP Import Certificate; harmonized tariff code, when applicable; total weight; and the organic standard the product was certified to (7 U.S.C. 6502(13)). For the purposes of uploading and tracking NOP Import Certificates, Form 2110-1 must be available as an electronic format to meet the requirements of the OFPA (7 U.S.C. 6514(d)(1)).

The OFPA, as amended by the 2018 farm bill, also states that AMS must establish a system of tracking NOP Import Certificates, and that AMS “may integrate the system into any existing information tracking systems for imports of agricultural products” (7 U.S.C. 6514(d) and 6522(c)).¹⁹ Because the OFPA enables AMS to access information available in CBP’s Automated Commercial Environment system (ACE) (7 U.S.C. 6521(c)), AMS expects that ACE will be used to track and store NOP Import Certificates, or equivalent electronic data.²⁰ ACE is an automated and electronic system for processing commercial trade data. ACE is the primary system through which the global trade community files information about imports and exports so that admissibility into the United States may be determined by government agencies (including AMS) to ensure compliance.

Use of the NOP Import Certificate.

The proposed rule includes two new terms, *organic exporter* and *organic importer of record*, that describe businesses that facilitate the international trade of organic products. An *organic exporter* is responsible for facilitating the trading, selling, consigning, shipping or exporting of organic product from a foreign country to the United States. An organic exporter must be certified organic by certifying agents accredited by the USDA or certifying agents authorized by a trade arrangement, and must maintain records required under § 205.103. Organic exporters may be the final physical handler of organic products within a foreign country or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States.

An *organic importer of record* is the entity responsible for receiving organic products within the United States. An organic importer of record must be certified and must maintain records required under 7 CFR

¹⁹ See section 10104(c) of the Agriculture Improvement Act of 2018, Public Law No: 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

²⁰ See sections 10104(h) and (j) of the Agriculture Improvement Act of 2018, Public Law No: 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

205.103. The proposed rule would specify that there is a consistent party, the organic importer of record, that is responsible for ensuring the compliance of organic agricultural products imported into the United States.

This proposed rule would require that a certified organic exporter sending organic products to the United States request an NOP Import Certificate, or equivalent, from their certifying agent for the organic products intended for export. As discussed in the proposed amendments to the USDA organic regulation at § 205.2, Terms defined, and § 205.101, Exemptions from certification, entities that facilitate the sale of organic products and arrange for the transport of organic products into the United States (e.g., organic exporters) would need to be certified. The request for an NOP Import Certificate must include information required for the organic exporter's certifying agent to complete the NOP Import Certificate or equivalent.

The organic exporter's certifying agent would issue the NOP Import Certificate, or equivalent, provided it has verified that the shipment complies with the USDA organic regulations or an equivalent standard. This means that: (1) the information submitted on the NOP Import Certificate, or equivalent, is accurate, including confirmation of the organic status of each product listed on the NOP Import Certificate; and (2) the final handler has the capacity to produce or handle the quantity of organic product to be exported. The final handler would typically be the exporter or the last handler that processed the product. Verifying that the product complies with the organic standards includes, but is not limited to, verifying that the import has not been exposed to a prohibited substance, treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across country borders.

Upon receiving a shipment, an organic importer of record must verify that the organic product(s) comply with the USDA organic regulations. This includes, but is not limited to, verifying that the import has not

been treated with a prohibited substance as a result of fumigation or treated with ionizing radiation at any point in the products' movements across country borders.

Both the organic exporter and organic importer of record must maintain records of NOP Import Certificates, and these records must be available for inspection by the NOP and certifying agents in accordance with § 205.103.

Only certifying agents accredited by the USDA, or foreign certifying agents authorized by a trade arrangement, may prepare and issue an NOP Import Certificate or equivalent. Once completed by the certifying agent, an NOP Import Certificate or equivalent is provided to the organic exporter, and the organic exporter must provide the data associated with the NOP Import Certificate to CBP by uploading the data into the ACE system as an electronic record.

An NOP Import Certificate, or equivalent, would also require use of the 10-digit NOP operation ID, or equivalent ID, name, and address of the organic importer of record in the United States, and the 10-digit NOP operation ID, or equivalent ID issued by a foreign certifying agent authorized under a trade arrangement, for the organic exporter of the product to be exported to the United States. The NOP Operation ID, or an equivalent ID, is a critical piece of data because it is a unique number generated in the Organic INTEGRITY Database for certifying agents accredited by the USDA, or in an equivalent system for foreign certifying agents authorized under a trade arrangement. This unique ID for each certified operation will link the exported organic product to the organic importer of record in the United States. This will strengthen the audit trail by ensuring that handlers on both sides of the transaction are known to Federal agents and can be linked when an organic product is imported into the United States.

AMS acknowledges the concern that using NOP Import Certificates may slow the importation of organic product. Therefore, AMS is requiring that organic imports that pass through U.S. Ports of Entry be associated with, but not accompanied by, an NOP Import Certificate. This means that a shipment

containing organic products may enter the United States without an NOP Import Certificate at the time of entry. However, the NOP Import Certificate, or equivalent data, must be uploaded into the ACE system within 10 calendar days of the shipment entering the United States. This is consistent with existing trade filing timeframes in ACE using the Entry Summary process.²¹ AMS expects that this 10-day timeframe will result in little to no impact to the timely importation of organic products. Regardless of when an NOP Import Certificate is completed, the organic exporter and organic importer of record are fully accountable for the compliance of the imported product(s).

Cooperation with U.S. Customs and Border Protection.

The OFPA, as amended by the Agriculture Improvement Act of 2018, requires the establishment of an Organic Agricultural Product Imports Interagency Working Group, consisting of members of both the USDA and CBP (see 7 U.S.C. 6521a).²² The mandatory use of NOP Import Certificates supports the working group's goal to ensure the compliance of organic agricultural products imported to the United States, and builds upon ongoing cooperation between the USDA and CBP.

AMS is working with CBP to verify that shipments of imported organic products are associated with unique NOP Import Certificates. In April 2020, the electronic version of the NOP Import Certificate (or "message set") was deployed in ACE as an optional filing step for organic imports. The use of the electronic NOP Import Certificate will be mandatory when the SOE final rule is implemented.

AMS expects some of the information collected via the NOP Import Certificate may be modified. In addition to the NOP Operation ID mentioned above, AMS is considering adding fields for the U.S. Customs Entry Number and the Purchase Order (PO) number to assist with tracking organic imports.

²¹ CBP Form 7501: Entry Summary. Available on the U.S. Customs and Border Protection website: <https://www.cbp.gov/trade/programs-administration/entry-summary/cbp-form-7501>

²² See section 10104(i) of the Agriculture Improvement Act of 2018, Public Law No: 115-334. Available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

Other fields may be eliminated to avoid collecting duplicate information already collected through the ACE database.

Once established, the availability of the electronic NOP Import Certificate in ACE would notify CBP officials of organic shipments and provide AMS with more data to identify specific shipments of organic imports.

Alignment with other supply chain traceability norms.

One of the goals of this action is to harmonize USDA regulatory requirements for importing organic products with international guidelines and norms. NOP considered international standards established by the Codex Alimentarius Commission (Codex)²³ and norms published by the International Federation of Organic Agriculture Movements (IFOAM).²⁴ Both provide for and support the use of transaction shipment certificates such as the NOP Import Certificate.

Future harmonization with sanitary and phytosanitary data systems.

Further, the use of health certificates, sanitary certificates, phytosanitary certificates, and other regulatory requirements in place to contain certain plant and animal pests or diseases may offer a possible resource for the NOP and other government agencies to document the movement of organic products across national borders. Over time, it is expected that the United States and foreign countries will automate and harmonize systems to support the more seamless exchange of electronic import and export data in organic trade. AMS will continue to work to improve, adapt to, and support seamless

²³ Section 7 of the *Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* recommends imported organic products to be marketed only where the competent authority or designated body in the exporting country has issued a certificate of inspection stating that the lot designated in the certificate was obtained within an organic system of production, preparation, marketing and inspection.

²⁴ IFOAM Norms define a transaction certificate as a “document issued by a certification body or by the operator, declaring that a specified lot or consignment of goods is certified.”

electronic paperless supply chain traceability and transparency using the International Trade Data System (ITDS) and other technologies as they evolve.

Request for comment.

AMS seeks comment regarding the use of NOP Import Certificates discussed in this proposed rule, including answers to the following questions:

1. Is the 30-day timeframe for certifying agents to review and issue an NOP Import Certificate appropriate? Why or why not?
2. How could the mode of transportation and frequency of shipments affect the use of the NOP Import Certificate?

3. Labeling of Nonretail Containers.

| Section | Action | Proposed Text |
|----------------|--------------|---|
| 205.307 | Revise title | Labeling of nonretail containers. |
| 205.307 (a) | Revise | <p>Nonretail containers used to ship or store certified organic product must display the following:</p> <p>(1) The term, “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable, to identify the product;</p> <p>(2) The statement, “Certified organic by (name of certifying agent),” or similar phrase, to identify the name of the certifying agent that certified the producer of the product, or, if processed, the certifying agent that certified the last handler that processed the product; and</p> |

| | | |
|----------------|--------|--|
| | | (3) The production lot number of the product, shipping identification, or other information needed to ensure traceability. |
| 205.307 (b) | Revise | <p>Nonretail containers used to ship or store certified organic product may display the following:</p> <p>(1) Special handling instructions needed to maintain the organic integrity of the product;</p> <p>(2) The USDA seal. Use of the USDA seal must comply with §205.311;</p> <p>(3) The name and contact information of the certified producer of the product, or if processed, the last certified handler that processed the product;</p> <p>(4) The seal, logo, or other identifying mark of the certifying agent that certified the producer of the product, or if processed, the last handler that processed the product; and/or</p> <p>(5) The business address, website, and/or contact information of the certifying agent.</p> |

Accurate labeling of non-retail containers used to ship or store organic products is critical to organic integrity. Detailed labeling reduces misidentification and mishandling, facilitates traceability through the supply chain, reduces the potential for organic fraud, and allows accurate identification of organic product by customs officials and transportation agents. Therefore, AMS proposes amending § 205.307 to add new requirements for the labeling of nonretail containers.

If implemented, this proposed action will require that nonretail containers used to ship or store organic products are labeled with two additional pieces of information: (1) a statement identifying the product as organic; and (2) the name of the certifying agent that certified either the producer of the product, or,

if the product is processed, the last handler that processed the product. In addition, the current requirement to show the production lot number on nonretail containers will be expanded, the option to include the name of the certified operation that produced or handled the product will be added, and the use of the USDA seal on nonretail containers will be clarified.

Nonretail containers are defined under § 205.2 of the USDA organic regulations as “any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.” Nonretail containers are used to ship or store either packaged or unpackaged organic products, and may include the following:

1. Produce boxes, totes, bulk containers, bulk bags, flexible bulk containers, harvest crates and bins; and
2. Boxes, crates, cartons, and master cases of wholesale packaged products.

Section 205.307 does not apply to large nonretail containers that are associated with a mode of transportation or storage, such as trailers, tanks, railcars, shipping containers, grain elevators/silos, vessels, cargo holds, freighters, barges, or other method of bulk transport or storage. As labeling of these types of large containers may be impractical, they do not need to be labeled with the information described in § 205.307. However, this information must be evident in documentation associated with and traceable to the container, to ensure that organic integrity is maintained during transport, storage, and handling.

The current regulations require only one piece of information on nonretail container labeling: a production lot number. Other information elements—such as identification of the product as organic, certifying agent information, and special handling instructions—are optional, but not required on nonretail container labels. Lack of this information creates gaps in the organic chain of custody, complicates the verification of organic integrity, and increases the vulnerability to organic fraud.

Nonretail containers labeled with only a production lot number provide no identifying information about the entity that provided that number. This can create problems when nonretail containers are used to store or ship unlabeled unpackaged product (e.g., produce or bulk commodities), because a production lot number alone is not sufficient to immediately identify the product as organic or conventional. An organic product stored or shipped in a nonretail container labeled with only a production lot number is at risk of having its organic integrity compromised, including treatment with a prohibited substance during border crossings, or comingling with conventional product during transport and aggregation.

This proposed amendment will provide an additional safeguard for organic integrity by alerting certifying agents, handlers, and border agents to the contents of nonretail containers, and by helping prevent unintentional mishandling of organic product. This proposed action also aligns with the OFPA requirement that an agricultural product which is sold or labeled as organic must have been produced and handled without prohibited synthetic chemicals (7 U.S.C. 6504(1)).

Some stakeholders have asked AMS to limit the applicability of § 205.307 to packaged organic products described in §§ 205.303–304, i.e., products labeled “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” AMS believes that amending the regulations to require a statement of organic status on all nonretail containers, including those which contain unpackaged and/or unlabeled product, is a more comprehensive and enforceable solution. Further, this will support the requirement for certified operations to maintain auditable records (§ 205.103(b)(2)). An *audit trail*, as defined by the regulations, includes documents that show the source, transfer of ownership, and transportation of any agricultural product with an organic label (§ 205.2). Obscuring the “organic” status of any product during a segment of the supply chain disrupts the audit trail. By clearly stating that nonretail containers must be labeled with the product’s organic status and the name of the certifying

agent (both currently optional), this proposed amendment will ensure that all organic product in nonretail containers is identifiable.

Organic products often pass through multiple handlers in the supply chain as they move from production source to consumer. However, the proposed rule does not require nonretail container labels to list the certifying agent of every operation that handled the product. The proposed amendments to § 205.307 require that nonretail container labels list either (1) the certifying agent that certified the producer, or, if the product is processed, (2) the certifying agent that certified the operation that last processed the product.²⁵ This means that:

1. If a product is not processed between production and sale, then the certifying agent of the producer must be listed on the nonretail container label;
2. If a product is processed after production, then the certifying agent of the processor must be listed on the nonretail container label;
3. If a product is processed sequentially by different operations (A, B, and C) after production, then only the certifying agent of the last processor (operation C) must be listed on the nonretail container label; and
4. The certifying agents of operations that handle, but do not process, organic products after production do not need to be listed on the nonretail container label.

Listing the certifying agent of the producer or last processor on nonretail container labels will provide a point of contact to verify the organic status of a product, without adding surplus information to the

²⁵ See definition of *processing* in § 205.2 of the USDA organic regulations.

label. However, to maintain a complete audit trail, all operations that produced, processed, handled, or transported the organic product must be visible in the product’s audit trail documentation.

Clearly labeling a nonretail container with organic identification, certifying agent, and production lot number will ease product traceability during audits, help to prevent unintentional contact with prohibited substances (e.g., fumigation) and comingling with conventional product, and help to ensure accurate representation of the product at the point of sale. In addition, this proposed amendment is also expected to reduce the vulnerability to organic fraud by ensuring that organic product status is visible throughout the supply chain.

Request for comment.

AMS seeks comment regarding the proposed amendments to the labeling of nonretail containers, specifically whether or not the certified operation that produced or last processed the product must be listed (i.e., not optional) on all nonretail container labels.

4. On-Site Inspections.

| Section | Action | Proposed Text |
|--------------------|-------------|---|
| 205.403 (b)–(e) | Redesignate | Redesignate paragraphs (b)–(e) as paragraphs (c)–(f) |
| 205.403 (b) | Add | <i>Unannounced inspections.</i> |
| 205.403 (b)(1) | Add | A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. |

| | | |
|-------------------|------------------------------|---|
| 205.403 (b)(2) | Add | Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections. |
| 205.403 (c) | Redesignate as 205.403(d) | <i>Verification of information.</i> The on-site inspection of an operation must verify: |
| 205.403 (d)(4) | Add | That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported; and |
| 205.403 (d)(5) | Add | That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21). |

Unannounced inspections.

Unannounced inspections are a critical enforcement tool for ensuring ongoing compliance by organic operations. AMS proposes amending § 205.403 of the organic regulations to require a minimum number of unannounced inspections that certifying agents must perform annually. The current regulations allow for, but do not require, unannounced inspections, leaving this to the discretion of the certifying agent. NOP has issued an instruction to certifying agents (NOP Instruction 2609) on unannounced inspections, which recommends that certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year as a tool in ensuring compliance with the regulations.²⁶ This NOP

²⁶ NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>

instruction was supported by a recommendation made by the NOSB in December 2011.²⁷ The majority of USDA-accredited certifying agents currently complete unannounced inspections at this frequency.²⁸ This provision would make these inspections a regulatory requirement.

Unannounced inspections are an effective and useful tool in the USDA organic regulations to ensure compliance across certified operations and bolster consumer trust in the organic label. Therefore, AMS is proposing to codify a requirement for certifying agents to conduct a minimum number of unannounced inspections annually of certified operations. This proposed amendment, consistent with NOP Instruction 2609, would require certifying agents to conduct unannounced inspections annually on a minimum of 5 percent of operations they certify. The operations may be selected randomly, risk-based, and/or in response to a complaint or investigation. The proposed requirement specifies that the number of unannounced inspections should be calculated by rounding up to the nearest whole number, so that certifying agents with very few certified operations (e.g., under 20 operations) would still be required to conduct at least one unannounced inspection per year.

The OFPA requires that organic operations make their records available at all times for inspection by the Secretary, the certifying agent, and State officials (7 U.S.C. 6506(b)(1)(B)). Additionally, the OFPA requires that certifying agents employ a sufficient number of inspectors to implement the organic regulations (7 U.S.C. 6515(b)). By establishing a baseline requirement for unannounced inspection activities, AMS can verify that certifying agents employ a sufficient number of inspectors (i.e., enough inspectors to perform annual inspections and unannounced inspections) and will ensure, through

²⁷ NOSB Recommendation, Unannounced Inspections. December 2, 2011. Available on the AMS website: <https://www.ams.usda.gov/sites/default/files/media/NOP%20CACCC%20Final%20Rec%20on%20Unannounced%20Inspections.pdf>

²⁸ 42 of the 49 USDA-accredited certifying agents the NOP audited in calendar years 2018 and 2019 completed unannounced inspections of 5% of the operations they certify.

unannounced inspections, that organic operations keep records related to their organic activities and comply with other requirements of the OFPA and the USDA organic regulations.

AMS also proposes a requirement that certifying agents only accept applications for certification from operations located where the certifying agent is able to conduct unannounced inspections. Further, certifying agents must be able to conduct unannounced inspections of any operation it continues to certify. To ensure consistency, transparency, and accountability, certifying agents would be expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review. This proposed requirement is also based on recommended practice in the NOP Instruction 2609 and was recommended by the NOSB in December 2011.

AMS proposes this requirement to ensure that all certified operations are subject to unannounced inspections, regardless of location. A certifying agent that cannot conduct unannounced inspections in an applicant's or certified operation's location due to logistical challenges, staffing, security, or other reasons, is considered to not have or no longer have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19). In this case, the certifying agent would need to document the specific reasons it does not have, or no longer has, the administrative capacity to certify in that area, and would need to inform the applicant or certified operation to seek certification from another certifying agent. If new certification is not obtained, the operation's certification would be suspended. This process would be similar to the current procedures used when a certifying agent surrenders its accreditation or is suspended; however, it would be limited to a specific well-defined location, with justifications specific to that area.

Supply chain audits during on-site inspections.

Additionally, AMS proposes two new requirements in § 205.403 to clarify the responsibilities of inspectors and certifying agents related to on-site inspections. AMS has consistently provided training to certifying agents which specifies that supply chain audits must be conducted at on-site inspections, but the types of audits required are not explicit in the current regulations. Audits can help detect organic fraud and should be routine practice during inspections. These proposed audit requirements are needed to ensure that AMS can take appropriate action against certifying agents that are not conducting adequate audits during inspections.

First, AMS proposes a requirement that certifying agents must verify that the quantity of organic product sold does not exceed the quantity of organic product that is produced or purchased. Second, AMS proposes a requirement that certifying agents verify that organic products and organic ingredients are traceable from the time of production or purchase to the time of sale or movement of product from the operation and vice versa. These new verification requirements are also referred to as “mass-balance” and “trace-back” audits. Certifying agents should determine the minimum number of products to review to assess whether the operation is compliant with the regulations. This should involve a risk-based sampling of products that span different time ranges and products.

For example, the inspection of a grain milling operation is to include an examination of the transaction and processing records for various commodities and time ranges. An inspection of a manufacturer of organic frozen meals, or other multi-ingredient products, is to examine records for various types of products to cover a range of ingredients and production dates.

During an on-site inspection, a certifying agent may also choose to conduct a broader review of an entire supply chain for an operation’s product(s), to fulfill the proposed requirement at § 205.501(a)(21) to conduct risk-based supply chain audits according to the certifying agent’s written procedures to meet

that audit requirement (see proposed § 205.504(b)(7)). Full supply chain audits are discussed in more detail later in this proposed rule.

The OFPA requires that organic operations maintain all records associated with the production and handling of organic products and make these records available to certifying agents at all times (7 U.S.C. 6519(a) and 6506(b)(1)(B)). The proposed inspection requirements support the review and verification of these required records.

5. Certificates of Organic Operation.

| Section | Action | Proposed Text |
|-------------|--------------|---|
| 205.2 | Add new term | <i>INTEGRITY</i> . The National Organic Program’s electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors. |
| 205.404 (b) | Revise | The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from INTEGRITY and may be provided to certified operations electronically. |
| 205.404 (c) | Redesignate | Redesignate as paragraph (d) |
| 205.404 (c) | Add | In addition to the certificate of organic operation provided for in §205.404(b), a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include: (1) Name, address, and contact information for the certified operation; (2) The certified operation’s unique ID number/code that corresponds to the certified operation’s ID number/code in USDA Organic INTEGRITY; |

| | | |
|--|--|--|
| | | <p>(3) A link to USDA Organic INTEGRITY or a link to the certified operation’s profile in USDA Organic INTEGRITY, along with a statement, “You may verify the certification of this operation at USDA Organic INTEGRITY,” or a similar statement;</p> <p>(4) Name, address, and contact information of the certifying agent;</p> <p>(5) “Addendum issue date;” and</p> <p>(6) “Addendum expiration date,” which must not exceed the expiration date of the certificate of organic operation.</p> |
|--|--|--|

The certificate of organic operation (“organic certificate”) communicates information about the organic certification of an operation and the raw and processed products it is permitted to represent as organic. The proposed rule would require certifying agents to provide organic certificates that are uniform in appearance. To achieve this uniformity, the proposed rule would require that certifying agents create and provide organic certificates that are generated from a USDA-hosted electronic web-based system known as the Organic INTEGRITY Database (“INTEGRITY”). In this way, AMS would be responsible for the functionality of INTEGRITY and ensure consistent content and style of all organic certificates. Buyers of organic products would be able to recognize and validate legitimate organic certificates. This is currently difficult due to wide variability in the content and style of certifying agent-generated organic certificates.

The appearance and format of current organic certificates vary depending upon which certifying agent issued the organic certificate. Currently, AMS accredits almost 80 certifying agents; only a few create organic certificates through INTEGRITY. As a result, more than 70 distinct formats of organic certificates exist in the market. This variation increases the chance of alteration and organic fraud. In addition, AMS consistently cites noncompliances to certifying agents who do not currently include all the required

information on their own organic certificates. Of the 49 USDA-accredited certifying agents audited by the NOP in calendar years 2018 and 2019, 16 were cited for issuing organic certificates not consistent with USDA organic regulation and instruction. The use of a uniform organic certificate generated through INTEGRITY would eliminate these inconsistencies.

The changes are proposed under AMS' authority provided in the OFPA to establish a program for organic certification (7 U.S.C. 6503(a)) and to facilitate interstate commerce of organic foods (7 U.S.C. 6501(3)). The proposed changes are also consistent with recommendations made by the NOSB between 2005 and 2007, including a recommendation that all certifying agents use a common database to issue and maintain organic certificates and that organic certificates include expiration dates.²⁹

The Organic INTEGRITY Database.

