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October 5, 2020

RE: AMS-NOP-17-0065; NOP-17-02 Strengthening Organic Enforcement Proposed Rule

Dear Dr. Tucker,

The Accredited Certifiers Association, Inc. (ACA) is submitting this comment in support of the Strengthening Organic Enforcement Proposed Rule. The ACA is a 501(c)(3) nonprofit educational organization created to benefit the organic certifier community and the organic industry. The ACA strives to ensure consistent implementation of the USDA Organic Regulations through collaboration and education of accredited certification agencies. We are committed to upholding organic integrity and maintaining stakeholder trust to facilitate the growth of the organic industry. Our organization is made up of 63 USDA NOP accredited certifying agencies worldwide, which includes all 47 accredited certifiers headquartered in the United States. We are the frontline decision-makers for the effective implementation of the National Organic Program.

We want to thank the NOP for their extensive work on the Strengthening Organic Enforcement proposed rule. This rule is a momentous achievement for the NOP and for the industry. It proposes much needed oversight to ensure consumer trust in the organic seal, and it has several benefits for the organic industry, including requiring certification of previously exempt operations, improved labeling and traceability, and regulations for fraud prevention and detection.

While we support the intent of the rule, we do have the following recommendations (suggested changes to the regulatory text are italicized with additions in <u>blue text</u>) which we feel are necessary to change in order to increase clarity and align with the goal to strengthen organic enforcement regulations. In several areas, we are not in support of specific proposed regulations. We have several questions and concerns throughout our comments that need to be addressed.



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Section (1) Applicability and Exemptions from Certification

The ACA strongly supports updating the regulations to limit the type of operations that are exempt and excluded from organic certification. The current exemptions and exclusions have allowed for fraud throughout the industry, often due to the difficulty in tracing products though complex supply chains with multiple uncertified handlers. The proposed rule requires some handlers of organic products who were previously exempt to now be certified, which would aid in traceability in the supply chain. The ACA supports the intent of the changes proposed in this section. However, some parts of the proposed language are unclear and not consistent with what is written in the preamble. For these reasons, we suggest changes, summarized below.

I. Definitions:

- a. §205.2 (Handle)- The ACA supports a definition of handle that covers all activities in the supply chain from production to sale to the final consumer, as that will aid in supply chain traceability. There are many more activities that occur from production to sale that are not included in the definition, so we have proposed to include some terms, such as private labeling, exporting and importing. Without specific reference to private labeling operations, traceability audits throughout the supply chain could not be conducted. Finally, we request a definition for brokering and clarification on activities that are considered facilitating sale or trade. The ACA agrees that Customs Brokers, or private individuals, partnerships, associations or corporations licensed, regulated and empowered by U.S. Customs and Border Protection (CBP) to assist importers and exporters in meeting Federal requirements governing imports and exports, should NOT be considered brokers and should not be required to be certified.
 - *i.* Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitate sale or trade, brokering, opening, packaging, repackaging, sorting, treating, closing, enclosing, labeling, relabeling, combining, containerizing, splitting, storing, receiving, private labeling, transloading, or loading.
- b. §205.2 (Handler) & (Handling Operation)- It is not clear why there are separate definitions for "Handler" and "Handling Operation." The differentiation between the two terms appears to be the clause "except for operations that are exempt from certification," included in the definition of the term "Handling Operation." However, based on the definition of "Person" at §205.2, these terms should be synonymous." Furthermore, there does not seem to be a distinction in the use of the terms "Handler" and "Handling Operation" throughout the organic regulations, so excluding exempt operations from one term but not the other is confusing. We recommend removing "except for operations that are exempt from certification", so that Handling Operation is a synonym for Handler.
 - *i.* Handling Operation (handler). Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification.



- c. §205.2 (Retail Operation)- In the preamble, §205.101(b) and (c) refers to and defines a "Virtual transaction". We suggest adding this as a separate term defined