The OFPA was amended in 2014 to, among other things, require the USDA to modernize database and technology systems. To that end, the NOP created the Organic Integrity Database. INTEGRITY contains information about certified operations as well as information about operations that have surrendered their organic certification or had their organic certification suspended or revoked. The data or information is provided directly from certifying agents. The information can be viewed and searched by the general public online at <https://organic.ams.usda.gov/Integrity/Default.aspx>.

²⁹ NOSB Formal Recommendation: Information on Certificates of Organic Operation, March 2005: <https://www.ams.usda.gov/sites/default/files/media/NOSB%20Rec%20Standardize%20Organic%20Certifications%20Certificates.pdf>

NOSB Formal Recommendation: Expiration Dates on Certificates of Organic Operation, November 2006: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Use%20of%20Expiration%20Dates%20on%20Certificates%20of%20Organic%20Op.pdf>

NOSB Formal Recommendation: Standardized Certificates, November 2007: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Standardization%20of%20Certificates.pdf>

INTEGRITY and organic certificates.

In 2016, NOP enhanced the functionality of INTEGRITY to allow for the generation of organic certificates. When the currently optional function is activated, INTEGRITY generates a one-page organic certificate and an accompanying detailed product list (together referred to as the “organic certificate”). Few certifying agents currently use INTEGRITY to generate organic certificates. This proposed rule would require all certifying agents to generate organic certificates through INTEGRITY. Foreign-based certifying agents that are accredited to and certify operations to the USDA organic regulations would be required to enter data in INTEGRITY to generate the organic certificates for USDA-certified operations. The proposed changes would adopt a March 2005 NOSB recommendation that the NOP establish a common database for all certifying agents to issue and maintain organic certificates and that the database allow certifying agents to upload data from their existing systems.³⁰ INTEGRITY is the system that certifying agents would use to perform these functions.

Once created in INTEGRITY, an organic certificate is available online via a unique link where it can be electronically downloaded or printed as a hard copy. A permalink to the online certificate is included on every organic certificate, including downloaded and printed organic certificates. If an operation’s certification has been suspended, revoked, or surrendered, information from the linked webpage will indicate that a valid organic certificate is no longer available.

AMS expects the proposed changes would promote access to robust information about individual operations and support timely verification of the organic status of operations and products. Additionally, we expect the changes would encourage a move toward sharing of real-time electronic documents and

³⁰ NOSB Formal Recommendation: Information on Certificates of Organic Operation; March 2005: <https://www.ams.usda.gov/sites/default/files/media/NOSB%20Rec%20Standardize%20Organic%20Certifications%20Certificates.pdf>

away from paper-based documents, which can quickly become outdated and can be more easily falsified. AMS also expects that the proposed change would reduce the administrative burden on operations in the supply chain that must verify the validity of organic certificates, especially for companies that purchase from many different organic operations.

Certifying agents that are not currently using INTEGRITY to generate organic certificates would need to modify their practices to routinely enter information in INTEGRITY before issuing organic certificates.

Specifically, these certifying agents may need to provide additional information in INTEGRITY to populate all fields that appear on the organic certificate, including: effective date of certification status, scope of organic certification (e.g., crops, handling), details about certified products (e.g., organic labeling category, brands), acreage, and livestock details. AMS would be responsible for the functionality of INTEGRITY, including the style and content of organic certificates.

Expiration dates on organic certificates.

The USDA organic regulations do not currently require expiration dates on organic certificates, and an operation's organic certification does not expire—once granted, it may only be suspended, revoked, or surrendered. Through this proposed rule, AMS intends to include certificate expiration dates on the organic certificates generated via INTEGRITY. AMS sees this as an important measure to establish a clear and consistent method for assessing whether an organic certificate is current and valid. This change was recommended by the NOSB in a November 11, 2006 recommendation titled “Expiration Dates on Certificates of Organic Operation.”³¹ Expiration dates would ensure the data on an organic certificate is up to date and current. Using current (i.e., unexpired) certificates would support verification of an

³¹ NOSB Formal Recommendation: Expiration Dates on Certificates of Organic Operation, November 2006: <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Use%20of%20Expiration%20Dates%20on%20Certificates%20of%20Organic%20Op.pdf>

operation's organic status. Expiration dates are intended to prompt the generation of an updated organic certificate, rather than to void or have any effect on the operation's certification status; an operation could remain certified even if their organic certificate has expired.

AMS intends to allow organic certificates to remain valid for 12 months from the date they are issued.

The expiration date would be calculated automatically by INTEGRITY and appear on all organic certificates. Certifying agents could validate information and create a new organic certificate in INTEGRITY at any time to generate a new organic certificate with a new expiration dated 12 months from the creation of the certificate. AMS believes this flexibility would allow certified operations to obtain valid organic certificates from their certifying agent in a timely fashion. Operations that are certified (i.e., that have not surrendered their certification or had their certification suspended or revoked) would continue to have a right to obtain a valid organic certificate from their certifying agent to demonstrate their certification.

Allowance for additional addenda to certificates of organic operation.

AMS recognizes that certifying agents have invested in systems to create their own unique addenda to organic certificates; AMS is not seeking to eliminate these unique sources of value offered by certifying agents. Under the proposed rule, certifying agents could continue to provide their own certification addenda that would communicate additional information about an operation's certification in a different format than generated by INTEGRITY.

For example, an addendum may include information about the compliance of the operation's crops or products with various international organic standards that may not be included on the INTEGRITY organic certificate. AMS is proposing six required elements (proposed § 205.404(c)) on any organic certificate addenda issued by certifying agents to deter organic fraud and provide consistency across

certifying agents. Primarily, the proposed requirements are intended to ensure that someone viewing the document is aware that the certification may be verified in INTEGRITY.

As with organic certificates from INTEGRITY, this proposed rule requires that any organic certificate addenda include an expiration date. Certifying agents would need to ensure that the expiration date of the addendum does not extend beyond the expiration date of the most recent organic certificate generated by INTEGRITY, to ensure an operation does not simultaneously possess a valid addendum and an expired organic certificate, which could cause confusion.

Request for comment.

AMS seeks comment on the proposed amendments regarding certificates of organic operation discussed above, including answers to the following questions:

1. How frequently should accredited certifying agents update the information in an operation's organic certificate?
2. Should a minimum reporting frequency (e.g., monthly, quarterly, etc.) be added to the regulations?
3. Should an expiration date be included on all certificates of organic operation? Would this make them more useful?

6. Continuation of Certification.

| Section | Action | Proposed Text |
|----------------|--------|---|
| 205.406 (a) | Revise | To continue certification, a certified operation must annually pay the certification fees and submit the following information to the certifying agent: |

| | | |
|----------------|--------|---|
| | | <p>(1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year; and</p> <p>(2) Any additions or deletions to the previous year’s organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.201;</p> <p>(3) Any additions to or deletions from the information required pursuant to §205.401(b); and</p> <p>(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.</p> |
| 205.406 (b) | Revise | The certifying agent must arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation at least once per calendar year. |

AMS proposes amending § 205.406 to clarify the annual update requirements for certified operations and to clarify that certifying agents must conduct annual inspections of certified operations.

The current regulations require that certified operations annually submit an updated organic production or handling system plan (§ 205.400(b)). Some certifying agents require that certified operations submit an organic system plan (OSP) in its entirety every year, while other certifying agents only require that operations annually submit revisions to the OSP. Clarifying in the regulations that operations are only required to submit sections of the OSP that have changed will eliminate unnecessary paperwork without compromising oversight of organic operations. The NOP previously described this approach in published

certifying agent Instructions (NOP 2615 and NOP 2601).³² These proposed changes are necessary to ensure legal enforceability, consistent practices between certifying agents, and reduce the paperwork burden of organic certification. The proposed changes in this section will not impact the requirements for certified operations to maintain an updated OSP or the requirement for an operation to notify their certifying agent of changes in their operation that may affect its compliance with the organic regulations (§ 205.400(f)). Further, the on-site inspection must verify that the entire OSP is implemented as described.

AMS also proposes removing current paragraph § 205.406(a)(3) to reduce paperwork and simplify the certification process. Section 205.406(a)(3) requires that certified operations provide, along with their annual update, an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. This requirement is duplicative and unnecessary, as certifying agents (when issuing a notice of noncompliance) must specify a date by which a certified operation must rebut or correct noncompliances (§§ 205.662(a)(3) and 205.404(a)). Certifying agents should establish this due date in accordance with the severity of the noncompliance. If a certified operation does not resolve noncompliances by the due date, their certifying agent should take further action (i.e., issue a notice of proposed suspension); therefore, AMS sees no benefit to requiring a partial response (i.e., an update) as part of the annual renewal. While removing this requirement, AMS proposes to maintain the allowance in this section for certifying agents to require other information from certified operations during the annual renewal process that they determine is necessary to assess

³² NOP 2601 The Organic Certification Process, December 16, 2013:

<https://www.ams.usda.gov/sites/default/files/media/2601.pdf>.

NOP 2615 Organic System Plans, Organic System Plan Updates, and Notification of Changes, December 16, 2013:

<https://www.ams.usda.gov/sites/default/files/media/2615.pdf>

compliance. AMS believes this will provide certifying agents with the flexibility they require to verify compliance.

Additionally, AMS proposes revising paragraph § 205.406(b) to simplify the regulatory text and to clarify that inspections are to be conducted on an annual basis. Current requirements at paragraph (b) could be interpreted to mean that an operation may be inspected once every 18 months on an ongoing basis (i.e., two inspections over a 36-month period compared to three inspections if conducted annually). Revision of paragraph (b) would clarify that all certified operations must be inspected at least annually, regardless of (1) when the certified operation was last inspected and (2) when, or if, the certified operation provided its annual updates. Additional inspections may be needed to ensure full compliance of complex operations (e.g., during and outside the grazing season for livestock operations). This requirement does not replace the need for additional unannounced inspections.

This revision would allow certifying agents flexibility to conduct on-site inspections at any time during the year (essential for verifying activities throughout the growing season, for example) while ensuring that an inspection is conducted every single calendar year. Annual inspection cycles are essential to vigilant oversight and AMS seeks to eliminate confusion around and deviations from alternative timing of on-site inspections.

7. Paperwork Submissions to the Administrator.

| Section | Current Text | Action | Proposed Text |
|--------------------|---|--------|---------------------------------------|
| 205.405 (c)(3) | Provide notice of approval or denial to the Administrator, pursuant to §205.501(a)(14). | Remove | |
| 205.501 (a)(15) | Submit to the Administrator a copy of: | Revise | Maintain current and accurate data in |

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| | <p>(i) Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance; and</p> <p>(ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;</p> | | <p>INTEGRITY for each operation which it certifies;</p> |
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AMS proposes amending § 205.405 and § 205.501 to reduce the paperwork burden of accredited certifying agents. In addition, AMS is proposing that certifying agents must maintain current data in INTEGRITY on all operations which they certify. The availability of accurate and current information about certified operations is an essential tool for certifying agents and operations in the organic supply chain to support the verification of specific organic products.

The proposed removal of paragraph (c)(3) of § 205.405 will eliminate the need to provide notices of approval or denial of certification to the Administrator following the issuance of a notice of noncompliance to an applicant for certification. The proposed rule would also amend provisions at § 205.501(a)(15) regarding information that accredited certifying agents must submit to the Administrator. The proposal removes the requirement for submission of any notices of denial of certification, notifications of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, or notification of suspension or revocation. Also, the proposed rule

removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified during the preceding year.

These two requirements will be replaced by a requirement for certifying agents to maintain updated data in INTEGRITY for each operation they certify; these mandatory data requirements will include listings of items and certified acreage, among other data fields. This proposed rule would require certifying agents to generate organic certificates in INTEGRITY, as discussed above in the proposed amendments to § 205.404. The organic industry, including certifying agents, certified operations, consumers, AMS, and other regulatory agencies, use INTEGRITY to confirm the certification status of an operation, organic status of a product, find product information about specific operations, and obtain data for investigation and enforcement. Timely updates to maintain data reflecting an operation's current status, including certified products and acreage, is critical to commerce and enforcement. As discussed later in this proposed rule, amendments to § 205.662 would require certifying agents to update INTEGRITY within three business days of accepting an operation's surrender, or suspending or revoking an operation's certification.

AMS believes the availability of complete data on certified operations, including complete information on certified items and acreage, will reduce the time certifying agents and AMS spend responding to inquiries about specific operations and will enable interested parties to obtain information with less time and effort. Therefore, we propose including INTEGRITY reporting as a general requirement for accreditation to reinforce that data reporting is a mandatory practice.

8. Personnel Training and Qualifications.

| Section | Action | Proposed Text |
|-----------------------|--------------|--|
| 205.2 | Add new term | <p><i>Certification review.</i> The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance with the USDA organic regulations. This does not include performing an inspection.</p> |
| 205.501 (a)(4) | Revise | <p>Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and persons who conduct certification review, to comply with and implement the USDA organic standards;</p> <p>(i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the required knowledge, skills, and experience to inspect operations of the scope and scale as assigned and to evaluate compliance with the applicable regulations of this part; and</p> <p>(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents; and</p> <p>(B) Initially and every year thereafter, inspectors must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to inspection. Training may include material delivered via the</p> |

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| | | <p>NOP learning management system, certifying agents, or other relevant training provider; and</p> <p>(C) Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect before assigning inspection responsibilities;</p> <p>(ii) Certifying agents must demonstrate that all persons who conduct certification review, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and scale assigned and to evaluate compliance with the applicable regulations of this part; and</p> <p>(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned; and</p> <p>(B) Initially and every year thereafter, all persons who conduct certification review activities must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to certification review. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and</p> <p>(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.</p> |
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| <p>205.501 (a)(5)</p> | <p>Revise</p> | <p>Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned;</p> <p>(i) Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties.</p> |
| <p>205.501 (a)(6)</p> | <p>Revise</p> | <p>Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services;</p> <p>(i) On-site evaluation of inspectors—Certifying agents must observe each inspector performing on-site inspections at least once every three years, or more frequently if warranted; and</p> <p>(A) On-site inspector evaluations must be performed by certifying agent personnel who are qualified to evaluate inspectors;</p> <p>(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and on-site inspector evaluations.</p> |

The USDA organic regulations at 7 CFR 205.501, General Requirements for Accreditation, require certifying agents and their inspection and certification personnel to have sufficient expertise in organic production and handling techniques to fully comply with and implement the USDA organic regulations. The OFPA establishes AMS’ authority to modify the USDA organic regulations at 7 CFR 205.501. The proposed rule amends § 205.501 to specify minimum qualifications and training requirements for inspectors and persons who perform certification review activities. The OFPA states that to be

accredited as a certifying agent, the certifying agent will have sufficient expertise in organic farming and handling techniques as determined by the Secretary (7 U.S.C. 6514(b)(2)).

Organic inspectors and review staff are the most direct form of enforcement and verification in the organic system. Inspectors protect organic integrity by inspecting certified organic operations onsite and reporting their findings to certifying agents. Persons performing certification review activities also ensure organic integrity by reviewing organic system plans, inputs, inspection reports, and other certification documents. It is essential that these personnel have knowledge, skills, and experience related to the scope and scale of the organic operations they inspect and review. The role of inspectors and reviewers has grown more critical as organic operations and supply chains become more complex and diverse.

The USDA organic regulations currently require that certifying agents “have sufficient expertise in organic production or handling techniques,” and maintain “a sufficient number of adequately trained personnel.” However, the regulations lack specific detail about qualifications, experience, and continual training for inspectors and reviewers. Certifying agents set their own policies and minimum qualifications to hire inspectors and reviewers. This can result in variability of inspection and certification review between certifying agents. Further, many inspectors are independent contractors who are responsible for establishing and maintaining their own knowledge base. This diversity of background and training creates an inconsistent baseline of knowledge and skill, exposing a potential weakness at one of the most critical points in the organic certification system.

This proposed rule would clearly define expertise requirements to ensure that all inspectors are capable of verifying an organic operation’s compliance with the USDA organic regulations. The requirements would ensure that all inspectors can identify non-compliant or fraudulent practices when observed during inspection and produce a technically accurate inspection report that is sent to the certifying

agent. The requirements would also ensure that persons performing certification review are competent in identifying any non-compliant or fraudulent practices of operations when reviewing inspection reports prepared by an inspector, organic system plans, or other certification documents. Examples of certification review includes reviewing applications for certification, reviewing certification documents, evaluating qualifications for certification, making recommendations concerning certification, or making certification decisions and implementing measures to correct any deficiencies in certification services. Establishing baseline criteria for qualifications and training of inspectors and certification review personnel would create a uniform level of scrutiny in inspections and certification compliance reviews for all USDA certified organic operations, leading to greater consistency and integrity in organic certification.

In a 2012 memo, the NOP notified certifying agents that all inspectors and reviewers, whether staff or independent contractors, must possess the expertise and qualifications needed to evaluate compliance with the USDA organic standards.³³ During audits performed twice every five years, AMS has observed that inspectors and certification review staff currently receive at least 10 hours of training per year from certifying agents on topics related to the USDA organic regulations.³⁴ In 2018, the NOSB provided recommendations for the specific qualification and training requirements for inspectors and persons performing certification review.³⁵ AMS has considered these recommendations and determined that the proposed changes align with the OFPA and would bolster the integrity of organic products.

³³ NOP Memo: Criteria and Qualifications for Organic Inspectors; April 2012:

<https://www.ams.usda.gov/sites/default/files/media/NOP-Notice-OrganicInspectorCriteria.pdf>

³⁴ Paperwork burden attributed to current training is accounted for in the NOP's 2020 Information Collections Renewal (ICR) (AMS-NOP-19-0090; OMB Control #: 0581-0191). Also, please see Paperwork Reduction Act chapter and Information Collection Request (ICR) package associated with this proposed rule for additional details regarding this proposed burden.

³⁵ NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018:

<https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorQualificationsRec.pdf>

The USDA organic regulations stipulate that accredited certifying agents must have sufficient expertise in organic production and handling techniques to fully comply with and implement the terms and conditions of the organic certification program. The regulations at § 205.501(a)(4) require that certifying agents use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and fully implement the organic certification program. It is essential that certifying agents maintain adequate staffing levels and the range of expertise needed to perform the full range of certification activities, including inspections and reviews. This includes maintaining an inspection staff to timely complete initial on-site inspections, annual inspections for all operations it certifies, unannounced inspections on a minimum of 5 percent of the operations it certifies annually, and any other inspections that may be warranted for investigations or reinstatements. If certifying agents reduce staffing levels, if the number of certified operations increases, or if certifying agents add new certification scopes to the certification services they provide, then the number and qualifications of personnel used by certifying agents may become insufficient to fully comply with the organic regulations.

Therefore, this proposed rule amends § 205.501(a)(4) to clarify that certifying agents must continuously use a sufficient number of qualified and adequately trained personnel. This proposed rule also specifies and strengthens requirements for organic inspectors and certification review personnel. These additional qualification and training requirements will help certifying agents meet their obligation to provide sufficient expertise in organic production and handling techniques. The new proposed requirements would specify the areas of knowledge, skills, and expertise required for certifying agents in using adequately trained inspection and certification review personnel for organic inspection and review activities.

Inspector qualifications and training.

The regulations at § 205.501(a)(4) currently do not contain requirements for specific qualifications or training of inspectors. Certifying agents depend on qualified inspectors who are experienced with the complexity of the organic market to verify the integrity of organic products. Organic inspections, a critical component for ensuring organic integrity, are an assessment of an entire production system, not just the final product. Therefore, when conducting organic inspections, inspectors must continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents. In addition, the knowledge, skills, and experience in these areas must be relevant to the scope and scale of the operation seeking or continuing organic certification.

Given that certifying agents may use a variety of inspectors, including staff, volunteers, and contract inspectors, there is variability in the level of experience and qualifications of inspectors performing the key function of ensuring organic integrity at the source of production and through the supply chain. This proposed rule adds subparagraph (i) requiring certifying agents to ensure all inspectors have the level of knowledge, skills, and experience needed to conduct the specific inspections assigned, based on the scope and scale of the operations to be inspected. The proposed rule clarifies that the requirement applies not only to staff inspectors, but to all inspectors (i.e., including volunteers and contractors) and further requires certifying agents to provide evidence of inspectors' qualifications, matching the scope and scale of inspection assignments.

This proposed rule at § 205.501(a)(4)(i)(A) describes the general scope of the knowledge and skills required for inspectors to be deemed adequately qualified. Inspections of organic operations provide

information to certifying agents to verify whether the practices and inputs used in an operation's implemented organic system plan are compliant with the USDA organic regulations. To ensure an adequate organic inspection, each inspector must be knowledgeable and competent both in inspection and auditing procedures, as well as in the processes of organic certification and inspection. Organic inspectors must know the USDA organic regulations and have expertise in the scope of the agricultural or processing system (i.e., crops, wild crops, livestock, or handling) being inspected.

In addition, inspectors must have sufficient knowledge of organic and general agricultural practices, as well as a general awareness of other rules and regulations that may be applicable to the operation being inspected. Qualified organic inspectors must also have skills in written and oral communications, auditing, investigation and observation techniques which support fraud detection, and sample collection. Inspectors must be proficient in orally communicating inspection findings both during the inspection closing meeting with the inspected operation, and in writing to provide detailed and technically accurate descriptions of the inspection findings in the report to the certifying agent. The inspection report is a critical tool used by certifying agents to verify if on-site practices are in compliance with the USDA organic regulations. As such, the quality and depth of the inspection report directly affects the integrity of organic products. An adequately qualified inspector would know how to independently apply knowledge in the above areas to assess whether an operation is complying with all applicable parts of the regulations and clearly communicate those findings to the certifying agent.

AMS proposes strengthening and specifying training requirements to § 205.501(a)(4)(i)(B) for all inspectors currently inspecting organic operations or seeking to become qualified to conduct organic inspections. For inspectors to remain qualified or to become qualified in any scope of organic inspection, they must obtain and continuously update knowledge, skills, and experience relevant to the types of operations they inspect. Organic training hours should include: organic and general agricultural practices; USDA organic regulations and guidance; inputs allowed for organic production and handling

(i.e., changes to the National List); new technology that may be used in organic production and handling; investigation and auditing techniques; and new developments in marketing organic products. To ensure consistency in inspector training and qualifications across the organic industry, this proposed rule requires that inspectors initially, and every year thereafter, complete at least 20 hours of training that may include material delivered via the NOP learning management system, certifying agents, or other relevant training providers.

In their 2018 recommendation, NOSB did not specify the number of hours of training that inspectors must complete annually. However, they requested that the NOP set the minimum training guidelines. A minimum of 20 hours of annual training for inspectors is consistent with standards established by other agencies or organizations (e.g., Preventive Controls Qualified Individuals per 2011 Food Safety Modernization Act; ISO 9001 Global Certified Lead Auditor). The proposed training requirements will ensure that inspectors meet the training requirements recommended by the NOSB, which state that continuing education is essential to “professional competence.”³⁶ Establishing baseline training criteria for inspectors across the organic industry is essential for ensuring that compliance with USDA organic standards would be assessed in all sectors of this rapidly growing and diversifying global industry. Additionally, requiring inspectors to continuously supplement their knowledge with a minimum annual training requirement is vital to ensuring the integrity of organic products amidst rapidly changing technologies and product supply chain practices.

Each scope of organic certification, as well as the scale and type of operation being inspected, provides different challenges to ensuring a comprehensive and sufficient organic inspection. Inspectors who are inexperienced with an agricultural production or handling system may underestimate the scale of an

³⁶ NOSB Formal Recommendation, Inspector Qualifications and Training, May 29, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorQualificationsRec.pdf>

operation or may miss components of that system during the inspection. Varied quality of inspections can result in an inconsistent organic certification process. In addition, to enhance inspection consistency and organic certification integrity, this rule proposes to add the requirement, in § 205.501(a)(4)(i)(C), that certifying agents must ensure and demonstrate an inspector has a minimum of one year of on-site experience related to the scope and size of the operation being inspected. The proposed requirement aligns with recommendations developed by the NOSB.

Certification review personnel qualifications and training.

The regulations in § 205.501(a)(4) currently do not contain requirements for specific qualifications or training of persons who conduct certification review. Certification review personnel are critical to ensuring organic integrity. Certification review activities include, but are not limited to, review of organic system plans, inputs (e.g., production aids, fertilizers, pesticides), seeds, planting stock, inspection reports, and residue tests for compliance with the USDA organic standards. Certification review personnel are responsible for verifying whether the procedures being implemented at the point of production or handling are compliant with the USDA organic standards. Certification review personnel must continuously maintain adequate knowledge about the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned. The level of knowledge, skills, and experience of certification review personnel must be relevant to the scope and scale of the operations seeking or continuing organic certification.

In addition, certification review personnel play a crucial role in determining if an operation is granted organic certification initially, if continued certification is warranted, and/or if issuing a non-compliance, proposed suspension, or revocation. In cases where an operation has been issued a non-compliance or has been suspended, the certification review personnel determine if sufficient corrective actions have

been taken to bring the operation into compliance. As such, the certification review personnel are integral to maintaining organic integrity. Therefore, this proposed rule adds a requirement at § 205.501(a)(4)(ii) that certifying agents are responsible for demonstrating that all certification review personnel, whether staff, volunteers, or contractors, have the knowledge, skills, and experience needed to conduct the specific reviews assigned.

This proposed rule at § 205.501(a)(4)(ii)(A) specifies the types of knowledge and essential skills in which certification review personnel must be proficient to be deemed qualified. To verify the integrity of organic products, reviewers must be knowledgeable and competent in current USDA organic regulations, guidance, and instructions; certification procedures; and practices specific to the type, volume, and range of review activities assigned by the certifying agent. To remain current with changes in technology, new developments in marketing or importing organic products, changes in organic standards, novel input materials, or changes to the National List, reviewers must continuously update knowledge, skills, and experience directly related to their specific review responsibilities.

To ensure consistency in reviewer training and qualifications across the organic industry, this proposed rule in § 205.501(a)(4)(ii)(B) requires that all persons conducting certification review activities initially, and every year thereafter, complete at least 20 hours of training that can include material delivered via the NOP learning management system, certifying agents, or other relevant training providers. A minimum of 20 hours of annual training for certification review personnel is consistent with training required by other agencies or organizations (e.g., Preventive Controls Qualified Individuals per 2011 Food Safety Modernization Act; ISO 9001 Global Certified Lead Auditor). Establishing baseline training criteria for certification review personnel across the organic industry is essential for ensuring that compliance with USDA organic standards would be assessed in all sectors of this rapidly growing and diversifying global industry. Additionally, requiring certification review personnel to continuously

supplement their knowledge with a minimum annual training requirement is vital to ensuring the integrity of organic products amidst rapidly changing technologies and product supply chain practices.

Documented training requirements and procedures.

The current regulations at § 205.504(a) require certifying agents to provide descriptions of personnel qualifications and training but do not contain requirements for documenting training procedures. This proposed rule adds § 205.501(a)(4)(iii) to require certifying agents to maintain current documented training requirements, procedures, and records for all inspectors and certification review personnel. This requirement would enable the NOP to verify if accredited certifying agents are meeting the requirement in § 205.501(a)(4) to maintain a sufficient number of qualified and adequately trained personnel to comply with and implement the organic certification program established under the Act.

Expertise.

The regulations in § 205.501(a)(5) require that certifying agents ensure that all persons with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production and handling techniques. However, the regulations currently do not contain requirements for specific expertise areas needed to ensure the integrity of organic products. This proposed rule adds § 205.501(a)(5)(i) to clarify the areas of expertise required. The change specifies that expertise must include knowledge of certification to USDA organic standards, as well as evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties. This clarification will assist certifying agents in evaluating potential hires for adequate expertise needed to perform certification duties. The added specificity regarding areas of expertise and the need for formal education or training aligns with

recommendations proposed by the NOSB.³⁷ AMS evaluated the proposed recommendations and found them to be consistent with the OFPA and therefore has included similar requirements in this proposed rule.

Performance evaluations.

The proposed rule also revises the requirements for annual performance evaluations, described in § 205.501(a)(6), to include requirements for regular field evaluation of inspectors and documentation of annual performance and field evaluation procedures and results. The proposed rule amends § 205.501(a)(6) to clarify the requirements for annual performance evaluations conducted by accredited certifying agents. Subparagraph (i) is added to address the evaluation of inspectors while performing on-site inspections. The proposed rule ensures that inspectors are evaluated regularly in the field (i.e., while performing an inspection on a farm, in a processing facility, etc.). The proposed change specifies a minimum frequency of every three years for on-site inspection evaluation, unless higher frequency is warranted based on experience level or past performance of the individual inspector. For inspectors that work for or contract with multiple certifying agents, the on-site evaluation conducted by one certifying agent may fulfill the on-site evaluation requirements for all certifying agents, provided that the report of the evaluation is shared. Another certifying agent may choose to independently conduct an on-site evaluation in addition to one performed by another certifying agent within the 3-year period. All certifying agents are required to ensure that all inspectors they employ or contract with have been evaluated during an on-site inspection at least once every three years. The proposed frequency of on-site inspection evaluation is based upon the frequency recommended in the NOSB proposal “Personnel

³⁷ “Training and Oversight of Inspector and Certification Review Personnel” proposal, August 17, 2018: <https://www.ams.usda.gov/sites/default/files/media/CACSTrainingOversightInspectorsProposalOct2018Web.pdf>

Performance Evaluations of Inspectors”³⁸ and aligns with the “Guidance on Organic Inspector Qualifications” published by the Accredited Certifiers Association, Inc.³⁹ (February 2018). AMS considered requiring more frequent on-site evaluations. However, the NOSB has indicated that requiring inspector on-site evaluations on a more frequent basis worldwide may pose undue financial burden on certifying agents. AMS also determined that inspector evaluations every year would create a significant resource constraint on certifying agents.

On-site evaluations of inspectors are necessary to verify that inspectors possess the knowledge and skills to evaluate the compliance of certified organic operations and to produce technically accurate inspection reports. Requiring recurring, on-site evaluations of inspectors would enhance the integrity of organic products by verifying competence of organic inspectors and ensuring consistency in organic certification inspections. Subparagraph (i)(A) is added to ensure that inspector on-site evaluations are performed by certifying agent personnel who are qualified to evaluate inspectors. This could include for example, a person who has prior experience as an inspector, conducts training for inspectors, and/or evaluates inspection reports to determine compliance.

Subparagraph (ii) is added to address the need for certifying agents to maintain detailed procedures regarding how performance evaluations are conducted. The text also requires certifying agents to document results of on-site inspector performance evaluations and results of annual performance evaluations for all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in

³⁸ “Personnel Performance Evaluations of Inspectors” proposal, December 13, 2016:

<https://www.ams.usda.gov/sites/default/files/media/CACSInspectorsProposal.pdf>

³⁹ The Accredited Certifiers Association, Inc. is a 501(c)(3) non-profit educational organization created to benefit the accredited organic certifying agent community and the organic industry: <https://www.accreditedcertifiers.org/>

certification services. This change would ensure uniformity in scope and frequency of performance evaluations implemented across certifying agents, thereby enhancing organic integrity.

Request for comment.

AMS seeks comment regarding certifying agent personnel qualifications and training, including answers to the following questions:

1. Is 20 training hours a year an appropriate amount of continuing education for organic inspectors and certification review personnel?
2. Should organic inspectors be evaluated on-site more frequently than once every three years?
3. Should any other types of knowledge, skills, and experience be specified?

9. Oversight of Certification Activities.

| Section | Action | Proposed Text |
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| 205.2 | Add new term | <i>Certification activity.</i> Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates. |
| 205.2 | Add new term | <i>Certification office.</i> Any site or facility where certification activities are conducted, except for certification activities that occur at certified |

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| | | operations or applicants for certification, such as inspections and sampling. |
| 205.501 (a)(22) | Add | Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities. |
| 205.640 | Revise | Fees and other charges equal as nearly as may be to the cost of the services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be reviewed, assessed, and collected from applicants in accordance with the following provisions: |
| 205.665(a) | Revise | <i>Notification.</i> (1) A written notification of noncompliance will be sent to the certifying agent when: (i) An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; or (ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or (iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part. |

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| | | <p>(2) Such notification must provide:</p> <p>(i) A description of each noncompliance;</p> <p>(ii) The facts upon which the notification of noncompliance is based;</p> <p>and</p> <p>(iii) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.</p> |
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AMS proposes amending §§ 205.2, 205.501, and 205.665 of the USDA organic regulations to strengthen oversight and enforcement of certifying agents and their activities. These proposed changes are primarily intended to address recent changes to the OFPA, as amended by the Agriculture Improvement Act of 2018 (see 7 U.S.C. 6515(i)–(j)).⁴⁰ Clarifying the oversight of certifying agents is a critical component of this proposed rule, because it will allow the NOP to provide robust enforcement of the USDA organic regulations, and ensure a level playing field for all accredited certifying agents and certified operations.

General clarification of oversight.

To clarify the USDA’s oversight of the certifying agents it accredits, AMS proposes adding the new term *certification activities* to the organic regulations. This new term defines the general activities which are considered essential to the function of a certifying agent, and therefore subject to oversight by the NOP. Any business operation conducted by a certifying agent as they implement the USDA organic regulations is considered a certification activity, including review, inspection, and certification of organic operations. The new term also clarifies that NOP oversight extends to the activities of any person performing work

⁴⁰ See section 10104(d) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>

on behalf of the certifying agent (e.g., a specific office operating in specific countries, or a subcontractor or subcontractor organization). Because the use of subcontractors is very common in the organic industry, effective enforcement depends upon oversight that reaches all persons involved in the certification of organic operations. This is reinforced by the proposed revision of § 205.665, at paragraph (a)(1)(ii), which clarifies the Program's authority to send notifications of noncompliance to a certifying agent based upon review of certification activities, including those of a person acting on behalf of the certifying agent.

Certifying agents with multiple offices of operation.

Certifying agents commonly operate multiple offices to ensure adequate service (e.g., sufficient capacity or proximity) to the operations they certify. This can result in a single certifying agent with multiple offices spread across several different countries, many of which act independently and are quite remote from the central office. NOP is aware that several certifying agents accredited by the USDA use multiple offices to perform certification activities. As part of our ongoing efforts to improve enforcement, AMS has requested information about certification offices and the types of certification activities that are conducted at those offices. The lack of specificity in the USDA organic regulations and the dynamic nature of relationships between a certifying agent and its offices create oversight challenges for the USDA. This has led to inconsistent application and enforcement of the regulations amongst certifying agents and offices.

To clarify the USDA's authority to oversee certification offices, AMS proposes the addition of the new term *certification office*, and the previously mentioned term *certification activities*. A certification office is defined as any site or facility where certification activities take place (except for activities that take place at certified operations or other specialized facilities, such as inspection, sampling, and testing). In combination with the proposed revisions to § 205.665 at paragraph (a)(1)(iii), this allows the NOP to

send notices of noncompliance to a certifying agent, based upon the certification activities at a specific certification office and in specific countries.

Another gap in the oversight of certification offices is the current lack of requirements to notify the NOP of the opening of new certification offices. Because of this, the NOP has difficulty readily quantifying how many certification offices exist; this is compounded by reports of offices opening and closing frequently and unpredictably, complicating the NOP's ability to effectively oversee the activities of these offices. To ensure more robust enforcement of certification offices, AMS proposes adding a new paragraph, (a)(22), to § 205.501, which will require that certifying agents notify the NOP within 90 calendar days of the opening of any office performing certification activities. The notification must include basic information to assist the NOP in effectively overseeing the office, including the countries serviced, location and nature of the certification activities, and the qualifications of the personnel that will provide the certification activities. Information on the location of new offices will enable AMS to more efficiently utilize personnel and travel resources to schedule on-site evaluations, and to specify countries in which the certifying agent's certification activities must cease should a certifying agent's office be suspended or revoked based on failure to resolve its noncompliances. Information on the types of certification activities being conducted will allow AMS to better evaluate the need for additional oversight; for instance, a new office located in a high-risk area with a history of organic fraud may require additional oversight.

The proposed rule, if finalized, will codify this practice and ensure that certifying agents are providing complete information about their certification offices in a timely manner. Accurate and timely reporting of information about certification activities will bolster the NOP's ability to oversee certifying agents, and provide for more equitable enforcement of the Act and the USDA organic regulations.

10. Accepting Foreign Conformity Assessment Systems.

| Section | Action | Proposed Text |
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| 205.2 | Add new term | <i>Conformity assessment system.</i> All activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product. |
| 205.2 | Add new term | <i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products. |
| 205.500(c) | Remove | |
| 205.511 | Add new section | Accepting foreign conformity assessment systems. |
| 205.511(a) | Add | Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country’s organic certification program may be sold, labeled, or represented as organically produced in the United States if AMS determines that such organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part (“equivalence determination”). |

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| 205.511(b) | Add | Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will conduct an assessment of the country's organic certification program to evaluate whether it is equivalent. |
| 205.511(c) | Add | AMS will describe the scope of an equivalence determination. |
| 205.511(d) | Add | AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government's organic certification program. AMS will reassess a country's organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government's technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued. |
| 205.511(e) | Add | AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country's technical requirements and/or conformity |

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| | | assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate to ensure that the country’s organic certification program is fully meeting the terms and conditions under the determination; or for other good cause. |
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AMS proposes adding a new section to the USDA organic regulations, § 205.511, on accepting foreign conformity assessment systems that oversee organic production in foreign countries. If this proposed rule is implemented, new § 205.511 will replace current § 205.500(c), which will be removed.

International trade is critically important to the economic vitality of the organic sector. The OFPA, under 7 U.S.C. 6505(b), allows imported products to be sold or labeled as organically produced if the Secretary determines that the products have been produced and handled under an organic certification program with requirements and oversight determined to be at least equivalent to those described in the OFPA. Under this authority, AMS has developed a process for determining the equivalence of foreign organic certification programs. AMS’ equivalence determination process is based on the similar processes used by other U.S. government agencies and foreign trading partners, and on guidelines from international organizations such as the World Trade Organization (WTO), the International Standards Organization (ISO), the Food and Agriculture Organization (FAO), and the International Federation of Organic Agriculture Movements (IFOAM). AMS’ process was roughly described in two previous certifying agent Instruction documents in the National Organic Program Handbook: NOP 2100—Equivalence Determination Procedure; and NOP 2200—Recognition and Monitoring of Foreign Government Conformity Assessment Systems.

AMS has used its equivalence determination process to establish trade arrangements for organic products with 10 other countries.⁴¹ These arrangements facilitate trade and are an important mechanism for ensuring robust oversight of imported organic products. The most common type of trade arrangement is a full organic equivalence determination, in which AMS determines a country's entire organic certification program to be equivalent to that of the United States. AMS has also established recognition agreements, where AMS determines that a foreign government's ability to accredit certifying agents and enforce standards is equivalent and authorizes that government to oversee certification of products to the USDA organic standards.

The USDA has direct oversight over the certifying agents it accredits under the NOP. In contrast, certifying agents accredited by a foreign government whose organic certification program has been determined to be equivalent are accredited by the foreign government or by an agent of that government. The USDA has no direct oversight of these certifying agents and relies upon the conditions of the equivalence determination to ensure compliance with the Act and the regulations.

The current USDA organic regulations address the USDA's authority to make equivalence determinations in general terms under § 205.500(c), but do not describe the criteria, scope, and other parameters to establish, oversee, or terminate such equivalence determinations, all of which are critical to the enforcement of organic imports. This proposed new section is necessary to adequately address AMS' authority and clarify the procedures that the agency follows for organic equivalence determinations. Importantly, the section codifies the agency's existing practices and does not establish any new requirements. The new regulatory language will strengthen AMS oversight and enforcement capacity of organic imports. Clear language in the regulations regarding equivalence determination will support

⁴¹ The United States has seven organic equivalence arrangements: Canada, the European Union, Japan, South Korea, Switzerland, Taiwan, and the United Kingdom. The United Kingdom equivalency will be effective in January 2021. The United States also has three recognition agreements: India, Israel, and New Zealand.

AMS authority to determine the scope of equivalence determinations. It will also support AMS' authority in reassessing, and either continuing or terminating equivalence determinations, as necessary. Finally, additional clarity in the regulations will increase transparency for stakeholders and foreign governments by establishing a foundation for AMS to develop more detailed documents that describe the process and requirements for equivalence determinations. Without adding this new section to the regulations, AMS could face challenges establishing and enforcing terms under current and future equivalence determinations that are critical to ensuring the integrity of imported organic products. To support proposed new § 205.511, AMS proposes adding two new terms to § 205.2: *conformity assessment system*; and *technical requirements*. These terms are defined to ensure that the process and requirements described in new § 205.511 are clear.

The term *conformity assessment system* would be defined as all activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product. *Technical requirements* would be defined as a system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products. A government's conformity assessment system and technical requirements would cover the full range of activities associated with administering a federal organic program (i.e., development of standards, policies and procedures, accreditation and oversight of certifying agents, and compliance and enforcement activities).

New § 205.511(a) describes AMS' authority under the OFPA to make equivalence determinations. New § 205.511(b) describes the process for initiating a request for equivalence used by AMS and other foreign governments. Since there are several factors that may impact whether AMS moves forward to review an equivalence request (i.e., agency resources, capacity to oversee the potential trade

arrangement, relative benefits for the U.S. organic sector), this section clarifies that AMS will determine if it can proceed with the evaluation process in each case.

New § 205.511(c) clarifies that AMS will determine the scope of each equivalence determination that it makes. It is important to make this clarification because not all determinations must cover the same organic products and activities and they may include different terms or conditions. These differences depend upon AMS' evaluation of each foreign government's unique technical requirements and conformity assessment system and are important to AMS' ability to ensure the integrity of organic products produced under different systems.

New § 205.511(d) lays out the current process that AMS and other foreign governments use to monitor equivalence determinations that have been made. The review cycles mirror ISO standards, which include a five-year reassessment cycle and mid-cycle reviews. The section provides some flexibility in the timing of the mid-cycle reviews to accommodate unavoidable factors in both countries that can impact timing (e.g., federal budgets, election cycles, growing seasons).

New § 205.511(e) describes the conditions under which AMS may terminate equivalence determinations. These conditions for termination are commonly accepted among countries that maintain equivalence determinations and are based upon the core concepts underlying equivalence. AMS must be able to terminate equivalence determinations under these conditions in order to fulfill its statutory obligation to assure that organic products sold in the United States are compliant with OFPA and the USDA organic regulations and maintain a level playing field for U.S. farms and businesses.

Request for comment.

AMS seeks comment regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships. Specifically, compared with organic equivalence

determinations, are there increased risks associated with recognition agreements where other countries' governments oversee the implementation of NOP certification?

11. Compliance—General.

| Section | Action | Proposed Text |
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| 205.660 (c)–(d) | Redesignate | Redesignate paragraphs (c)–(d) as paragraphs (d)–(e) |
| 205.660 (c) | Add | The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies, directly or indirectly, that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part. |
| 205.661 | Revise section title | Investigation. |

AMS proposes adding new paragraph (c) to § 205.660, to clarify that the NOP Program Manager may initiate an enforcement action against any violator of the OFPA, as amended (7 U.S.C. 6501 et. al). The proposed change will clarify that the OFPA grants the Secretary administrative powers to enforce the Act against any violator, regardless of certification status. This clarification is important because noncertified status does not protect an operation that commits organic fraud from enforcement action. The NOP currently pursues enforcement actions against uncertified parties for which AMS has evidence of OFPA violations.

This proposed change is consistent with the enforcement authority granted to the Secretary in the OFPA. All agricultural products sold, labeled, or represented as organic must be produced and handled

in compliance with the USDA organic regulations. The OFPA at 7 U.S.C. 6505(a)(1) states: (A) a person may sell or label an agricultural product as organically produced only if such product is produced and handled in accordance with this chapter; and (B) no person may affix a label to, or provide other 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 this chapter. Further, the OFPA at 7 U.S.C. 6506(a)(7) requires that the NOP provide for appropriate and adequate enforcement procedures, as determined by the Secretary to be necessary and consistent with this chapter.

AMS also proposes amending the title of § 205.661 from “Investigation of certified operations” to “Investigation.” The proposed change is intended to further clarify that the OFPA grants the Secretary administrative powers to enforce the Act against any violator, regardless of the person’s certification status.

The proposed changes are necessary to emphasize the Secretary’s administrative powers to investigate and enforce against operations who are not certified to the USDA organic standards. During calendar years 2011–2017, over 70% of complaints received by the NOP alleging violations of the OFPA involved uncertified operations representing products as organic. Therefore, continued AMS enforcement against uncertified operations is central to the effective administration of the OFPA.

12. Noncompliance Procedure for Certified Operations.

| Section | Action | Proposed Text |
|--------------------|--------|--|
| 205.100 (c) | Revise | Any person or responsibly connected person that: |

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| 205.662 (e)(3) | Add | Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation’s surrender, the certifying agent must update the operation’s status in INTEGRITY. |
| 205.662 (f)(1) | Revise | A certified operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. |
| 205.662 (g)(1) | Revise | Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1)(xxxvii) of this title per violation. |

AMS proposes amending §§ 205.100 and 205.662 to clarify that a person who is responsibly connected to an operation that violates the OFPA or the USDA organic regulations may be subject to a suspension of certification (if the responsibly connected person is certified), or civil penalties or criminal charges and/or may be ineligible to receive certification. This will bolster the enforcement capacity of AMS by ensuring that penalties for violations of the OFPA extend to all accountable parties.

The USDA organic regulations, at section § 205.2, define *responsibly connected* as “Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.” The OFPA provides that any person who (1) attempts to label a product as organic and who knows or should have known that the product is

noncompliant; or (2) makes a false statement to the USDA; or (3) otherwise does not comply with the USDA organic regulations is ineligible to receive organic certification for 5 years (7 U.S.C. 6519(c)(3)). In addition, the OFPA states that any person who knowingly sells or labels a nonorganic product as organic, or makes a false statement to the Secretary, a State organic program, or a certifying agent, shall be subject to civil penalty fines or imprisonment, respectively (7 U.S.C. 6519(c)(1)–(2)).

This proposed rule clarifies that a person responsibly connected to a violator of the OFPA may be complicit in the OFPA violation(s) because of that association, and may be ineligible to receive certification. This parallels the current provisions in the USDA organic regulations for revocation of certification, where a certified operation or person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for 5 years (§ 205.662(f)(2)). AMS expects that when issuing a proposed suspension, certifying agents will identify all persons responsibly connected, and when such persons exist, notify the appropriate certifying agent(s) or the NOP, as applicable.

This proposed rule also clarifies that a person responsibly connected to a person that knowingly sells nonorganic product as organic or makes a false statement to authorities about compliance with the OFPA, may be subject to fines and/or imprisonment (18 U.S.C. 1001). This will enable AMS to take comprehensive enforcement action to hold all responsible individuals accountable and prevent persons that enable or assist in activities that violate the OFPA from continuing that activity.

AMS also proposes adding new paragraph § 205.662(e)(3) to require certifying agents to timely update the status of an operation that has been suspended or revoked, or that has surrendered its certification. The updates should be completed within three business days of issuing a notification of suspension or revocation, or from the effective date of a surrender. Timely updates to INTEGRITY are critical to inform other certifying agents, operations in the supply chain, and consumers when an operation is no longer

certified and can help prevent noncompliant products from entering or continuing in the stream of commerce.

Finally, AMS proposes amending § 205.662(g)(1) to update the citation which specifies the maximum civil penalty amount for violations of the OFPA. This aligns with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. On March 14, 2018, the USDA published in the Federal Register its annual inflation adjustment for 2018 (83 FR 11129). This most recent adjustment increased the civil penalty amount from \$11,000 to \$17,952 for violations of the OFPA which occurred on or after March 14, 2018.

13. Mediation.

| Section | Action | Proposed Text |
|---------|--------|---|
| 205.663 | Revise | <p>(a) A certifying agent must submit with its administrative policies and procedures provided in §205.504(b): decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions.</p> <p>(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.</p> <p>(1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.</p> |

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| | <p>(2) A certifying agent or State organic program may accept or reject a request for mediation based on its own decision criteria.</p> <p>(i) If a certifying agent rejects a mediation request, it must provide this rejection in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to §205.681, within 30 calendar days of the date of the written notification of rejection of the request for mediation.</p> <p>(c) Both parties must agree on the person conducting the mediation.</p> <p>(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.</p> <p>(e) The parties to the mediation have a maximum of 30 calendar days to reach an agreement following a mediation session. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to §205.681.</p> <p>(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Secretary may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.</p> |
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| | (g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice that it has issued. |
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AMS proposes revising § 205.663 to improve the general readability of this section and to more clearly explain how mediation may be used in noncompliance procedures. When successful, mediation is an efficient way to bring operations into compliance and resolve conflicts among certifying agents and operations. The USDA organic regulations require that certifying agents and State organic programs provide applicants for certification and certified operations the right to request mediation when they issue a denial of certification, notice of proposed suspension, or proposed revocation of certification (§§ 205.405(d) and 205.662(c)). Section 205.663 provides requirements for requesting mediation, responding to a mediation request, the time frame for reaching an agreement, and what happens when mediation is unsuccessful.⁴²

The USDA organic regulations require certifying agents and State organic programs to notify operations of the option to request mediation as an alternative dispute resolution to resolve noncompliance findings that have led to a proposed suspension, revocation, or denial of certification. This will facilitate resolution of these issues before they escalate to an appeal to AMS or a State organic program.

AMS proposes revising the existing requirements for mediation to support a process that is efficient and accessible to producers and handlers who want to resolve a denial of certification, proposed suspension, or revocation of certification. Mediation should be a collaborative process between a certifying agent and an operation. A successful mediation addresses the noncompliance(s) and leads to full compliance

⁴² The OFPA does not specifically mention mediation. The OFPA does require that the USDA have procedures for producers and handlers to appeal adverse determinations. The right to request mediation in the regulations provides an additional opportunity for producers and handlers to resolve adverse actions while preserving their right to appeal if mediation is unsuccessful.

with the USDA organic regulations. In summary, the proposed changes would clarify the process for engaging in mediation and would clarify that a settlement agreement is the outcome of successful mediation. The revised rule would permit certifying agents and certified operations or applicants to engage in mediation without a third-party mediator, provided that all parties agree upon the person who will serve as the mediator.

After a certifying agent issues a denial of certification, proposed suspension, or revocation of certification, a certified operation and certifying agent may discuss the option of mediation prior to receiving a request for mediation. However, for mediation to proceed as a form of alternative dispute resolution, an operation must request mediation in writing to the certifying agent. This proposed rule provides 30 calendar days to request mediation. This aligns with the length of time provided to submit an appeal of a proposed adverse action.

A certifying agent determines whether to accept or reject a written request for mediation. This proposed rule requires certifying agents to include mediation acceptance decision criteria as part of the administrative policies and procedures which certifying agents are required to submit under § 205.504(b). Parties to the mediation may develop conditions, such as cost, timeframes to reach a settlement agreement, and any incremental steps, only after a certifying agent accepts a mediation request. A certifying agent must not impose any preconditions for the acceptance of mediation (i.e., the certifying agent cannot require that the operation take a specific action—other than submitting a written request for mediation—before it will consider mediation).

In accepting mediation, a certifying agent may also, at its discretion, offer a settlement agreement for an operation to consider. A settlement offer may be useful when the corrective action(s) is clear and the noncompliance(s) is not recurrent. As part of the mediation, an operation may accept or reject the settlement agreement, negotiate the terms with the certifying agent, or request a mediator to try and

reach a settlement agreement. Settlement agreements may impose additional compliance requirements or may include agreed-upon suspensions or revocations of organic certificates, as appropriate to the noncompliance.

This proposed rule clarifies that mediation does not require a third-party mediator to reach a settlement agreement. The certifying agent and operation may agree that mediation will be between only those two parties. For example, mediation may consist of a phone call or series of phone calls between the operator and the certifying agent to discuss the terms of a settlement offer prior to signing the agreement.

In some cases, the use of a mediator may be appropriate, either because the operation initially requested this, or the operation rejected a settlement offer and then requested a mediator. To accommodate this situation, the proposed rule would require each certifying agent submit a process to identify a qualified mediator and set the time and location of mediation session(s), mediation format (in-person, video, phone), and mediation fees and payment.

The outcome of a successful mediation is a settlement agreement that brings an operation into compliance with the USDA organic regulations. A settlement agreement must clearly describe the corrective actions and timeframes for implementing corrective actions, and may impose additional actions (e.g., unannounced inspections, sampling for residue testing) to ensure the operation maintains compliance. A settlement may also include a suspension of organic certification.

This proposed rule would also clarify that the Secretary does not require, manage, or otherwise participate in mediation between operations and certifying agents or State organic programs. This does not change the authority of the Secretary to review an agreement that results from the mediation for conformity to the OFPA and the USDA organic regulations and reject any nonconforming provision or agreement.

This proposed change is needed to clarify and emphasize that mediation under the USDA organic regulations is an alternative dispute resolution mechanism, conducted between a certified operation or applicant for certification and a certifying agent or State organic program. The Secretary is not involved in determining the outcome of a mediation, notwithstanding his or her authority to review dispute resolution terms for conformity with the OFPA and the USDA organic regulations.

This proposed change would not affect AMS' ability to carry out oversight, compliance, and enforcement activities on behalf of the Secretary. For example, AMS may conduct informal mediation, at its discretion, and enter into mutually agreeable settlement agreements with parties that receive an NOP-issued proposed adverse action.

14. Adverse Action Appeal Process—General.

| Section | Action | Proposed Text |
|----------------|--------------|--|
| 205.2 | Add new term | <i>Adverse action.</i> A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty. |
| 205.680 (a) | Revise | Persons subject to the Act who believe they are adversely affected by an adverse action of the National Organic Program's Program Manager, may appeal such decision to the Administrator. |
| 205.680 (b) | Revise | Persons subject to the Act who believe they are adversely affected by an adverse action of a State organic program may appeal such decision to the State organic program's governing State official who |

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| | | will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary. |
| 205.680 (c) | Revise | Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent may appeal such decision to the Administrator, Except, That when the person is subject to an approved State organic program, the appeal must be made to the State organic program. |
| 205.680 (d) | Redesignate | Redesignate as paragraph (f) |
| 205.680 (d) | Add | Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in §205.663. |
| 205.680 (e) | Revise and redesignate as paragraph (g) | All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed. |
| 205.680 (e) | Add | All appeals must comply with the procedural requirements in §205.681(c) and (d) of the USDA organic regulations. |

AMS proposes to revise and clarify parts of the adverse action appeals process in §§ 205.680 and 205.681. In summary, these changes will clarify which actions can be appealed, recognize the use of alternative dispute resolution practices in lieu of a formal administrative proceeding to resolve an appeal, and reinforce that appeal submissions need to comply with the basic requirements in the regulations. We expect that these changes will support an expedited appeals process.

The OFPA authorizes an expedited appeals procedure that gives persons the opportunity to appeal actions that adversely affect the person(s) (7 U.S.C. 6520). The current USDA organic regulations describe how certified operations, accredited certifying agents, and applicants for certification or accreditation may appeal a noncompliance decision that would affect their certification or accreditation status or eligibility to become certified or accredited (§ 205.680(a)). The current regulations explain when an appeal may be submitted, how it must be submitted, and what the appeal submission must contain. Specifically, appeals of noncompliance decisions of a certifying agent or the NOP are appealable to the AMS Administrator, or to the State organic program if the appellant is located in a State with an approved State organic program.⁴³ In addition, the current regulations explain that a decision to sustain an appeal results in a favorable action with respect to the appellant’s certification or accreditation, and a decision to deny an appeal requires AMS to initiate a formal administrative proceeding (i.e., a hearing). AMS explains how it administers the adverse action appeal process, the status of an appellant during an appeal, and the possible outcomes of an appeal in NOP 4011, Adverse Action Appeal Process.⁴⁴

The proposed rule would add the new term *adverse action* to clarify which actions may be appealed under the USDA organic regulations. *Adverse action* would be defined as a noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.⁴⁵ This term would replace the use of “noncompliance decision” throughout this section. AMS is proposing to change “noncompliance decision” in the current regulation to *adverse action*. This clarifies the scope of actions which may be appealed.

⁴³ As of the publication of this proposed rule, California is the only approved State organic program.

⁴⁴ NOP 4011, Adverse Action Appeal Process. December 23, 2011:
<https://www.ams.usda.gov/sites/default/files/media/4011.pdf>

⁴⁵ Only AMS issues civil penalties.

This proposed rule would add a new provision that reminds operations of the option to request mediation when a certifying agent or State organic program has issued an adverse action. The option to request mediation is provided in addition to the option to appeal (mediation is covered in § 205.663, and proposed changes to this section are discussed above). The mediation process can be a viable path to resolve noncompliances that are correctable, and not willful or recurrent. If mediation is rejected or is not successful, the operation maintains the right to appeal.

Finally, this proposed rule would add an explicit requirement that appeals must be properly filed, as described in paragraphs (c) and (d) of § 205.681. This means that an appeal must be timely filed, sent to the correct address, include a copy of the adverse action, and explain why the adverse action is incorrect. In effect, this requirement will help to expedite the review of appeals and supports AMS' decisions to dismiss appeals which are not timely filed.

15. Adverse Action Appeal Process—Appeals.

| Section | Action | Proposed Text |
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| 205.681 (a) | Revise | <i>Adverse actions by certifying agents.</i> An applicant for certification may appeal a certifying agent’s notice of denial of certification, and a certified operation may appeal a certifying agent’s notification of proposed suspension or proposed revocation of certification to the Administrator, Except, That, when the applicant or certified operation is subject to an approved State organic program, the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary. |

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| 205.681 (a)(2) | Revise | If the Administrator or State organic program denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the certification. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture’s Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program’s rules of procedure. |
| 205.681 (b) | Revise | <i>Adverse actions by the NOP Program Manager.</i> A person affected by an adverse action, as defined by 205.2, issued by the NOP Program Manager, may appeal to the Administrator. |
| 205.681 (b)(1) | Revise | If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be waived and a cease-and-desist notice will be withdrawn, as applicable to the operation. |
| 205.681 (b)(2) | Revise | If the Administrator denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture’s Uniform Rules of Practice, 7 CFR part 1, subpart H. |
| 205.681 (c) | Revise | <i>Filing period.</i> An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered “filed” on the date received by the Administrator or by the State organic program. An adverse action will become final and nonappealable unless an appeal is timely filed. |

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| 205.681 (d)(1) | Revise | Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave., S.W., Room 2642, Stop 0268, Washington, D.C. 20250, or electronic transmission, NOPAppeals@ams.usda.gov. |
| 205.681 (d)(3) | Revise | All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper or made in accordance with applicable program regulations, policies, or procedures. |

AMS is proposing several changes to § 205.681 to revise and clarify appeal procedures. We propose revising the title of paragraph (a) from “Certification appeals” to “Adverse actions by certifying agents,” and the title of paragraph (b) from “Accreditation appeals” to “Adverse actions by the NOP Program Manager.” This is necessary because certifying agents and the NOP Program Manager may issue different types of adverse actions, and the respective appeal decisions will have different effects.

AMS proposes clarifying the process when the Administrator denies an appeal and upholds an adverse action. The current regulations, at §§ 205.681(a)(2) and (b)(2), state that the USDA will initiate a formal administrative proceeding (hearing) to finalize the action, i.e., suspend, revoke or deny certification.

AMS proposes changing “will” to “may” to reflect actual practice and to recognize that AMS may pursue the resolution of appeals through expedited, alternative means, such as settlement agreements, before initiating a formal administrative proceeding. In current practice, an appellant whose appeal is denied by the Administrator has the option to request or waive a hearing. If the appellant does not request a hearing, AMS does not initiate a formal administrative proceeding and the Administrator’s appeal decision is final and takes effect.⁴⁶ When an appellant requests a hearing, AMS and the appellant may

⁴⁶ This is described in NOP 4011.

enter into a settlement agreement prior to the hearing. This proposed revision provides flexibility to resolve appeals outside of the formal administrative process.

AMS also proposes revising current paragraph (b), “Accreditation appeals,” to address the scope of adverse actions issued by the NOP which may be appealed to the Administrator. This could include appeals of proposed suspensions or revocations of accreditation or certification, denials of accreditation, denials of reinstatement, or civil penalties.

AMS proposes clarifying the requirement for the appeal filing period in paragraph § 205.681(c). The wording, “noncompliance decision” is removed because that term is being removed or replaced throughout the Adverse Action Appeal Process section. In addition, we are proposing to replace the phrase, “A decision to deny, suspend, or revoke certification or accreditation will become final” with “An adverse action will become final” because the use of the term “adverse action” is broader and includes denials of reinstatement, cease and desist notices, and other actions that could affect certification.

Additionally, this proposed rule would update the address for filing appeals and provide an email address for submitting appeals electronically in § 205.681(d)(1). The address in the current regulation is outdated and does not provide an option for electronic submission, even though this occurs in practice.⁴⁷

Finally, this proposed rule would revise the term “adverse decision” to “adverse action” in § 205.681(d)(3) to be consistent with the use of the term “adverse action” throughout this section. This maintains the requirement that an appellant must submit a copy of the adverse action which they are contesting with their appeal.

⁴⁷ The AMS website has the current information for filing an appeal either by mail or electronically: <https://www.ams.usda.gov/services/enforcement/organic/appeals>.

16. Grower Group Operations.

| Section | Action | Proposed Text |
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| 205.2 | Add new term | <i>Grower group member.</i> A person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation. |
| 205.2 | Add new term | <i>Grower group operation.</i> A single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation. |
| 205.2 | Add new term | <i>Grower group production unit.</i> A defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops. |
| 205.2 | Add new term | <i>Internal control system.</i> An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer. |
| 205.201 (c) | Add | In addition to paragraph (a) of this section, a grower group operation’s organic system plan must describe its internal control system. The description of the internal control system must: (1) Define the organizational structure, roles, and responsibilities of all personnel; |

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| | <p>(2) Identify grower group production units and locations;</p> <p>(3) Define geographical proximity criteria for grower group members and grower group production units;</p> <p>(4) Describe characteristics of high-risk grower group members and grower group production units;</p> <p>(5) Describe shared production practices and inputs;</p> <p>(6) Describe the internal monitoring, surveillance, and auditing methods used to assess the compliance of all grower group members;</p> <p>(7) Describe the system of sanctions for noncompliant grower group members, including procedures to address noncompliances detected among grower group members, impose sanctions, and remove grower group members when warranted, and procedures for reporting noncompliances to the certifying agent;</p> <p>(8) Describe measures to protect against potential conflicts of interest;</p> <p>(9) Describe how training, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;</p> <p>(10) Have clear policies and procedures to verify the grower group operation's and grower group members' compliance with the USDA organic regulations; and</p> <p>(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.</p> |
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| <p>205.400 (g)</p> | <p>Add</p> | <p>In addition to paragraphs (a) through (f) of this section, a grower group operation must:</p> <ol style="list-style-type: none"> (1) Be a single producer organized as a person; (2) Sell, label, or represent only crops and/or wild crops as organic; (3) Use centralized processing, distribution, and marketing facilities and systems; (4) Be organized into grower group production units; (5) Ensure that all crops and/or wild crops sold, labeled, or represented as organic are from grower group members only; (6) Ensure that grower group members do not sell, label, or represent their crops and/or wild crops as organic outside of the grower group operation unless they are individually certified; (7) Report to the certifying agent on an annual basis the name and location of all grower group members and grower group production units, and the crops, wild crops, estimated yield, and size of production and harvesting areas of each grower group member and grower group production unit; (8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors, which must include mass-balance audits and reconciliation of each grower group member's and grower group production unit's production yield and group sales; (9) Document and report to the certifying agent the use of sanctions to address noncompliant grower group members, at least annually; and |
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| | | (10) Implement procedures to ensure all production and handling by the grower group operation is compliant with the USDA organic regulations and the Act, including recordkeeping requirements to ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution. |
| 205.403 (a)(2) | Redesignate | Redesignate as paragraph (a)(3) |
| 205.403 (a)(2) | Add | <p>Initial and annual on-site inspections of a grower group operation as defined in §205.2 must:</p> <p>(i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.</p> <p>(ii) Conduct witness audits of internal control system inspectors performing inspections of the grower group operation.</p> <p>(iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk according to criteria in 205.201(c)(4). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.</p> <p>(iv) Inspect each handling facility.</p> |

AMS proposes clarifying regulatory requirements for crop and/or wild crop production and handling operations with multiple member growers that are certified as a single producer. Operations with multiple grower and gatherer members can pose higher risks to traceability and organic integrity

because of their unique structure and composition, longer and more complex supply chains, and reliance upon internal quality control systems. Specific certification requirements are therefore needed to ensure adequate and consistent oversight of these types of operations and facilitate enforcement action.

Grower group structure and function.

In this proposed rule, operations with multiple growers organized and certified as a single crop and/or wild crop producer are referred to as grower group operations, also commonly known as grower groups. Individual growers, known as grower group members, grow or gather the same crops and/or wild crops in geographical proximity to one another using similar practices with centralized handling, processing, and marketing. Shared farming or gathering practices may include fertility management, pest control, acceptable inputs (including seeds), and post-harvest handling practices. There is one organic certificate for the grower group operation and the certification applies only to the grower group operation as a whole; individual members do not independently sell or market their own crops and/or wild crops using the grower group's organic certificate. There is one organic system plan for the grower group operation as a single producer using shared handling and marketing facilities, and a common recordkeeping system.

Grower group structure is different than traditional, individually certified organic operations. As such, they require special controls to ensure compliance with the USDA organic regulations. Central to the function of a grower group is an internal control system (ICS). An ICS consists of both personnel and procedure that act a grower group's internal governance and verification system. The ICS is described in the grower group operation's organic system plan, and ensures that grower group production and handling activities are compliant with the USDA organic regulations. The ICS is unique to grower groups; it acts as a third tier of enforcement and verification between the grower group members and the

certifying agent. The ICS is responsible for direct enforcement of the grower group and its members, including inspection of all grower group members. In grower group certification, the certifying agent's primary role is to assess and enforce the function of the ICS, not the individual members.

Unique certification challenges of grower groups.

Grower group operations present unique certification challenges relative to traditional, individually certified organic operations. Grower groups are inherently more complex because they are collectives of many members organized under a single organic certification. Grower groups commonly have thousands of members spread across a large area, and utilize centralized collection, handling, processing, and marketing. This complicates all aspects of enforcement, including inspection, product traceability, and mass-balance assessment. Most significantly, this complexity demands the use of an ICS as an additional tier of enforcement.

The current USDA organic regulations do not include specific provisions addressing the certification of grower groups. In particular, the regulations lack grower group eligibility criteria and requirements describing ICS function and organization. As a result, the NOP regularly observes inconsistent grower group certification practices during audits and certification appeals.

NOP staff accompanying certifying agents during witness audits frequently report that grower groups lack a functioning ICS. This often results in poorly trained ICS personnel that do not use effective sanctions policies to enforce against noncompliant members, fail to inspect all members, and do not complete mass-balance audits. The lack of specific requirements in the organic regulations inhibits the effective function of an ICS, which in turn threatens the integrity of products produced by grower group operations.

The NOP also often cites noncompliances to certifying agents who fail to adequately assess the structure of a grower group and the function of an ICS. In the absence of specific regulation, some certifying

agents struggle to define the acceptable limits of grower groups (geographical, numerical, and scope). This can result in too many members distributed over too large an area, complicating effective enforcement. A lack of specific requirements also makes it difficult for certifying agents to adequately assess the ICS's ability to enforce all members of a grower group operation. Some certifying agents also attempt to directly enforce grower group members, not the ICS, leading to inadequate oversight. There is a clear need for specific criteria grower groups must meet to qualify for organic certification, and practices certifying agents should use to inspect grower groups and assess compliance of an ICS. Describing these requirements in the organic regulations would allow for more effective oversight of grower groups and their organic products.

Authority and background.

The OFPA authorizes the certification of groups because it defines *person* as an "individual, groups of individuals, corporation, association, organization, cooperative, or other entity." (7 U.S.C. 6502). The OFPA also defines *handler* and *producer* as persons. Further, the OFPA provides for producers and handlers to seek certification (7 U.S.C. 6503(a)). Therefore, grower group operations are production and handling operations which are eligible for organic certification as a single producer.

Grower group certification was developed in the 1990s to reduce barriers for small-scale farms in developing countries entering the global organic market. Initially, organic farmer associations obtained group certification for organic coffee and cacao operations to export products to the United States and Europe. Presently, growers organized as grower group operations export many organic agricultural products to the United States, such as coffee, cocoa, bananas, tea, and spices. This method of certification gives small growers or gatherers organized into grower groups access to organic markets while expanding consumer choices. Grower group certification supports U.S. consumer demand for organic products that are not produced in the United States, such as coffee, cacao, and bananas.

The International Federation of Organic Agriculture Movements (IFOAM)⁴⁸ Organics International started to develop criteria for grower group certification in 1994, and in 2003 published its position on “Small Holder Group Certification for organic production and processing” to support the concept.⁴⁹ The criteria formed the basis for acceptance of grower group certification in the European Union and United States. Grower group operation certification is also utilized by other standards organizations, such as the International Accreditation Forum and GlobalG.A.P., to provide small-holder farming operations access to markets while ensuring the integrity of the supply chain.⁵⁰

On January 21, 2011, the NOP issued Policy Memorandum 11-10, “Certification of Grower Groups,”⁵¹ which specified how certifying agents could certify grower group operations, using 2002 and 2008 NOSB recommendations.⁵² The NOSB recommendations identified criteria for grower group operations to qualify for certification, and auditing practices and methodologies for certifying agents to inspect grower groups and assess the compliance of the internal control system.

This proposed rule codifies many of the requirements described in the 2002 and 2008 NOSB recommendations, and adds several requirements, including more detail about documentation requirements and inspection methods. AMS and certifying agents need clear standards for the certification of grower group operations as a single producer to effectively identify and enforce against noncompliant activities. Grower group operations present an elevated risk to organic integrity because

⁴⁸ <http://www.ifoam.bio/>

⁴⁹ https://www.ifoam-eu.org/sites/default/files/page/files/small_holder_group_certification_0.pdf

⁵⁰ <https://www.iaf.nu/>; https://www.globalgap.org/uk_en/

⁵¹ Policy Memorandum 11-10, Certification of Grower Groups. January 21, 2011:

<https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>

⁵² NOSB Recommendation: Criteria for Certification of Grower Groups. October 20, 2002:

<https://www.ams.usda.gov/sites/default/files/media/Rec%20Criteria%20for%20Certification%20of%20Grower%20Groups.pdf>

NOSB Recommendation: Certifying Operations with Multiple Production Units, Sites, and Facilities under the National Organic Program. November 19, 2008:

<https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Rec%20Certifying%20Operations%20with%20Multiple%20Sites.pdf>

of their structure (numerous growers conform to one organic system plan), longer and more complex supply chains, and use of an internal control system for oversight of grower group members, grower group production units, and handling facilities. Therefore, requirements for consistent certification practices for grower group operations are critical. AMS' proposed requirements for grower group operations will strengthen the oversight of organic supply chains by enabling certifying agents to more readily assess whether a grower group operation is complying with the USDA organic regulations and supporting enforcement actions when necessary.

Definitions.

AMS proposes adding four new terms to the USDA organic regulations to clarify the certification of a grower group operation as a single producer: *grower group operation*, *internal control system*, *grower group member*, and *grower group production unit*.

A *grower group operation* would be defined as a single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation. Therefore, the requirements for production and handling operations throughout the regulations would apply to a grower group operation as a single producer. AMS has not committed to a specific maximum distance for geographic proximity and is not proposing parameters for the physical extent of a grower group operation.

Certifying agents will need to determine if the locations of grower group members within a grower group production unit and grower group operation meet the "geographical proximity" requirement based on the conditions of an operation. Generally, this will vary depending on site-specific conditions and crops.

A *grower group member* would be defined as a person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation. The practices of each grower group

member would need to align with the organic system plan. The requirements for producers and handlers throughout the regulations would also apply to grower group members, although some requirements may be met collectively by the grower group operation, such as the organic production and handling system plan.

The proposed rule defines an *internal control system (ICS)* as an internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer. The ICS is a key component of a grower group operation certified as a single producer. The ICS verifies that the grower group operation is implementing the organic system plan, ensuring that growers or gatherers and handling facilities know how to comply. The ICS is responsible for the overall compliance of the grower group operation and its adherence to the organic system plan.

Finally, this rule proposes adding the term *grower group production unit*: a defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops. Adding this proposed term will clarify that each grower group production unit within a grower group operation requires an initial and annual inspection by the certifying agent, as required by § 205.403(a)(1) of the organic regulations. The term also clarifies that a grower group operation may produce and market more than one type of crop or wild crop, with each grower group production unit described and managed under a single organic system plan of a grower group operation.

Certification requirements for grower group operations.

This proposed rule would add provisions to the general requirements for certification (§ 205.400) which are specific to grower group operations. These criteria would clarify the eligibility requirements for

grower group operations. Entities that do not meet all criteria would need to be certified separately in order to sell, label, or market agricultural products certified to the USDA organic regulations.

The proposed rule would require that a grower group operation is a single producer legally organized as a person. The OFPA and the USDA organic regulations apply to a *person* as the basic regulatory unit. The organization of a grower group operation as a person clarifies that certification is granted to the grower group operation as a single producer, rather than individual grower members engaged in the activity of growing or gathering within the grower group operation.

Under the proposed rule, a grower group operation may sell, label, or represent only crops or wild crops as organic; any non-crop agricultural products (e.g., livestock or livestock products) would not be eligible for certification under the grower group operation. AMS acknowledges that many organic farming systems utilize integrated crop-livestock systems—especially operations in developing areas where grower group operation certification is more likely to occur. Therefore, the use of integrated or mixed crop-livestock systems is compatible with and would be permitted in certified grower group operations. However, the management of any non-crop agricultural products must not affect the integrity of the organic crops or wild crops produced and handled by the operation, and non-crop agricultural products must not be sold, labeled, or represented as organic by the grower group operation. Individual grower group members seeking to sell non-crop agricultural products would need their non-crop agricultural products certified independently from the grower group operation.

The proposed rule also specifies that grower group operations must use centralized processing, distribution, and marketing facilities and systems. In addition, AMS proposes a requirement that all crops and/or wild crops sold, labeled, or represented as organic by a grower group operation must be grown or gathered by grower group members only. A grower group operation may not buy crops and/or wild crops from non-member growers and sell, label, or represent them as organic using the grower

group certification. In turn, AMS also proposes that grower group members must not market crops and/or wild crops as organic outside of the grower group operation unless they are individually certified.

Finally, this proposed rule would add a requirement that grower group operations provide their certifying agent with the name and location of all grower group members, grower group production units, and the crops, wild crops, estimated yield, and growing/gathering areas (acreage) of each grower group member and grower group production unit. This information must be submitted at least annually as part of the organic system plan.

The internal control system.

This proposed rule would add an additional requirement for organic system plans for grower group operations. Specifically, an organic system plan (OSP) for a grower group operation would need to include a description of the internal control system (ICS) and how it verifies the operation's compliance with the USDA organic regulations. For all operations, the OSP describes shared farming and handling practices, inputs to be used (including seeds), monitoring practices and procedures, recordkeeping systems, and practices to prevent commingling and contact with prohibited substances (§ 205.201(a)).

The ICS serves as the grower group operation's internal governance and verification system to ensure that grower group operation production and handling activities at every level are implemented in accordance with the OSP and are compliant with the USDA organic regulations. A grower group operation's OSP must describe the function of the ICS. This description must:

- (1) Define the organizational structure, roles and responsibilities of all personnel;
- (2) Identify grower group production units and locations;
- (3) Define geographical proximity criteria for grower group members and grower group production units;

- (4) Describe characteristics of high-risk grower group members and grower group production units;
- (5) Describe shared production practices and inputs;
- (6) Describe the internal monitoring, surveillance, and auditing methods used to assess the compliance of all grower group members;
- (7) Describe the system of sanctions for noncompliant grower group members, including procedures to address noncompliances detected among grower group members, impose sanctions, and remove grower group members when warranted; and procedures for reporting noncompliances to the certifying agent;
- (8) Describe measures to protect against potential conflicts of interest;
- (9) Describe how training, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;
- (10) Have clear policies and procedures to verify the grower group operation's and grower group members' compliance with the USDA organic regulations; and
- (11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.

This proposed rule would set inspection and oversight requirements for the ICS. Specifically, the ICS would need to use qualified internal inspectors (ICS personnel) free of conflicts of interest to conduct independent and impartial inspections, at least annually. Consistent with the scope of an on-site inspection of any organic producer, the inspection of a grower group member should cover all areas of the organic system plan, including a review of all production or gathering areas managed by each grower group member, all post-harvest handling and storage facilities, inputs and resources used, and

records maintained by each grower group member and grower group production unit. ICS personnel must also conduct mass-balance audits of each grower group member, grower group production unit, and handling facility, including reconciliation of individual grower group member and grower group production unit production with the grower group operation's sales. ICS personnel conducting inspections should focus on critical organic control points such as buffer areas, condition of crops and/or wild crops, soil quality indicators, input and equipment use and storage areas, and level of understanding of organic requirements by the grower group members. AMS expects that qualified ICS personnel would be familiar with the local production practices, general organic production and handling practices, the USDA organic regulations, ICS procedures and regulations, and be fluent in the language(s) of the grower group members and the ICS.

Finally, AMS proposes a requirement that the ICS must develop and implement procedures to ensure that all production and handling activities of the grower group operation are compliant with the USDA organic regulations. This includes recordkeeping which demonstrates complete audit trails for all crops and/or wild crops sold, labeled, or represented as organic by the grower group operation, and a system to sanction noncompliant members, production units, and handling facilities of the grower group operation so that those members, production units, and handling facilities do not jeopardize the compliance status of the grower group operation.

On-site inspections by the certifying agent.

This proposed rule would establish requirements for how certifying agents must conduct annual on-site inspections of grower group operations. The certifying agent would need to inspect the ICS, review internal inspections conducted by the ICS, and observe ICS personnel conducting inspections. Certifying agents would need to inspect each handling facility and inspect at least 1.4 times the square root of the total number of grower group members. This number must include all high-risk members (determined

according to the criteria in proposed § 205.400(g)(8)), and at least one grower member in each grower group production unit (as defined in § 205.2), to ensure all grower group production units are inspected.

Inspections should include a full inspection of the growing or gathering areas and records of the grower group members selected. Selection of members should include all high-risk members; however, the certifying agent should also select members from across the risk spectrum—including lower-risk members. This may require a sample size larger than the minimum required by the proposed regulation (i.e., more than 1.4 times the square root of the number of grower group members). As a best practice, after all risk-based and other inspection selection criteria are satisfied, certifying agents should randomly select the remaining member inspections so that different lower-risk grower group members are inspected each year.

The square root sampling methodology was formalized for use by agricultural regulatory inspectors by the Association of Official Agricultural Chemists (AOAC) in 1927.⁵³ The formula used was the square root (Sqrt) of the lot size (N) + 1. The 1.4 multiplier aligns with the highest minimum sampling number under the IFOAM accreditation system and therefore provides a common minimum sampling number for all grower group operations around the world. All numbers must be rounded up to the next whole number (e.g., 50 members = 10 inspections, 100 members = 14 inspections, 500 members = 32 inspections, and 1000 members = 45 inspections).

Risk-based inspections rely upon certifying agents having policies and procedures to determine the risk factors associated with grower group operations. The certifying agent should apply the risk assessment procedures to determine and instruct the inspector on which grower group members to inspect. When

⁵³ Blanck, F.C. (1927). "Report of the Committee on Sampling," J. Assoc. Official Agricultural Chemists, 10, 92–98. The square root sampling scheme was developed in the 1920s as a sampling scheme for agricultural regulatory inspectors.

assessing the risks of the grower group operation to determine which grower group members to inspect, the certifying agent should consider:

- Noncompliance history;
- The criteria used to designate a collection of grower group members as a single grower group production unit;
- Application of prohibited materials adjacent to member fields;
- Split or parallel operations (i.e., they are also producing nonorganic crops and/or wild crops);
- Integrated crop-livestock systems;
- Grower group members with incomes greater than \$5000 USD per year;
- The procurement, availability and distribution of inputs and resources to members;
- The prevalence of nonorganic production of similar crops in the region;
- Geographic proximity of grower group members and grower group production units;
- Post-harvest handling practices designed to prevent comingling and contact with prohibited substances;
- New entrants to the grower group operation;
- Size of grower group member's production or gathering areas; and
- Significant expansion of a grower group member's production area.

As a best practice, the inspection of the ICS should also include: document review; auditing of production and sales/distribution records; reconciliation of product inventory; review of procurement and distribution of inputs; review of the inspections conducted by the ICS; review of ICS personnel

qualifications; witness audits to observe ICS inspectors; review of noncompliance actions for grower group members; examination of organic control points and high-risk areas; interviews with managers responsible for the OSP, governance of the ICS, and grower group members and individuals overseen by the ICS; and review of training provided to ICS staff and grower group members.

Request for comment.

AMS seeks public comment regarding the certification of grower group operations, including answers to the following questions:

1. Should there be limits on gross sales or field sizes of individual grower group members? If yes, please describe these limits.
2. Should there be a limit on the maximum number of members allowed in a grower group operation or in a grower group production unit? If yes, please describe these limits.
3. Should there be a limit to the geographical distribution of members? This includes limits to the maximum geographical proximity or distance between grower group members, grower group production or gathering areas, or grower group production units within a single grower group operation. If yes, please describe these limits.

17. Calculating the Percentage of Organically Produced Ingredients.

| Section | Action | Proposed Text |
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| 205.302 (a)(1) | Revise | Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of all ingredients. |

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| 205.302 (a)(2) | Revise | Dividing the fluid volume of all organic ingredients (excluding water and salt) at formulation by the fluid volume of all ingredients (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of the ingredients and all ingredients. |
| 205.302 (a)(3) | Revise | For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid organic ingredients and the weight of the liquid organic ingredients (excluding water and salt) at formulation by the total weight (excluding water and salt) of all ingredients. |

While most of this proposed rule focuses on certification and compliance provisions, clarification of standards is also a critical element of organic integrity. To ensure cross-industry consistency in the certification of multi-ingredient processed products, AMS proposes revising § 205.302, which describes how to calculate the organic content of multi-ingredient products. This calculation is performed by certifying agents to classify products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” The proposed revisions would streamline calculations and ensure consistent enforcement of the USDA organic regulations.

The USDA organic regulations (§ 205.302(a)) describe how to measure or quantify the organic content in a multi-ingredient product. To calculate organic content, the weight or volume of the organic ingredients is divided by the total weight or volume of the product. Water and salt added as ingredients are excluded from the calculation.

Section 205.302(a) currently refers to “finished product” and includes the phrase “total weight of the finished product.” This terminology has created confusion, unnecessary paperwork burden, and

enforcement challenges for certifying agents and organic handlers, as it is not clear if “finished product” is meant to specifically describe the product after processing or if it simply means the sum of all ingredients at the time of formulation. The proposed changes would clarify that the calculation of organic content is to be made at the time of formulation, regardless of whether processing (currently defined at § 205.2) occurs after formulation.

When ingredients are combined and subsequently processed (e.g., cooked, baked, dehydrated, freeze dried), the post-processing weight of all ingredients can be less than the weight of all ingredients at the time of formulation due to loss of water from ingredients (i.e., not added water). Calculating organic content based on the weight of ingredients at formulation divided by the weight of the finished product (after processing) could result in a calculation of organic content in excess of 100 percent, which is not possible. The same can be true of calculations based on fluid volume, as allowed at § 205.302(a)(2). AMS is proposing these changes to ensure accurate and consistent calculation of organic content by requiring calculation at the time of formulation.

In December 2016, AMS published draft guidance⁵⁴ on the topic of calculating organic content to respond to an April 2013 NOSB recommendation,⁵⁵ inform the public of AMS’ current thinking, and to invite public comment.⁵⁶ The calculation of organic content described in this proposed rule is consistent with NOP 5037. AMS received no objections via public comments to calculating organic content based

⁵⁴ The draft guidance and comments can be viewed at <https://www.regulations.gov/document?D=AMS-NOP-16-0085-0001> and in the NOP Program Handbook:

<https://www.ams.usda.gov/sites/default/files/media/NOP5037DraftGuidancePercentCalculations.pdf>

⁵⁵ NOSB Recommendation, Calculating Percentage Organic in Multi-Ingredient Products, April 11, 2013:

<https://www.ams.usda.gov/sites/default/files/media/NOP%20CACC%20Final%20Rec%20Calculating%20Percentage.pdf>

⁵⁶ Notice of Draft Guidance for Calculating the Percentage of Organic Ingredients in Multi-Ingredient Products, December 6, 2016: <https://www.federalregister.gov/documents/2016/12/06/2016-29173/national-organic-program-notice-of-draft-guidance-for-calculating-the-percentage-of-organic>

on the weight of ingredients at the time of formulation. The proposed changes are consistent with the NOSB recommendation to amend § 205.302(a)(1)–(3).

18. Supply Chain Traceability and Organic Fraud Prevention.

| Section | Action | Proposed Text |
|---------------|--------------|---|
| 205.2 | Add new term | <i>Organic fraud.</i> Intentional deception for illicit economic gain, where nonorganic products are labeled, sold, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” |
| 205.103(b)(2) | Revise | Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, including identification in records of products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable; |
| 205.103(b)(3) | Redesignate | Redesignate as paragraph (b)(4) |
| 205.103(b)(4) | Redesignate | Redesignate as paragraph (b)(5) |
| 205.103(b)(3) | Add | Include audit trail documentation for product handled or produced by the certified operation; |
| 205.201(a)(3) | Revise | A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status |

| | | |
|-------------------------|--------|---|
| | | of products received, and to prevent organic fraud, as appropriate to the certified operation's activities; |
| 205.501(a)(10) | Revise | Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except: |
| 205.501 (a)(10)(i) | Add | For information that must be made available to any member of the public, as provided for in §205.504(b)(5); |
| 205.501 (a)(10)(ii) | Add | For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and |
| 205.501 (a)(10)(iii) | Add | If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange. |

| | | |
|----------------|-------------|--|
| 205.501(a)(13) | Revise | Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500. Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations; |
| 205.501(a)(21) | Redesignate | Redesignate as paragraph (a)(23) |
| 205.501(a)(21) | Add | Annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s). |
| 205.504(b)(4) | Revise | A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10); |
| 205.504(b)(7) | Add | A copy of the criteria to identify high-risk operations and products; and procedures to conduct risk-based supply chain audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator. |

This proposed rule addresses many different sections of the USDA organic regulations to enhance oversight, protect the integrity of the organic label, and assure consumers that organic products meet a consistent standard (see 7 U.S.C. 6501). Perhaps the most critical component, and one which affects all aspects of this proposed rule, is supply chain traceability from source to consumer (i.e., “farm to table”).

Because organic products are credence goods, the organic system relies upon on trust between entities in organic supply chains.⁵⁷ Therefore, traceability and verification are essential to the function of a healthy organic market. This is especially true today, with organic supply chains growing longer and more complex. Organic products and ingredients are often handled by dozens of operations, including many uncertified entities, on their way to the consumer. This may expose organic products to greater risk—including opportunities for mishandling and fraud.

Underlying the value of the USDA organic label is an assumption that organic products are not compromised at any step in the supply chain. To verify the source at any step in the supply chain would require complete visibility of the entire supply chain. However, certified operations and certifying agents do not generally have access to this information. Organic certification is typically verified back to the last certified organic operation in the supply chain. In complex supply chains, where products and ingredients are often handled multiple times, information about a product's source may be difficult to verify, especially where source information/origin is intentionally obscured by some parties in the supply chain to protect confidential business information.

Many parts of this proposed rule have already discussed ways to address and improve supply chain traceability, largely through indirect methods. These include:

- Clarifying who needs to be certified, including previously excluded operations (§ 205.101);
- NOP Import Certificates (§ 205.273);
- Clear identification of organic status and lot numbers on nonretail containers (§ 205.307);
- Trace-back audits and mass-balance audits during on-site inspections (§ 205.403);

⁵⁷ A credence good is something with value or qualities that cannot be easily determined by the consumer before, or even after, purchase.

- Specific qualification and training standards for organic inspectors and certification review personnel (§ 205.501); and
- Additional reporting of information about certified organic operations in the Organic INTEGRITY Database (§ 205.501).

These proposed amendments will improve the industry's ability to perform trace-back audits (and therefore ensure organic integrity). However, AMS also proposes several additional amendments to more directly address traceability. AMS expects both certified operations and accredited certifying agents to share responsibility for product traceability. The following proposed amendments will clarify expectations for trace-back audits and product verification:

- Organic operations must maintain audit trail documentation to facilitate supply chain traceability, including identification of products as organic on documents (§ 205.103);
- Organic operations must describe in their organic system plan the monitoring practices and procedures used to prevent organic fraud and verify suppliers and organic product status (§ 205.201);
- Certifying agents must share information with other certifying agents to verify supply chains and conduct investigations (§ 205.501 and § 205.504); and
- Certifying agents must have procedures for (1) identifying high-risk operations and agricultural products to conduct risk-based supply chain audits and for (2) reporting credible evidence of organic fraud to the USDA (§ 205.504).

All successful systems of traceability include three common elements: (1) traceability within a single operation; (2) traceability one step forward and one step back from an operation in a supply chain; and (3) bidirectional traceability along an entire supply chain, source to consumer, by a third party. The

proposed rule supports traceability by clarifying who is responsible for each element: certified organic operations are responsible for traceability within their operation, back to their suppliers, and forward to their customers; certifying agents are responsible for tracing products along a supply chain back to their origin, and assessing the traceability efforts of operations.

This proposed rule would also add the new term *organic fraud*, defined as intentional deception for illicit economic gain, where nonorganic products are labeled, sold, or represented as organic. AMS is including *organic fraud* to clarify actions this proposed rule is intended to reduce.

Certified operations.

This proposed rule would require certified operations to maintain an audit trail for products that they produce, receive, and/or handle. In addition, certified operations would be required to describe and implement a plan to: (1) detect and prevent organic fraud in any organic product that they produce, receive and/or handle; and (2) identify, verify, and document their suppliers. These changes are proposed to ensure that certified operations keep documentation that is sufficient to verify the source, ownership history, and movement of organic products (see *audit trail* definition in § 205.2) and to take measures to verify that the organic product they receive is legitimately represented as organic. These proposed amendments are intended to support AMS' goal of full supply chain traceability.

Although all entities in a supply chain are responsible for organic integrity, these proposed amendments do not intend to shift liability from one operation to another. An operation that encounters fraud committed by a supplier may not be liable for that fraud, provided that the operation, while following adequate detection and prevention procedures, did not detect the fraud or deliberately continue to represent a fraudulent product as organic.

AMS proposes amending the recordkeeping requirements at § 205.103(b)(2) to clarify that records maintained by certified operations must identify agricultural products as "100% organic," "organic," or

“made with organic (specified ingredients or food group(s)), as applicable. This proposed amendment is needed to ensure that a product’s organic status is clear throughout the audit trail. AMS anticipates that most organic operations already maintain records that meet this requirement, because product-specific records are generally a good business practice and are necessary to ensure that records are auditable. This proposed action is not intended to limit an operation’s flexibility to use alternative abbreviations or indicators of a product’s organic status on nonretail labels or other recordkeeping. This may include use of abbreviations such as “MWO” (i.e., “made with organic”), ORG (i.e., “organic”), color designations, or other tracking systems that are used internally within a certified organic operation to denote a product’s organic status. Retail labels must continue to comply with the requirements at Subpart D—Labels, Labeling, and Market Information.

The USDA organic regulations currently require certified operations to maintain records that fully disclose all activities and transactions in sufficient detail to be readily understood and audited (§ 205.103(b)(2)). The regulations also define the term *audit trail* but do not use this term within the regulations. By inserting *audit trail* into the recordkeeping requirements, this proposed rule clarifies the type and extent of records that a certified operation needs to maintain.

Lastly, AMS proposes that certified operations must describe and implement practices to verify the organic status of suppliers and products in their supply chain and to prevent organic fraud. Such procedures and practices are often referred to as “fraud prevention plans.” Under the current organic regulations, certified operations are already required to describe in their organic system plan (OSP) “monitoring practices and procedures” to “verify that the [OSP] is effectively implemented” (7 CFR 205.201(a)(3)). This proposed rule would explicitly state that an OSP must describe how existing monitoring and verification practices are used to verify suppliers and products and detect and prevent fraud. This will ensure that certified operations use appropriate and effective means to prevent organic

fraud, help maintain organic integrity as products travel along a supply chain, and help certifying agents to assess the effectiveness of certified operations' anti-fraud efforts.

Traceability is a shared responsibility across all entities in a supply chain, but the use of effective procedures at the operation level is especially critical. Certified operations have first-hand knowledge of their supply chains and are therefore better able to detect and prevent fraud than a third party.

Operation-level traceability is also key to full supply chain trace backs; a gap or deficiency of information at any step may prevent a full trace-back. As part of a larger integrated system of traceability, fraud prevention plans and procedures allow certified operations to verify that the products in their supply chains are compliant with the USDA organic regulations, and have been handled only by certified organic operations (see 7 U.S.C. 6506(a)(1)).

The scope and complexity of a fraud prevention plan will depend on the type of operation. For example, AMS does not expect a producer who does not handle products produced by another operation to develop supplier verification practices, beyond verifying that any purchased inputs meet organic requirements. In contrast, a processor that receives many organic ingredients from numerous suppliers would need to augment their organic system plan to describe practices to minimize organic fraud risks in lengthy supply chains.

In general, AMS expects that a robust plan for supply chain oversight and organic fraud prevention would include:

- A map or inventory of the operation's supply chain which identifies suppliers;
- Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;
- A vulnerability assessment to identify weaknesses in the operation's practices and supply chain;

- Practices for verifying the organic status of any product they use;
 - A process to verify suppliers and minimize supplier risk to organic integrity;
 - Mitigation measures to correct vulnerabilities and minimize risks;
 - Monitoring practices and verification tools to assess the effectiveness of mitigation measures;
- and
- A process for reporting suspected organic fraud to certifying agents and the NOP.

AMS is aware of private initiatives in the organic sector to develop best practices for organic operations to detect and prevent organic fraud.⁵⁸ We predict that these best practices will provide organic operations with practical tools to assess, monitor, and mitigate organic fraud risks within their organic supply chains.

Certifying agents.

To facilitate trace-back audits, investigations, and verification, AMS proposes amending the organic regulations to clarify that certifying agents must share information with one another for the purposes of certification and enforcement. This change would not affect the existing requirement that certifying agents maintain strict confidentiality with respect to its clients and not disclose business-related information to third parties that are not involved in the regulation or certification of operations, as required by the OFPA (7 U.S.C. 6515(f)). For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to investigate an operation to determine compliance with the USDA organic regulations. Certifying agents must share information during any

⁵⁸ A good example is the Organic Trade Association's "Organic Fraud Prevention Solutions" project: <https://ota.com/OrganicFraudPrevention>

investigation to make a compliance determination, including assessment of applications for certification, noncompliance investigations, and suspension/revocation of certification.

If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, and/or investigate that operation, certifying agents are to exchange that information for the purposes of enforcing the Act; however, the information in question still retains its proprietary character even after it is exchanged, and all certifying agents involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange. AMS expects that this change will support verification of the organic integrity of product as it moves through the supply chain while maintaining confidentiality of information outside of the required parties.

Finally, AMS is proposing a requirement that certifying agents develop and maintain procedures and criteria for identifying which operations and products among those it certifies are at high risk for organic fraud. Identifying organic fraud is a key role of certifying agents, and the OFPA requires that certifying agents fully implement organic law and regulations (7 U.S.C. 6515(a)) and that appropriate and adequate enforcement procedures be employed (7 U.S.C. 6506(a)(7)). The proposed rule would require that certifying agents conduct supply chain audits on a sample of operations and products which it determines to be high-risk.

AMS expects that certifying agents would need to develop risk-assessment criteria by identifying the characteristics of operations, agricultural products, and supply chains which are vulnerable to organic fraud or unintentional mishandling. These could include: products for which there is a relatively high demand, low supply, and high organic premium; products which may be subject to treatment with prohibited substances after production; unpackaged products which are not enclosed in final retail containers; products with multiple handlers in the supply chain; products from a supplier that lacks a record of compliance; a sudden increase in the available supply of an organic product or commodity;

operations which change certifying agents frequently; and operations which are certified by more than one certifying agent. A certifying agent could rank or weight these vulnerabilities and determine that the presence of a certain number of these factors equates to high risk, while also considering the total volume of product produced or handled by the operation. The vulnerability criteria would change based on market trends, enforcement actions, and changing practices within the organic industry; certifying agents would need to ensure that the procedures and criteria remain applicable and accurate. Because a product or operation's level of risk may change over time, it is important that certifying agents conduct supply chain audits of lower-risk products (in addition to supply chain audits of high-risk products) to support proactive fraud prevention and detection.

The proposed rule does not establish a specific metric for the number of annual supply chain audits that a certifying agent needs to conduct, because the quantity and types of high-risk operations will vary by certifying agent. The supply chain audits should adequately assess high-risk areas. AMS recognizes that certifying agents' ability to conduct supply chain audits depends on the implementation of other requirements in this proposed rule, for example, certification of previously excluded operations (e.g., brokers, traders, importers, and other trade facilitators) and the mandatory use of NOP Import Certificates. Therefore, we expect that certifying agents will increase the number of supply chain audits they conduct annually as this rule is fully implemented and use of technology for supply chain traceability is more widely adopted among certified operations. By requiring written procedures, AMS expects that certifying agents will make better use of information sharing with other certifying agents to assess organic integrity. As a requirement of accreditation, certifying agents' processes and procedures would be reviewed during regular accreditation audits.

A final proposed change requires that certifying agents report credible evidence of organic fraud to AMS. This requirement is expected to help AMS take action against bad actors more quickly and is required by the OFPA at 7 U.S.C. 6519(c)(4). Certifying agents will need to develop procedures for

evaluating evidence to determine if evidence is credible and develop procedures for reporting suspected organic fraud. USDA will review these procedures and examine specific cases during regular accreditation audits.

Electronic supply chain traceability systems.

In addition to the amendments proposed above, AMS will continue to work toward its goal of full supply chain traceability and fully verifiable organic products to support and enforce the OFPA requirements (see 7 U.S.C. 6506(a)(1)). Looking forward, AMS expects electronic tracking systems, including digital ledger technology (DLT), will play an essential role in supply chain traceability. DLT can provide secure, verifiable, transparent, and near-instantaneous tracking at the item level in complex supply chains. Critically, DLT can also protect confidential business information and trade secret information by automatically restricting sensitive information to authorized entities. The utility of electronic tracking in food systems has been demonstrated by several successful, high-profile pilot programs.⁵⁹ AMS expects interest within the community to grow as stakeholders realize the potential of this technology.

Electronic supply chain tracking systems have the potential to address many of the issues discussed in this proposed rule. However, they are often based on emergent technology; additional time and development is required before a universal electronic system could feasibly be implemented across the organic industry. Barriers to widespread adoption of an electronic tracking system include inadequate access to technology and connectivity in rural areas, acceptance of universal electronic standards

⁵⁹ Walmart partnered with IBM to create blockchain traceability systems for mangos and pork:
<https://jbba.scholasticahq.com/article/3712-food-traceability-on-blockchain-walmart-s-pork-and-mango-pilots-with-ibm>

Nestle is testing a public blockchain for milk supply chains:
<https://www.forbes.com/sites/benjaminpirus/2019/07/09/nestle-tests-public-blockchain-for-dairy-supply-chain/#7a89053b5f0f>

Bumble Bee Foods partnered with SAP to trace yellowfin tuna with blockchain technology:
<https://news.sap.com/2019/03/bumble-bee-foods-sap-create-blockchain-track-fish/>

(interoperability), and distribution of costs. Despite these barriers, AMS encourages the development and use of electronic tracking systems. We anticipate that electronic tracking technologies will allow AMS to achieve its goal of full supply chain traceability, and foresee incorporation of electronic tracking systems into future enforcement strategies.

Request for comment.

AMS seeks comment from the public and organic stakeholders regarding the proposed amendments to address supply chain traceability and organic fraud, including answers to the following questions:

1. Does the proposed definition of *organic fraud* encompass the types of fraudulent activities you witness in the organic supply chain?
2. Should certifying agents be required to perform a minimum number of trace-back audits each year?
3. Should more specific fraud prevention criteria be included in the regulation?

19. Technical Corrections.

| Section | Current Text | Action | Proposed Text |
|-------------------|---|--------|---|
| 205.301 (f)(2) | Be produced using ionizing radiation, pursuant to §205.105(f); | Revise | Be processed using ionizing radiation, pursuant to §205.105(f); |
| 205.301 (f)(3) | Be processed using sewage sludge, pursuant to §205.105(g); | Revise | Be produced using sewage sludge, pursuant to §205.105(g); |
| 205.400 (b) | Establish, implement, and update annually an organic production or handling system plan that is | Revise | Establish, implement, and update annually an organic production or handling system plan that is |

| | | | |
|-------------|--|--------|--|
| | submitted to an accredited certifying agent as provided for in §205.200; | | submitted to an accredited certifying agent as provided for in §205.201; |
| 205.401 (a) | An organic production or handling system plan, as required in §205.200; | Revise | An organic production or handling system plan, as required in §205.201; |

AMS proposes amending § 205.301 to correct a technical error in the description of the prohibition of ionizing radiation and sewage sludge. A previous technical correction (80 FR 6429) contained an error in the language used to describe the prohibition on ionizing radiation and sewage sludge. The terms “produced” and “processed” are erroneously used to describe the use of ionizing radiation and sewage sludge, respectively, in the current regulatory text. This proposed action would correct the language at paragraphs (f)(2) and (f)(3) to clarify that all products labeled as “100% organic” or “organic” and all ingredients identified as organic in the ingredient statement of any product must not be processed using ionizing radiation or produced using sewage sludge.

AMS also proposes amending §§ 205.400(b) and 205.401(a), to correct the reference to organic system plans (§ 205.201), which is incorrectly cited in the current organic regulation.

20. Additional amendments considered but not included in this Proposed Rule.

Packaged Product Labeling.

If implemented, the proposed amendments to §§ 205.2 and 205.100–101 would require the certification of operations that sell or represent organic products. This would include operations in “private-label” relationships; both the operation that produced/processed the organic product (the “contract manufacturer”), and the operation that sells the product under its own label (the “brand name” or “distributor”), would require certification under this proposed rule. However, the current regulations, at

§§ 205.303–304, do not clearly specify which certified operation and certifying agent must be listed on the label of a private-label organic product. This causes inconsistent interpretation of the regulation and variable labeling practices. Part of the challenge is variation in the terms used to describe the operations involved in the manufacturing, labeling, and distribution of packaged products. AMS considered amending the labeling requirements for packaged products to better align with the proposed updates to §§ 205.100–101 and clarify who is responsible for the compliance of private-labeled organic products. Amending the labeling requirements of §§ 205.303–304 may also improve traceability and transparency, and ease verification of organic status. Although AMS has chosen not to include packaged product labeling amendments in this proposed rule, we seek public comment on the following questions regarding private-labeled organic products. Please explain how your answers could improve organic integrity and transparency, and facilitate the verification and traceability of organic products.

1. For private-label packaged products, which certified operation(s) should be listed on the retail label (brand name/distributor, contract manufacturer, or both)?
2. Which certifying agent(s) should be listed?
3. Should the certifying agent listed on a label always be the certifying agent of the certified operation listed on the label (i.e., should the certifying agent match the operation)?
4. Should listing contract manufacturers on labels be mandatory? Should it be optional?
5. What terminology should be used to describe private-labeled organic products?
6. What terminology should be used to describe the operations involved in packaged product or private labeling (e.g., brand name manufacturer, contract manufacturer, and distributor)?

Expiration of Certification.

In this proposed rule, AMS proposes requiring expiration dates on organic certificates (without the expiration date affecting the status of an operation's certification). AMS also considered proposing expiration of certification, in which an operation's certification would expire on an annual basis if the operation did not submit fees and update its certificate of organic operation. Expiration of certification would fundamentally shift the current process of certification, which allows organic certification to continue until certification is surrendered, suspended, or revoked. Although AMS has decided not to include annual expiration of certification in this proposed rule, AMS seeks comment on the following questions:

1. How might annual expiration of certification improve organic integrity?
2. What are the limitations of requiring expiration of certification?
3. What minimum requirements must be met before renewing certification?
4. Could an operation with unresolved adverse actions renew certification?
5. Would a grace period be appropriate for operations that failed to renew by the expiration date?
If so, what length grace period would be appropriate?
6. What process should exist for an operation to regain organic certification should it allow its certification to expire?
7. Should certifying agents notify certified operations of their upcoming expiration of certification?

Fees to AMS and Oversight of Certifying Agents' Fees

Since the final rule establishing the National Organic Program (NOP) was first published in the Federal Register in 2000, the production, marketing, and sale of organic foods has undergone tremendous

growth. The proposed rule is intended to strengthen enforcement of the USDA organic regulations through many actions, including strengthened certification processes and coverage of importers, brokers, and traders of organic products. Section 2107 (a)(10) of the Act allows the NOP to include fees from producers, certifying agents and handlers. AMS periodically reviews the fees for accreditation and accreditation services to ensure that they are in compliance with Circular A-25.⁶⁰ AMS also oversees the NOP fees that certifying agents and others charge for their services. AMS is seeking public comments in this proposed rule on how fees in the NOP could strengthen testing and enforcement across all stakeholders to ensure that the NOP keeps pace with the rapid growth and better serves the industry.

⁶⁰ <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf>

IV. Statutory and Regulatory Authority

A. Summary of Economic Analyses

This rule is regulatory meets the definition of a significant regulatory action under Executive Order 12866, therefore triggering the requirements set forth in Executive Order 13771. The Executive Order 13771 value is \$7.3 million, discounted at 7 percent, annualized over a 15-year time horizon. The impact of benefits are likely to result in a rule that would have an annual effect of \$100 million or more on the economy. See Office of Management and Budget's (OMB) Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).⁶¹

Executive Orders 12866, 13563, and 13771 control regulatory review.^{62,63} Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.⁶⁴ Executive Order 13771 directs Agencies to identify at least two existing regulations to be repealed for every new regulation unless prohibited by law. The total incremental cost of all regulations issued in a given fiscal year must have costs within the amount of

⁶¹ Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs': https://www.whitehouse.gov/sites/whitehouse.gov/files/briefing-room/presidential-actions/related-omb-material/eo_interim_guidance_reducing_regulations_controlling_regulatory_costs.pdf

⁶² Executive Order 12866, Regulatory Planning and Review, September 30, 1993: https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

⁶³ Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, January 30, 2017: <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/>.

⁶⁴ <https://www.federalregister.gov/executive-order/13563>

incremental costs allowed by the Director of OMB, unless otherwise required by law or approved in writing by the Director of OMB.

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market.

AMS proposes amending several portions of the USDA organic regulations (7 CFR Part 205) to strengthen oversight and enforcement of the production, handling, sale, and marketing of organic agricultural products in the United States. Parts of the current regulations lack requirements for traceability and oversight throughout the organic supply chain. This creates vulnerabilities for fraud in the organic market and inconsistent certification practices to mitigate that risk. The proposed amendments would reduce the types of operations exempt from organic certification (e.g., brokers, traders, importers, and exporters); require the mandatory use of NOP Import Certificates for all shipments of organic products imported to the United States; and clarify recordkeeping and fraud prevention procedures. Additional amendments would further clarify organic labeling, accreditation, and certification requirements. Collectively, these proposed amendments would address gaps in the organic standards to deter organic fraud and create a level playing field for farms and businesses. This will assure consumers and stakeholders that organic products meet a robust, consistent standard, and reinforce the value of the organic label.

The new and modified organic standards in this proposed rule would affect: certifying agents; certified operations (farms, processors, and handlers); and operations that are currently excluded or exempt from organic certification (e.g., brokers, traders, importers, exporters).

The costs associated with this proposed rule are primarily due to new or additional reporting and recordkeeping (paperwork) activities. In addition, there is some cost associated with currently excluded and exempt operations becoming certified to handle organic products. AMS estimated the benefits of this proposed rule by quantifying the organic fraud that will be prevented by implementation of the proposed rule; the potential benefits are expected to outweigh the estimated costs. Total costs and benefits of the proposed rule are summarized in Table 1 in the Executive Summary of this document.

AMS also performed additional analysis to determine the proposed rule's impact to small businesses. This analysis revealed that small businesses producing, selling, handling, and marketing organic products would not be adversely affected by the amendments proposed in this rule. AMS expects that most of the entities affected by this proposed rule are small businesses as defined by Small Business Administration criteria. For each category of affected entity (certifying agents, certified operations, and exempt or excluded operations that need to become certified), AMS estimates that the costs of the proposed rule for each business type would be less than 1 percent of the annual revenue.

A full economic analysis of this proposed rule is available at <https://www.regulations.gov/>. AMS invites the public to comment on the economic analysis. You may submit comments on this proposed rule and economic analysis to the Federal eRulemaking Portal at <https://www.regulations.gov/>. You can access this proposed rule, economic analysis, and instructions for submitting public comments by searching for document number AMS-NOP-17-0065.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect. To prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private

persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under §§ 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

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

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

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection totaling 275,417 hours for the reporting and

recordkeeping requirements contained in this proposed rule. OMB previously approved information collection requirements associated with the NOP and assigned OMB control number 0581-0191. AMS intends to merge this new information collection, upon OMB approval, into the approved 0581-0191 collection. Below, AMS has described and estimated the annual burden, i.e., the amount of time and cost of labor, for entities to prepare and maintain information to participate in this proposed voluntary labeling program. The Organic Foods Production Act of 1990 (OFPA), as amended, provides authority for this action.⁶⁵

Title: National Organic Program.

OMB Control Number: 0581-NEW.

Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection.

Abstract

Information collection and recordkeeping are necessary to implement reporting and recordkeeping necessitated by amendments to §§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273, 205.300–205.302, 205.307, 205.310, 205.400, 205.403–205.404, 205.406, 205.500–501, 205.504, 205.511, 205.660–205.663, 205.665, 205.680, and 205.681 of the USDA organic regulations to protect organic product integrity and build consumer and industry trust in the USDA organic label. The proposed rule would strengthen organic control systems, improve organic import oversight, clarify organic certification

⁶⁵ The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this proposed rule. This document is available at: <https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim>

standards, and enhance farm to market traceability, using a risk-based approach to oversight to assure consumers that organically produced products meet a consistent standard.

This proposed rule would amend several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen the NOP's ability to oversee and enforce the production, handling, marketing, and sale of organic agricultural products as established by the OFPA. This proposed rule would improve organic integrity throughout the organic supply chain and benefit stakeholders at all levels of the organic industry. The proposed amendments would close gaps in the current regulations to build consistent certification practices, deter organic fraud, and improve transparency and product traceability. The NOP identified the need for many of the proposed amendments as part of its direct experience in administering this program, particularly via complaint investigation and audits of certifying agents. Other proposed amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018;⁶⁶ the recommendations of a 2017 Office of Inspector General audit;⁶⁷ the recommendations of the federal advisory committee to the NOP, the National Organic Standards Board (NOSB); and industry stakeholder feedback.

This proposed rule will strengthen enforcement with amendments to the USDA organic regulations and will modify the reporting and recordkeeping burdens as summarized below.

1. Reduces the types of uncertified handling operations in the organic supply chain that operate without USDA oversight.⁶⁸ The proposed amendments would require certification of operations that facilitate the sale or trade of organic products, including but not limited to, brokers,

⁶⁶ The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the "2018 farm bill," is available at <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>. Organic certification is discussed in Title X, Section 10104.

⁶⁷ The National Organic Program International Trade Arrangements and Agreements Audit Report 01601-0001-21, September 2017: <https://www.usda.gov/oig/webdocs/01601-0001-21.pdf>

⁶⁸ Mandated by the Agriculture Improvement Act of 2018. See section 10104(a).

importers, and traders. These handlers would be required to obtain organic certification by developing an organic system plan (OSP) to describe the practices and procedures used in their operations. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Because traders and brokers do not farm or manufacture organic products, the OSPs for traders and brokers would address fewer sections of the current rule than OSPs for operations that farm or manufacture organic products. Therefore, reporting impacts for traders and brokers are estimated at 40 hours for each uncertified handling operation to prepare its initial OSP. AMS estimates a recordkeeping burden of 10 hours annually. The estimated annual reporting burden for each entity to update its OSP in future years is 20 hours (§§ 205.2, 205.100, 205.101, and 205.103).

2. Requires all currently certified organic operations and new applicants to describe their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and the products received to prevent organic fraud. This information would be part of the OSP. AMS estimates that each currently certified operation and applicant seeking certification would need 30 minutes to describe the supply chain verification procedures and monitoring practices proposed by this regulation (§§ 205.103 and 205.201).
3. Requires that each shipment of organic products imported into the United States through U.S. Ports of Entry must be declared as organic to U.S. Customs and Border Protection (CBP) and associated with an NOP Import Certificate (NOP 2110-1)⁶⁹ or an equivalent data source.⁷⁰ The NOP Import Certificate contains specific information about the quantity and source of a specific

⁶⁹ Office of Management and Budget (OMB)-approved form NOP 2110-1 NOP Import Certificate: <https://www.ams.usda.gov/resources/nop-2110-1>

⁷⁰ Mandated by The Organic Foods Production Act of 1990 (OFPA), as amended by the Agriculture Improvement Act of 2018. See sections 10104(b)–(c).

physical shipment of imported organic products. NOP Import Certificates are currently used for organic products imported from countries with which the NOP holds equivalency arrangements. This proposed rule would expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin. AMS estimates that exporters and certifying agents would need 30 minutes to report mandatory data, and prepare and review the NOP Import Certificate, respectively. AMS estimates that importers would need an average of one-tenth (0.1) of an hour, or 6 minutes, to compare the shipping manifest with the NOP Import Certificate to verify the accuracy and organic compliance of each shipment (§§ 205.273 and 205.300).

4. Clarifies that previously optional information must now be provided on nonretail container labels used to ship or store organic products. Along with the production lot number that is already required, nonretail labels would need: (1) the word "organic" to identify the product as organic; and (2) the name of the certifying agent that certified the product. These changes would help maintain the integrity of organic products by reducing misidentification and mishandling, facilitating traceability through the supply chain, reducing organic fraud, and allowing accurate identification of organic product by customs officials and transportation agents. AMS estimates that producers and/or processors would need one-tenth (0.1) of an hour, or 6 minutes, to add the word "organic" and the name of the certifying agent to the labels that are displayed on nonretail containers (§ 205.307).
5. Codifies current practices for the certification of groups of crop producers as a single operation.⁷¹ The proposed rule describes the criteria to qualify as a grower group, how grower

⁷¹ NOP Policy Memo 11-10, Grower Group Certification, October 31, 2011:
<https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>

group operations can comply with the existing USDA organic regulations, and how certifying agents should inspect these operations. It also sets a risk-based benchmark to determine how many grower group members in an operation need to be inspected annually. AMS expects that these requirements would not add to current paperwork impacts for grower group operations to prepare an OSP and maintain their certification, or for certifying agents and inspectors auditing and inspecting these operations for compliance with organic standards (§§ 204.400 and 204.403).

6. Requires certifying agents to create fraud prevention procedures to: (1) identify high-risk operations, supply chains, and agricultural products, (2) conduct risk-based unannounced inspections and supply chain trace-back and mass-balance audits, (3) share information with other certifying agents to verify supply chains and conduct investigations, and (4) report credible evidence of organic fraud to the USDA. AMS estimates each certifying agent would spend one hour documenting these procedures (§§ 205.403, 205.501 and 205.504).
7. Requires that certifying agents conduct unannounced inspections on at least 5% of the operations they certify, which is the current recommended practice in NOP Instruction 2609.⁷² For the purposes of estimating paperwork impacts, AMS expects that half of the unannounced inspections (2.5% of total inspections) would meet the requirement for a full annual inspection and would not impact current paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) would target high-risk operations and supply chains and would not count as a full annual inspection. Examples of targeted, limited-scope unannounced inspections include, but are not limited to, verifying livestock on pasture or performing targeted

⁷² NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <https://www.ams.usda.gov/sites/default/files/media/2609.pdf>

mass-balance and trace-back audits. AMS estimates that the paperwork impacts associated with these unannounced inspections would average inspectors 5 hours per inspection; half of the estimated 10 hours for a full annual inspection (§ 205.403).

8. Requires certifying agents to issue standardized certificates of organic operation generated from the USDA's publicly available Organic Integrity Database (INTEGRITY).⁷³ This would require an initial upload of mandatory data for each operation and maintenance, at least annually, to ensure that data in INTEGRITY are current and accurate. Currently, all certifying agents have voluntarily uploaded and maintain 50% or more data on all certified operations per the recommendations found in the NOP's Data Quality Best Practices.⁷⁴ The proposed amendments would require a new, one-time burden of reporting hours for certifying agents to upload remaining data pertaining to currently certified operations into INTEGRITY for the first time. It is estimated that uploading these data into INTEGRITY would require 30 minutes for each operation and would be performed by administrative support personnel who have a lower wage rate than review and compliance staff.

The proposed amendments would simultaneously eliminate the requirement to physically mail the Administrator or State Organic Program paper copies of: (1) the list of operations certified annually; (2) notifications of proposed adverse actions, approvals, or denials of corrective actions; and (3) notifications of executions of adverse actions regarding certified operations or operations applying for certification (§§ 205.404 and 205.501). AMS is not seeking to modify the estimate of paperwork burden associated with these changes in requirements because any

⁷³ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>

⁷⁴ Data Quality Best Practices: <https://www.ams.usda.gov/sites/default/files/media/INTEGRITY%20Data%20Quality.pdf>

change would be trivial and these activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time.

9. Requires certifying agents to submit their decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions with its administrative policies and procedures provided in § 205.504(b). AMS estimates each certifying agent would spend one hour documenting these procedures that they are already implementing.
10. Clarifies how certified operations may submit annual updates to their OSP. This includes practices or procedures that have changed since their last approved OSP, rather than submitting an OSP in its entirety. This would reduce unnecessary paperwork without compromising oversight because operations would continue to maintain an OSP that accurately reflects current practices and procedures of the operation. This codifies current policy and does not modify the paperwork burden (§ 205.406).
11. Requires certifying agents to establish inspection oversight procedures and demonstrate that they are sufficiently staffed with qualified personnel and that all inspectors, certification reviewers, and in-field evaluators meet knowledge, skills, and experience qualifications. AMS estimates that each certifying agent would spend 60 minutes to draft policies and procedures for conducting inspector field evaluations. Further, certifying agents must observe an inspector performing an on-site inspection at least once every three years. AMS estimates each certifying agent would conduct an average of four inspector field evaluations per year and that this activity would require 7.5 hours per evaluation (§§ 205.2 and 205.501).

12. Requires inspectors and certification review staff to complete an additional 10 hours of training annually.⁷⁵ Through two audits every 5 years, AMS estimates that inspectors and certification review staff currently receive at least 10 hours of training per year from certifying agents on topics related to the USDA organic regulations. Inspectors and certification review personnel play a crucial role in determining whether an operation is granted organic certification initially and whether certified operations are compliant with the USDA organic regulations. Certification review personnel may also serve as inspectors. AMS is proposing an additional 10 hours of training annually, calculated as two (2) five-hour trainings. Training offered by the NOP through its new online Organic Integrity Learning Center (OILC) and training provided by the certifying agents or other providers may qualify towards the total of 20 hours of required training (§§ 205.2 and 205.501).

13. Clarifies AMS responsibilities for equivalent organic conformity with foreign governments.⁷⁶ The OFPA at § 6505(b), and the current USDA organic regulations at § 205.500(c), provide the authority to establish organic equivalency. The proposed regulations describe the criteria, scope, and other parameters for ongoing peer review audits of foreign organic conformity systems to determine whether the USDA should continue, revise, or terminate such trade arrangements. These peer review audits of trade arrangements would occur twice within a five-year period and would result in new periodic paperwork impacts for foreign governments. AMS estimates the paperwork impacts for foreign governments when USDA reviews the applicable

⁷⁵ Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by our 78 certifying agents will be documented.

⁷⁶ Currently, the United States has established organic trade arrangements with Canada, the European Union, the United Kingdom (effective January 2021), India, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

trade arrangement to be 60 hours per year, which is comparable to the estimated paperwork impacts for AMS audits of certifying agents (§ 205.511).

Respondents

AMS has identified four primary types of entities (respondents) that would need to submit and maintain information as a result of this proposed rule: certified organic operations; accredited certifying agents; organic inspectors; and foreign governments. Three respondent types—certified operations (producers and handlers), certifying agents, and inspectors—have been identified in a currently approved information collection (0581-0191). To implement a 2018 Farm Bill mandate, AMS is requiring certification of additional types of operations in the organic supply chain and regular audits of trade arrangements with foreign governments.⁷⁷ This adds new types of handlers as a subcategory of certified operations and foreign governments as a new type of respondent.

To more precisely understand the paperwork impacts of this proposed rule, AMS has divided the categories of respondents into domestic and foreign, as appropriate, to show the potential impacts on domestic-based versus foreign-based USDA-accredited certifying agents, inspectors, and certified operations, along with foreign-accredited certifying agents, and foreign- governments serving as accrediting bodies. For each type of respondent, we describe the general paperwork submission and recordkeeping activities and estimate: (1) the number of respondents; (2) the hours they spend, annually, creating and storing records to meet the paperwork requirements of the organic labeling program; and (3) the costs of those activities based on prevailing domestic and foreign wages and benefits.

⁷⁷ See Section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf>.

1. Certifying agents. Certifying agents are State, private, or foreign entities accredited by the USDA, or by accreditation bodies of foreign governments with whom USDA has equivalency, to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the USDA organic regulations. Certifying agents determine whether a producer or handler meets the organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors. Currently, there are 78 USDA-accredited certifying agents (46 are based in the United States and 32 are headquartered in foreign countries). Both domestic- and foreign-based USDA-accredited certifying agents certify operations based in the United States and abroad. AMS assumes all currently accredited certifying agents evaluate all types of production and handling operations for compliance with the USDA organic regulations and would be subject to the reporting and recordkeeping burdens of the proposed amendments. In addition, AMS assumes there are 32 foreign government-accredited foreign-based certifying agents that certify handlers to the USDA organic regulations and that would issue NOP Import Certificates, or their equivalent, for organic product shipments to the United States.⁷⁸

Certifying agents of operations that export to the United States would need to issue import certificates for all shipments of imported organic products. The USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS) showed 67,023 shipments of organic product coming into the U.S. in 2017.⁷⁹ Thirty-two (32) USDA-accredited certifying agents based in foreign countries certify 92% of the foreign operations certified under USDA organic standards. Of the 46 domestic-based USDA accredited certifying agents, 16 certifying agents certify 8% of the foreign operations certified under USDA.⁸⁰ This

⁷⁸ An estimate based on the number of foreign-based USDA accredited certifying agents.

⁷⁹ Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected: <https://apps.fas.usda.gov/gats/default.aspx>

⁸⁰ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>

means that 30 domestic-based USDA-accredited certify agents only certify domestic-based operations that do not import foreign organic products or ingredients. AMS estimates 32 foreign-accredited certifying agents that certify foreign operations under trade agreements.⁸¹ AMS would review documents regarding imports during the accreditation audits of USDA-accredited certifying agents. AMS estimates 30 minutes for: (1) USDA-accredited domestic-based certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate (Form NOP 2110-1) for 8% of 67,023 annual shipments; (2) USDA-accredited foreign-based certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 67,023 annual shipments; and (3) foreign-accredited certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 67,023 annual shipments.

AMS is proposing amendments that would reduce the current paperwork burden of accredited certifying agents by eliminating the need to provide notices of approval or denial of certification to the Administrator following the issuance of a notice of noncompliance or adverse action to an applicant for certification. Also, the proposed rule removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified. Certifying agents would instead be required to update data in INTEGRITY for each operation they certify. AMS is not seeking to modify the estimate of paperwork burden with these changes in requirements because any change would be trivial. These activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time. In addition, all USDA-accredited certifying agents would need to write procedures to identify high-risk operations and products they certify and procedures to conduct supply-chain audits of those high-risk products. Certifying agents would also be required to issue organic certificates generated by INTEGRITY. Certifying agents would be required to write procedures to demonstrate how they are

⁸¹ An estimate based on the number of foreign-based USDA-accredited certifying agents.

sufficiently staffed and that all persons who perform certification review activities and on-site inspections (inspectors) are qualified and complying with annual training requirements increased from 10 hours to 20 hours per year. Certifying agents would also be required to write mediation procedures as per §205.504(b).

AMS projects that the proposed changes would increase the overall reporting and recordkeeping burden for certifying agents (See Summary Table 1: *Certifying Agents*). AMS estimates the annual collection cost per domestic-based USDA-accredited certifying agents would be \$12,788.95.⁸² This cost is based on an estimated 123.36 labor hours per certifying agent per year for staff with certification review responsibilities at \$45.91 per labor hour, including 31.7% benefits, for a total salary component of \$5,663.55 per year.⁸³ The estimated cost for domestic certifying agents also includes 300.24 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to INTEGRITY at \$23.73 per labor hour, including 31.7% benefits, for a total salary component of \$7,125.40 per year.⁸⁴

In addition, AMS estimates the annual collection cost for all domestic-based USDA-accredited certifying agents would be \$589,458.85. This cost is based on a total of 5,720.60 hours for all staff with certification review responsibilities at \$45.91 per labor hour, including 31.1% benefits, for a total salary component of \$262,636.29 for all staff with certification review and procedure writing responsibilities of

⁸² In this assessment, all domestic labor rates are sourced from the U.S. Bureau of Labor Statistics National Compensation Survey, Occupational Employment and Wages, May 2018: https://www.bls.gov/oes/current/oes_nat.htm. Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs. December 14, 2018: <https://www.bls.gov/news.release/ecec.nr0.htm>

⁸³ The labor rate for certification review staff is based on Occupational Employment Statistics group 13-1041, *Compliance Officers*. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere.

⁸⁴ The labor rate for administrative support staff is based on Occupational Employment Statistics group 43-9199, *Office and Administrative Support Workers*, who support general office work and data entry functions.

all domestic-based USDA-accredited certifying agents. The estimated cost for all domestic-based certifying agents also includes 13,771.19 hours total hours for administrative support staff uploading data about certified operations to INTEGRITY at \$23.73 per labor hour, including 31.7% benefits for a total salary component of \$326,822.56.

| SUMMARY TABLE 1: <i>Certifying Agents</i> | | | | | | |
|---|------------------------------|-------------------------|-----------------------------|------------------------------|------------------------|------------------------|
| Respondent Categories | Number of Respondents | Wages + Benefits | Hours per respondent | Cost/ respondent type | Total All Hours | Total All Costs |
| U.S.-Based USDA Certifying Agents | 46 | \$45.91 | 124.36 | \$5,709.37 | 5,720.60 | \$262,636.29 |
| U.S.-Based USDA Certifying Agents—data entry | 46 | \$23.73 | 300.24 | \$7,124.70 | 13,771.19 | \$326,822.56 |
| <i>Subtotal U.S.- Based USDA Certifying Agents</i> | 46 | | | \$12,834.06 | 19,491.79 | \$589,458.85 |
| Foreign-Based USDA | 32 | \$24.59 | 547.74 | \$13,468.93 | 17,527.63 | \$430,181.78 |

| | | | | | | |
|--|-----|---------|--------|-------------|-----------|----------------|
| Certifying Agents | | | | | | |
| Foreign-Based USDA Certifying Agents—data entry | 32 | \$12.71 | 300.24 | \$3,816.05 | 9,569.81 | \$121,633.35 |
| Subtotal Foreign-Based USDA Certifying Agents | 32 | | | \$17,286.98 | 27,097.44 | \$551,815.13 |
| Total USDA-Accredited Certifying Agents | 78 | | | \$30,119.04 | 46,589.23 | \$1,141,273.98 |
| Foreign-Accredited Certifying Agents | 32 | \$24.59 | 481.73 | \$11,844.69 | 15,415.29 | \$379,030.04 |
| Total All Certifying Agents | 110 | | | | 62,004.52 | \$1,520,304.02 |

For foreign-based USDA-accredited certifying agents, AMS estimates the annual cost per certifying agent would be \$17,527.63 per year. This cost is based on an estimated 547.74 labor hours for staff with certification review and procedure writing responsibilities at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$13,468.93 per foreign-based USDA-accredited certifying agent per year. These estimated costs primarily pertain to the issuance and review of NOP Import Certificates. The estimated cost for foreign-based USDA-accredited certifying agents also includes 300.24 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to INTEGRITY at \$12.71 per labor hour, including 35.92% benefits, for a total salary component of \$3,816.08 per year.⁸⁵

AMS estimates the annual collection cost for all foreign-based USDA accredited certifying agents would total \$551,815.13. This cost is based on a total of 17,527.63 hours for all staff with certification review responsibilities at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$430,181.78 for staff with certification review and procedure writing responsibilities of all foreign-based USDA-accredited certifying agents. The estimated cost for all foreign-based USDA-accredited certifying agents also includes 9,569.81 hours total hours for administrative support staff uploading data about certified operations to INTEGRITY at \$12.71 per labor hour, including 35.92% benefits, for a total salary component of \$121,633.35.

For foreign-accredited certifying agents, AMS estimates the annual cost will be \$11,844.69 per certifying agent. This cost is based on an estimated 481.73 labor hours per year for staff to issue and review NOP

⁸⁵ In this assessment, all foreign labor rates are based on a review of World Bank data, which indicates that labor rates in foreign countries with USDA-accredited certifying agents are approximately 52% of equivalent U.S. labor rates: <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 35.92% of total compensation in foreign countries with USDA-accredited certifying agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

Import Certificates, or an equivalent data source, at \$24.59 per labor hour plus 35.92% benefits. The total for all foreign-accredited certifying agents is estimated to be \$379,030.04. The cost is based on an estimated 15,415.29 total hours for all staff involved in the issuance and review of NOP Import Certificates, or an equivalent data source, at \$24.59 per labor hour plus 35.92% benefits.

The total cost for all certifying agents as a whole includes all costs for all 78 USDA-accredited certifying agents, domestic- and foreign-based, and all costs for the 32 foreign-accredited certifying agents who certify operations that export products to the U.S. The total costs for all certifying agents is \$1,520,304.02. This cost is based on 62,004.52 total hours at their respective wage rates and benefits to comply with the proposed requirements.

2. Organic Inspectors. Inspectors conduct on-site inspections of certified operations and operations applying for certification and report the findings to the certifying agent. Inspectors may be independent contractors or employees of certifying agents. Certified operations must be inspected annually, and a certifying agent may call for additional inspections or unannounced inspections on an as-needed basis (§ 205.403(a)). Any individuals who apply to conduct inspections of operations would need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)). Inspectors must also complete 20 hours of standardized organic training every year. AMS estimates that 10 hours per year for each inspector is a new paperwork burden associated with the proposed rule.

Inspectors provide an inspection report to the certifying agent for each operation inspected (§ 205.403(e)) but are not expected to store the record. Currently, AMS estimates that inspectors spend 10 hours on average to complete an inspection report for a full annual inspection of an organic operation. The additional unannounced inspections that would be newly required by this proposed rule are likely to be more limited in scope (such as pasture or dairy surveillance, or mass-balance and trace-back audits). AMS projects, on average, that inspectors would spend 5 hours to complete an inspection

report for the unannounced targeted scope inspection. AMS Inspectors do not have recordkeeping obligations; certifying agents maintain the records of inspection reports (see Summary Table 2: *Inspectors*).

| SUMMARY TABLE 2: <i>Inspectors</i> | | | | | | |
|---|------------------|----------------|------------------|-----------------|------------------|---------------------|
| Respondent | Number of | Wages + | Hours per | Cost per | Total All | Total All |
| USDA U.S.-based | 148 | \$28.45 | 33.34 | \$948.43 | 4917.80 | \$139,897.57 |
| USDA Foreign- | 102 | \$15.27 | 33.34 | \$508.99 | 3417.45 | \$52,172.66 |
| All USDA | 250 | | | | 8335.25 | \$192,070.23 |

According to the International Organic Inspectors Association (IOIA), there are approximately 250 inspectors currently inspecting crop, livestock, handling, and/or wild crop operations that are certified or have applied for certification. AMS estimates that 148 inspectors are working for USDA-accredited certifying agents in the U.S. For the additional training and unannounced targeted-scope inspections, AMS estimates the annual paperwork impact cost per domestic-based inspector to be \$948.43. This is based on an estimated 33.34 labor hours per year at \$28.45 per labor hour, including 31.7% benefits. The total annual cost for all domestic-based inspectors is \$139,897.57. This cost is based on 3,417 total hours for all domestic based inspectors at \$28.45 per labor hour, including 31.7% benefits.⁸⁶

AMS estimates that 102 inspectors are working for USDA-accredited certifying agents in foreign countries. AMS estimates the annual paperwork impact cost per foreign-based inspector to be \$508.99. This estimate is based on an estimated 33.34 labor hours per year at \$15.27 labor hour, including 35.92% benefits for attending 10 hours of training and conducting 4.67 unannounced targeted scope

⁸⁶ The labor rate for inspectors is based on Occupational Employment Statistics group 45-2011, *Agricultural Inspectors*. Agricultural inspectors inspect agricultural commodities, processing equipment, facilities, and fish and logging operations to ensure compliance with regulations and laws governing health, quality, and safety.

inspections. There are no recordkeeping costs for inspectors. The total annual cost for all foreign-based inspectors is \$52,172.66 at \$15.27 per labor hour, including 35.92% benefits. The total annual cost for all inspectors working for USDA-accredited certifying agents is \$192,070.23, at their respective wage rates and benefits.

3. Producers and handlers. Domestic and foreign producers and handlers seeking organic certification must submit an OSP that details the practices and activities specific to their operation. Once certified, operations are required to update any changes in their operation or practices to their certifying agent at least annually.

a) *Uncertified Handlers.* This proposed rule would require that operations that facilitate the sale or trade of organic products—including, but not limited to, brokers, importers, and traders—obtain certification and submit and maintain an OSP. AMS estimates that 961 domestic,⁸⁷ and an equal number of foreign-based, operations would need to become certified as a result of this rule. As stated previously, the OSPs for these handling operations would address fewer sections of the current rule than OSPs for operations that farm or manufacture organic products. Traders and brokers do not farm or manufacture organic products so the OSPs for traders and brokers would address fewer sections of the current rule than OSPs for operations that produce or manufacture organic products. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Therefore, AMS estimates that preparation of an initial OSP would require 40 reporting hours, plus 10 hours of annual

⁸⁷ These businesses are identified by NAICS Category 425: *Wholesale Electronic Markets and Agents and Brokers*. These businesses arrange for the sale of goods owned by others, generally on a fee or commission basis. They act on behalf of the buyers and sellers of goods. This subsector contains agents and brokers as well as business-to-business electronic markets that facilitate wholesale trade. Please refer to the “Applicability and Exemptions from Certification (§§ 205.100–101)” chapter in the Regulatory Impact Analysis (RIA) for an explanation of how previously excluded domestic handlers were estimated.

recordkeeping. The estimated annual reporting burden for each entity to update its OSP in future years is 20 hours (See Summary Table 3a: *Uncertified Handlers*).

All operations that export organic products to the United States would need to request an NOP Import Certificate, or its equivalent, from their certifying agent for each organic shipment imported to the United States. Further, operations that import organic products would need to verify that each shipment is associated with and matches the data on an NOP Import Certificate, and that organic integrity was maintained throughout the import process. In addition, domestic and foreign handlers that would be required to obtain organic certification as a result of this proposed rule may also need to comply with the proposed requirements for labeling nonretail containers.

| SUMMARY TABLE 3a: <i>Uncertified Handlers</i> | | | | | | |
|--|------------------------------|-------------------------|-----------------------------------|---------------------------------------|------------------------|------------------------|
| Respondent Categories | Number of Respondents | Wages + Benefits | Total hours per respondent | Total cost per respondent type | Total All Hours | Total All Costs |
| Formerly Excluded Handlers— Domestic | 961 | \$50.86 | 56.97 | \$2,897.49 | 54,752.30 | \$2,784,701.98 |
| Formerly Excluded Handlers— Foreign | 961 | \$27.13 | 84.87 | \$2,302.56 | 81,561.50 | \$2,212,763.50 |

| | | | | |
|---|-------------|--|-------------------|-----------------------|
| All Formerly Uncertified Handlers | 1922 | | 136,313.80 | \$4,997,465.47 |
|---|-------------|--|-------------------|-----------------------|

AMS estimates the annual paperwork impact for each domestic handler to prepare their initial organic system plan and to verify that imported shipments match their respective NOP Import Certificates is \$2,897.71. This is based on an estimated 56.97 labor hours at \$50.86 per labor hour, including 31.7% benefits. The total cost to all previously uncertified domestic handlers is \$2,784,701.98. This cost is based on 55,752.30 total labor hours at \$50.86 per labor hour, including 31.7% benefits.⁸⁸

AMS estimates the annual paperwork impact for each foreign-based handler to prepare their initial organic system plan and to work with their certifying agent to prepare their NOP Import Certificates for the products they export is \$2,302.56. This is based on an estimated 84.87 labor hours per year at \$27.13 per labor hour, which includes 35.92% for benefits. The total cost to all previously uncertified foreign handlers is \$2,784,701.98. This cost is based on 55,752.30 total labor hours at \$27.13 per labor hour, which includes 35.92% for benefits. Total costs to the 1922 previously uncertified handlers, domestic and foreign, is \$4,997,465.47, based on 136,313.80 total labor hours at their respective domestic and foreign wage rates and benefits to prepare and keep their initial OSP and related records, and to prepare and review NOP Import Certificates for compliance.

b) *Certified Operations and New Applicants under Current Rules.* There currently are 42,259 organic operations worldwide that are certified to the USDA organic standards. Over the next 12 months, AMS expects 2,501 operations will seek organic certification, based on the 5.9% rate of growth in number of

⁸⁸ For uncertified handlers, AMS chose to use the same labor rate as certified producers and handlers: Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*.

operations observed in the last 12 months under current rules.⁸⁹ Therefore, AMS estimates that 26,408 operations based in the United States, and 18,352 operations based in foreign countries, including the respective applicants for certification, will be impacted by this proposed rule.

All currently certified organic operations and projected new applicants would need to describe their procedures for monitoring, verifying and demonstrating the organic status of their suppliers and products received to prevent organic fraud as part of their initial or updated OSP. All certified organic operations would need to comply with the proposed nonretail labeling requirements, and would be required to keep all records about their organic production and/or handling for five years (§ 205.103(b)(3)). See Summary Table 3b: *Certified Organic Operations and New Applicants*.

| SUMMARY TABLE 3b: <i>Certified Organic Operations and New Applicants</i> | | | | | | |
|---|------------------------------|-------------------------|--------------------------------|------------------------------------|------------------------|------------------------|
| Respondent Categories | Number of Respondents | Wages + Benefits | Total hours/ respondent | Total cost/ respondent type | Total All Hours | Total All Costs |
| Certified Producers & Handlers—New and Existing Domestic | 26,408 | \$50.86 | 1.54 | \$78.33 | 47,815.50 | \$2,432,017.86 |
| Certified Producers & Handlers—New | 18,352 | \$27.13 | 1.54 | \$41.78 | 20,466.00 | \$555,242.58 |

⁸⁹ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>. Calculated on April 3, 2019.

| | | | | | | |
|--|---------------|--|--|--|------------------|-----------------------|
| and Existing Foreign | | | | | | |
| All New and Existing Producers & Handlers | 44,760 | | | | 68,281.50 | \$2,987,260.44 |

AMS estimates that the average annual paperwork impact for domestic certified organic producers and handlers to create a fraud prevention procedure and to comply with nonretail labeling requirements is \$78.33. This is based on an estimated 1.54 labor hours at \$50.86 per labor hour, including 31.7% benefits. The total cost for all domestic certified organic producers and handlers to comply with these new requirements is \$2,432,017.86. This cost is based on 47,815.50 labor hours at \$50.86 per labor hour, including 31.7% benefits.⁹⁰

AMS estimates the average annual paperwork impact for foreign-based USDA-certified organic producers and handlers to create a fraud prevention procedure and to comply with nonretail labeling requirements to be \$41.78. This is based on an estimated 1.54 labor hours per year at \$27.13 per labor hour, including 35.92% benefits. The total cost for all foreign producers and handlers certified to the USDA organic standards is \$555,242.58. This cost is based on 20,446 labor hours year at \$27.13 per labor hour, including 35.92% benefits. The total cost for the 44,760 current certified organic and projected new producers and handlers under current rules, both domestic and foreign, is \$2,987,260.

⁹⁰ The labor rate for producers and handlers is based on Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*, who plan, direct, or coordinate the management or operation of farms, ranches, or other agricultural establishments.

This cost is based on 68,281.50 labor hours at their respective domestic and foreign wages and benefits, to create their new fraud prevention procedures and comply with new nonretail label requirements.

4. Foreign Governments. The USDA has arrangements with 10 foreign governments to facilitate the international trade of organic products.⁹¹ The current regulations address this authority in general terms under § 205.500(c) but do not describe the criteria, scope, and other parameters to establish, oversee, or terminate such arrangements. The proposed rule describes equivalency determinations in more detail; this creates a new type of PRA respondent category. The proposed rule would allow a trade arrangement if AMS determines that the technical requirements and conformity assessment system under which foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations. The proposed rule would also require periodic assessment.

AMS expects these periodic peer review assessments would be similar in depth and frequency to the audits of accrediting certifying agents under USDA organic regulations and estimates a comparable level of reporting and recordkeeping burden by foreign governments with whom AMS has negotiated trade arrangements. AMS estimates the annual collection cost per foreign government would be \$1,721.15. This cost is based on an estimated 60 reporting labor hours and an estimated 10 hours of recordkeeping per foreign government per year at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$1,721.15 per year. The total cost for all foreign governments, with whom AMS has negotiated trade arrangements, to allow AMS to determine whether their foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the

⁹¹ Canada, the European Union, the United Kingdom (effective January 2021), India, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland. Taiwan is not included in this assessment because costs were calculated prior to May 2020, when the United States–Taiwan equivalency arrangement became effective.

USDA organic regulations is \$13,768.24. This cost is based on 560 total labor hours for all foreign governments at \$24.59 per labor hour, including 35.92% benefits.⁹²

Total (Domestic and Foreign) Information Collection Cost (Reporting and Recordkeeping) of Proposed Rule: \$9,711,656 (Also, see Summary Table 4: *All Reporting and Recordkeeping Hours and Costs, and All Domestic Reporting and Recordkeeping Hours and Costs*)

Total All Reporting Burden Cost: \$8,497,036

Estimate of Burden: Public reporting burden for the collection of information is estimated to average .38 hours per year per response

Respondents: Certifying agents, certified operations, inspectors, and foreign governments.

Estimated Number of Reporting Respondents: 47,050

Estimated Number of Reporting Responses: 644,269

Estimated Total Annual Burden on Reporting Respondents: 244,927 hours

Estimated Total Annual Reporting Responses per Reporting Respondents: 13.69 reporting responses per reporting respondents

Total All Recordkeeping Burden Cost: \$1,214,620

Estimate of Burden: Public recordkeeping burden is estimated to be an annual total of 0.65 hours per year per respondent.

Respondents: Certifying agents, certified operations, and foreign governments.

⁹² The labor rate for foreign governments is estimated at 52% of the labor rate for Occupational Employment Statistics group 13-1041, *Compliance Officers*.

Estimated Number of Recordkeeping Respondents: 46,768

Estimated Total Recordkeeping Burden on Respondents: 30,568 hours.

Estimated Total Recordkeeping Responses per Recordkeeping Respondents: 1 recordkeeping response per recordkeeping respondents

Total Domestic Only Information Collection Cost (Reporting and Recordkeeping) of Proposed Rule:

\$5,946,076

Total Domestic Only Reporting Burden Cost: \$5,119,399

Estimate of Burden: Public domestic only reporting burden is estimated to be an annual total .29 hours per year per domestic respondent

Respondents: Certifying agents, certified operations, and inspectors.

Estimated Number of Domestic Reporting Respondents: 27,563

Estimated Number of Domestic Reporting Responses: 380,119

Estimated Total Annual Reporting Burden on Domestic Respondents: 110,719 hours

Estimated Total Domestic Reporting Responses per Reporting Respondents: 13.79 reporting response per reporting respondents

Total Domestic Only Recordkeeping Burden Cost: \$826,677

Estimate of Burden: Public domestic only recordkeeping burden is estimated to be an annual total of 0.59 hours per year per respondent.

Respondents: Certifying agents and certified operations.

Estimated Number of Domestic Recordkeeping Respondents: 27,415

Estimated Total Annual Recordkeeping Burden on Domestic Respondents: 16,288 hours.

Estimated Number of Domestic Recordkeeping Responses: 27,542

Estimated Total Domestic Recordkeeping Responses per Recordkeeping Respondents: 1 recordkeeping response per recordkeeping respondents

| Summary Table 4: All Reporting and Recordkeeping Hours and Costs and All Domestic Reporting and Recordkeeping Hours and Costs | | | | |
|--|----------------|--------------------|------------------------------|--|
| | Hours | Costs | Number of Respondents | Respondent Types |
| Total Reporting & Recordkeeping | 275,495 | \$9,711,656 | 47,050 | Certifying agents, certified operations, inspectors, and foreign governments |
| All Reporting | 244,927 | \$8,494,137 | 47,050 | Certifying agents, certified operations, inspectors, and foreign governments |
| All Recordkeeping | 30,568 | \$1,214,620 | 46,768 | Certifying agents, certified operations, and foreign governments. |
| Reporting & Recordkeeping— Domestic | | | | |
| Reporting & Recordkeeping— Domestic | 126,977 | \$5,946,076 | 27,563 | Certifying agents, certified operations, and inspectors |
| Domestic Reporting | 110,719 | \$5,119,399 | 27,563 | Certifying agents, certified operations, and inspectors |

| | | | | |
|---------------------------|--------|-----------|--------|---|
| Domestic Recordkeeping | 16,258 | \$826,677 | 27,415 | Certifying agents and certified operations |
|---------------------------|--------|-----------|--------|---|

Comments

AMS is inviting comments from all interested parties concerning the information collection and recordkeeping required as a result of the proposed amendments to 7 CFR Part 205. AMS seeks comment on the following subjects:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility.
2. The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Ways to enhance the quality, utility, and clarity of the information to be collected.
4. Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.
5. AMS estimates that the total number of certified organic operations will grow by 5.6% annually, based on the increase in operations recorded in INTEGRITY during the last 12 months. Is this a reasonable and accurate projection of future growth, given the additional burdens imposed by this proposed rulemaking?⁹³

Comments that specifically pertain to the information collection and recordkeeping requirements of this proposed rule may be sent to the Federal eRulemaking Portal at <https://www.regulations.gov/>. You can

⁹³ Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>. Calculated on April 3, 2019.

access this proposed rule and instructions for submitting public comments by searching for document number, AMS-NOP-17-0065. Comments may also be sent to Valeria Frances, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, Room 2642-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250-0268 and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, D.C. 20503. Comments on the information collection and recordkeeping requirements should reference the date and page number of this issue of the *Federal Register*. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. The comment period for the information collection and recordkeeping requirements contained in this proposed rule is 60 days.

D. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, *Consultation and Coordination with Indian Tribal Governments*. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule does not have tribal implications that require consultation at this time. If a tribe requests consultation AMS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

E. Civil Rights Impact Analysis

AMS has reviewed this proposed rule in accordance with the Department Regulation 4300-4, Civil Rights Impact Analysis, to address any major civil rights impacts the proposed rule might have on minorities, women, and persons with disabilities. AMS has determined that this proposed rule has no potential for affecting producers, handlers, certifying agents, or inspectors in protected groups differently than the general population of producers, handlers, certifying agents, or inspectors.

List of Subjects in 7 CFR Part 205

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

For the reasons set forth in the preamble, the United States Department of Agriculture proposes to amend 7 CFR part 205 as follows:

7 CFR PART 205—NATIONAL ORGANIC PROGRAM

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

Authority: 7 U.S.C. 6501–6524.

2. Amend § 205.2 by:

- a. Revising the definitions *“Handle”*, *“Handler”*, and *“Handling operation”*;
- b. Removing the term *“Retail food establishment”*; and
- c. Adding in alphabetical order the terms *“Adverse action,” “Certification activity,” “Certification office,” “Certification review,” “Conformity assessment system,” “Grower group member,” “Grower group operation,” “Grower group production unit,” INTEGRITY,” “Internal control system,” “Organic exporter,” “Organic fraud,” “Organic importer of record,” “Retail operation,”* and *“Technical requirements”*.

The revisions and additions read as follows:

§205.2 Terms defined.

* * * * *

Adverse action. A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.

* * * * *

Certification activity. Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.

Certification office. Any site or facility where certification activities are conducted, except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.

* * * * *

Certification review. The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance with the USDA organic regulations. This does not include performing an inspection.

* * * * *

Conformity assessment system. All activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product.

* * * * *

Grower group member. A person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation.

Grower group operation. A single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation.

Grower group production unit. A defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops.

Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, labeling, combining, containerizing, storing, receiving, or loading.

Handler. Any person engaged in the business of handling agricultural products.

Handling operation. Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification.

* * * * *

INTEGRITY. The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors.

Internal control system. An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer.

* * * * *

Organic exporter. The owner or final exporter of the organic product who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic product from a foreign country.

Organic fraud. Intentional deception for illicit economic gain, where nonorganic products are labeled, sold, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

Organic importer of record. The operation responsible for accepting imported organic products within the United States.

* * * * *

Retail operation. An operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions.

* * * * *

Technical requirements. A system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products.

* * * * *

3. Amend § 205.100 by revising paragraphs (a) and (c) introductory text to read as follows:

§205.100 What has to be certified.

(a) Except for the exempt operations described in §205.101, each operation, or portion of an operation, that produces or handles agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food

group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

* * * * *

(c) Any person or responsibly connected person that:

* * * * *

4. Revise § 205.101 to read as follows:

§205.101 Exemptions from certification.

The following operations in paragraphs (a) through (e) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, including the provisions for prevention of contact of organic products with prohibited substances set forth in §205.272, and the specific additional requirements stipulated in §205.101(a) through (f).

(a) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation. Such operations must comply with the labeling provisions of §205.310.

(b) A retail operation or a portion of a retail operation that sells, but does not process, organically produced agricultural products.

(c) A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer. Such operations must comply with the labeling provisions of §205.310, and must maintain records sufficient to:

(1) Prove that agricultural products identified as organic were organically produced and handled;
and

(2) Verify quantities produced or sold from such agricultural products.

(d) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in §205.301(d)), or that only identifies organic ingredients on the information panel. Such operations must comply with the labeling provisions of §§205.305 and 205.310 and must maintain records sufficient to:

(1) Prove that agricultural products identified as organic were organically produced and handled;
and

(2) Verify quantities produced or sold from such agricultural products.

(e) An operation that only stores, receives, and/or loads agricultural products, but does not process or alter such agricultural products.

(f) Records described in subparagraphs (a)–(d) of this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs’ governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

5. Amend § 205.103 by:

- a. Revising paragraph (b)(2);
- b. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and
- c. Adding new paragraph (b)(3).

The revision and addition read as follows:

§205.103 Recordkeeping by certified operations.

* * * * *

(b) * * *

(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, including identification in records of products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable;

(3) Include audit trail documentation for product handled or produced by the certified operation;

* * * * *

6. Amend § 205.201 by:

- a. Removing “or excluded” in paragraph (a) introductory text;
- b. Revising paragraph (a)(3); and
- c. Adding paragraph (c).

The revision and addition read as follows:

§205.201 Organic production and handling system plan.

(a)***

(3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate to the certified operation's activities;

* * * * *

(c) In addition to paragraph (a) of this section, a grower group operation's organic system plan must describe its internal control system. The description of the internal control system must:

(1) Define the organizational structure, roles, and responsibilities of all personnel;

(2) Identify grower group production units and locations;

(3) Define geographical proximity criteria for grower group members and grower group production units;

(4) Describe characteristics of high-risk grower group members and grower group production units;

(5) Describe shared production practices and inputs;

(6) Describe the internal monitoring, surveillance, and auditing methods used to assess the compliance of all grower group members;

(7) Describe the system of sanctions for noncompliant grower group members, including procedures to address noncompliances detected among grower group members, impose sanctions, and remove

grower group members when warranted, and procedures for reporting noncompliances to the certifying agent;

(8) Describe measures to protect against potential conflicts of interest;

(9) Describe how training, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;

(10) Have clear policies and procedures to verify the grower group operation's and grower group members' compliance with the USDA organic regulations; and

(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.

7. Add § 205.273 to subpart C to read as follows:

§205.273 Imports to the United States.

Each shipment of organic products imported into the United States through U.S. Ports of Entry must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with a valid NOP Import Certificate (Form NOP 2110-1) or equivalent data source.

(a) Persons exporting organic products to the United States must request an NOP Import Certificate, or provide data through an equivalent data source, from a certifying agent, for each physical shipment of certified organic products prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement may issue an NOP Import Certificate or approve a listing in an equivalent data source (e.g., a third-party export system).

(b) The certifying agent must review an NOP Import Certificate request, determine whether the shipment complies with the USDA organic regulations, and issue the NOP Import Certificate or equivalent within 30 calendar days of receipt if the shipment complies with the USDA organic regulations.

(c) Each compliant organic shipment must be declared as organic to U.S. Customs and Border Protection through a U.S. Port of Entry by uploading the unique NOP Import Certificate, or equivalent electronic data entry, into the U.S. Customs and Border Protection's Automated Commercial Environment system.

(d) Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to § 205.272 or exposure to ionizing radiation pursuant to § 205.105, since export.

(e) The use of the term equivalent in this section refers to electronic data, documents, identification numbers, databases, or other systems verified as an equivalent data source to the NOP Import Certificate.

8. Amend § 205.300 by revising paragraph (c) to read as follows:

§205.300 Use of the term, "organic."

* * * * *

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply with the requirements in §205.273, Imports to the United States.

* * * * *

9. Amend § 205.301 by revising paragraphs (f)(2) and (f)(3) to read as follows:

§205.301 Product composition.

* * * * *

(f) * * *

(2) Be processed using ionizing radiation, pursuant to §205.105(f);

(3) Be produced using sewage sludge, pursuant to §205.105(g);

* * * * *

10. Amend § 205.302 by revising paragraphs (a)(1), (2), and (3) to read as follows:

§205.302 Calculating the percentage of organically produced ingredients.

(a) * * *

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of all ingredients.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) at formulation by the fluid volume of all ingredients (excluding water and salt) if the product and ingredients are liquid. If

the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of the ingredients and all ingredients.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid organic ingredients and the weight of the liquid organic ingredients (excluding water and salt) at formulation by the total weight (excluding water and salt) of all ingredients.

* * * * *

11. Amend § 205.307 by:

- a. Revising the section heading;
- b. Revising paragraphs (a) and (b); and
- c. Removing “and excluded” in paragraph (c)

The revisions read as follows:

§205.307 Labeling of nonretail containers.

(a) Nonretail containers used to ship or store certified organic product must display the following:

(1) The term, “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable, to identify the product;

(2) The statement, “Certified organic by (name of certifying agent),” or similar phrase, to identify the name of the certifying agent that certified the producer of the product, or, if processed, the certifying agent that certified the last handler that processed the product; and

(3) The production lot number of the product, shipping identification, or other information needed to ensure traceability.

(b) Nonretail containers used to ship or store certified organic product may display the following:

(1) Special handling instructions needed to maintain the organic integrity of the product;

(2) The USDA seal. Use of the USDA seal must comply with §205.311;

(3) The name and contact information of the certified producer of the product, or if processed, the last certified handler that processed the product;

(4) The seal, logo, or other identifying mark of the certifying agent that certified the producer of the product, or if processed, the last handler that processed the product; and/or

(5) The business address, website, and/or contact information of the certifying agent.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt operations under §205.101.

§ 205.310 [Amended]

12. Amend § 205.310 by removing “or excluded” wherever it appears.

13. Amend § 205.400 by:

- a. In paragraph (b), removing “§205.200” and adding in its place “§205.201”; and
- b. Adding new paragraph (g).

The addition reads as follows:

§205.400 General requirements for certification.

* * * * *

* * * * *

(g) In addition to paragraphs (a) through (f) of this section, a grower group operation must:

- (1) Be a single producer organized as a person;
- (2) Sell, label, or represent only crops and/or wild crops as organic;
- (3) Use centralized processing, distribution, and marketing facilities and systems;
- (4) Be organized into grower group production units;
- (5) Ensure that all crops and/or wild crops sold, labeled, or represented as organic are from grower group members only;
- (6) Ensure that grower group members do not sell, label, or represent their crops and/or wild crops as organic outside of the grower group operation unless they are individually certified;
- (7) Report to the certifying agent on an annual basis the name and location of all grower group members and grower group production units, and the crops, wild crops, estimated yield, and size of production and harvesting areas of each grower group member and grower group production unit;

(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors, which must include mass-balance audits and reconciliation of each grower group member's and grower group production unit's production yield and group sales;

(9) Document and report to the certifying agent the use of sanctions to address noncompliant grower group members, at least annually; and

(10) Implement procedures to ensure all production and handling by the grower group operation is compliant with the USDA organic regulations and the Act, including recordkeeping requirements to ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution.

§ 205.401 [Amended]

14. Amend § 205.401(a) by removing “§205.200” and adding in its place “§205.201”.

15. Amend § 205.403 by:

- a. Redesignating paragraph (a)(2) as paragraph (a)(3);
- b. Adding new paragraph (a)(2);
- c. Redesignating paragraphs (b) through(e) as paragraphs (c) through (f);
- d. Adding new paragraph (b);
- e. In newly redesignated (d)(2), remove “§205.200” and add in its place “§205.201”; and
- f. Adding new paragraphs (d)(4) and (5).

The additions read as follows:

§205.403 On-site inspections.

(a) * * *

(2) Initial and annual on-site inspections of a grower group operation as defined in §205.2 must:

(i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.

(ii) Conduct witness audits of internal control system inspectors performing inspections of the grower group operation.

(iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk according to criteria in 205.201(c)(4). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.

(iv) Inspect each handling facility.

(b) *Unannounced inspections.* (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.

(2) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.

(d) ***

(4) That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported; and

(5) That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21).

16. Amend § 205.404 by:

- a. Revising paragraph (b);
- b. Redesignating paragraph (c) as paragraph (d); and
- c. Adding new paragraph (c).

The revisions and additions read as follows:

§205.404 Granting certification.

* * * * *

(b) The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from INTEGRITY and may be provided to certified operations electronically.

(c) In addition to the certificate of organic operation provided for in §205.404(b), a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include:

- (1) Name, address, and contact information for the certified operation;

(2) The certified operation's unique ID number/code that corresponds to the certified operation's ID number/code in USDA Organic INTEGRITY;

(3) A link to USDA Organic INTEGRITY or a link to the certified operation's profile in USDA Organic INTEGRITY, along with a statement, "You may verify the certification of this operation at USDA Organic INTEGRITY," or a similar statement;

(4) Name, address, and contact information of the certifying agent;

(5) "Addendum issue date;" and

(6) "Addendum expiration date," which must not exceed the expiration date of the certificate of organic operation.

§ 205.405 [Amended]

17. Amend § 205.405 by removing paragraph (c)(3).

18. Amend § 205.406 by revising paragraphs (a) and (b) to read as follows:

§205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information to the certifying agent:

(1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year; and

(2) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.201;

(3) Any additions to or deletions from the information required pursuant to §205.401(b); and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) The certifying agent must arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation at least once per calendar year.

* * * * *

§ 205.500 [Amended]

19. Amend § 205.500 by removing paragraph (c).

20. Amend § 205.501 by:

- a. Revising paragraphs (a)(4), (5), (6), (10), (13), and (15);
- b. Redesignating paragraph (a)(21) as paragraph (a)(23); and
- c. Adding new paragraphs (a)(21) and (a)(22).

The amendments read as follows:

§205.501 General requirements for accreditation.

(a) * * *

(4) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and persons who conduct certification review, to comply with and implement the USDA organic standards;

(i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the required knowledge, skills, and experience to inspect operations of the scope and scale as assigned and to evaluate compliance with the applicable regulations of this part; and

(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents; and

(B) Initially and every year thereafter, inspectors must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to inspection. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and

(C) Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect before assigning inspection responsibilities;

(ii) Certifying agents must demonstrate that all persons who conduct certification review, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform

certification review of operations of the scope and scale assigned and to evaluate compliance with the applicable regulations of this part; and

(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned; and

(B) Initially and every year thereafter, all persons who conduct certification review activities must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to certification review. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and

(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.

(5) Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned;

(i) Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties.

(6) Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services;

(i) On-site evaluation of inspectors—Certifying agents must observe each inspector performing on-site inspections at least once every three years, or more frequently if warranted; and

(A) On-site inspector evaluations must be performed by certifying agent personnel who are qualified to evaluate inspectors;

(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and on-site inspector evaluations.

* * * * *

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except:

(i) For information that must be made available to any member of the public, as provided for in §205.504(b)(5);

(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and

(iii) If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange.

* * * * *

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500. Certifying agents must provide information to other certifying agents to

ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;

* * * * *

(15) Maintain current and accurate data in INTEGRITY for each operation which it certifies;

* * * * *

(21) Annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s).

(22) Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.

* * * * *

21. Amend § 205.504 by:

(a) Revising paragraph (b)(4); and

(b) Adding paragraph (b)(7).

The revision and addition read as follows:

§205.504 Evidence of expertise and ability.

* * * * *

(b) * * *

(4) A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10);

* * * * *

(7) A copy of the criteria to identify high-risk operations and products; and procedures to conduct risk-based supply chain audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.

* * * * *

22. Adding § 205.511 to subpart F to read as follows:

§205.511 Accepting foreign conformity assessment systems.

(a) Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country's organic certification program may be sold, labeled, or represented as organically produced in the United States if AMS determines that such organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part ("equivalence determination").

(b) Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request

this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will conduct an assessment of the country's organic certification program to evaluate whether it is equivalent.

(c) AMS will describe the scope of an equivalence determination.

(d) AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government's organic certification program. AMS will reassess a country's organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government's technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued.

(e) AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country's technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government's organic control system is inadequate to ensure that the country's organic certification program is fully meeting the terms and conditions under the determination; or for other good cause.

23. Amend § 205.640 by revising the introductory paragraph to read as follows:

§205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be reviewed, assessed, and collected from applicants in accordance with the following provisions:

* * * * *

24. Amend § 205.660 by:

- a. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e); and
- b. Adding new paragraph (c).

The addition read as follows:

§205.660 General.

* * * * *

(c) The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies, directly or indirectly, that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.

24. Amend § 205.661 by revising the section heading to read as follows:

§205.661 Investigation.

* * * * *

26. Amend § 205.662 by:

- a. Adding new paragraph (e)(3);

- b. Revising the first sentence of paragraph (f)(1); and
- c. Revising paragraph (g)(1).

The amendments read as follows:

§205.662 Noncompliance procedure for certified operations.

* * * * *

(e) * * *

(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in INTEGRITY.

(f) ***

(1) A certified operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. * * *

* * * * *

(g) * * *

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1)(xxxvii) of this title per violation.

* * * * *

27. Revise § 205.663 to read as follows:

§205.663 Mediation.

(a) A certifying agent must submit with its administrative policies and procedures provided in §205.504(b): decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions.

(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.

(1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.

(2) A certifying agent or State organic program may accept or reject a request for mediation based on its own decision criteria.

(i) If a certifying agent rejects a mediation request, it must provide this rejection in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to §205.681, within 30 calendar days of the date of the written notification of rejection of the request for mediation.

(c) Both parties must agree on the person conducting the mediation.

(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.

(e) The parties to the mediation have a maximum of 30 calendar days to reach an agreement following a mediation session. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to §205.681.

(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Secretary may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice that it has issued.

28. Amend § 205.665 by revising paragraph (a) to read as follows:

§205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* (1) A written notification of noncompliance will be sent to the certifying agent when:

(i) An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; or

(ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or

(iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part.

(2) Such notification must provide:

(i) A description of each noncompliance;

(ii) The facts upon which the notification of noncompliance is based; and

(iii) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

* * * * *

29. Revise § 205.680 to read as follows:

§205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by an adverse action of the National Organic Program's Program Manager, may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe they are adversely affected by an adverse action of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent may appeal such decision to the Administrator, Except, That when the person is subject to an approved State organic program, the appeal must be made to the State organic program.

(d) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in §205.663.

(e) All appeals must comply with the procedural requirements in §205.681(c) and (d) of the USDA organic regulations.

(f) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(g) All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed.

29. Amend § 205.681 by:

- a. Revising paragraphs (a) introductory text and (a)(2);
- b. Revising paragraphs (b) and (c)
- c. Revising paragraph (d)(1); and
- d. Revising paragraph (d)(3).

The amendments read as follows:

§205.681 Appeals.

(a) *Adverse actions by certifying agents.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or proposed revocation of certification to the Administrator, Except, That, when the applicant or certified operation is subject to an approved State organic program, the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

*** **

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the certification. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.

(b) *Adverse actions by the NOP Program Manager.* A person affected by an adverse action, as defined by 205.2, issued by the NOP Program Manager, may appeal to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be waived and a cease-and-desist notice will be withdrawn, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H.

(c) *Filing period.* An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. An adverse action will become final and nonappealable unless an appeal is timely filed.

(d) *Where and what to file.* (1) Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave., S.W., Room 2642, Stop 0268, Washington, D.C. 20250, or electronic transmission, NOPAppeals@ams.usda.gov.

* * * * *

(3) All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper or made in accordance with applicable program regulations, policies, or procedures.

Bruce Summers,

Administrator,

Agricultural Marketing Service.

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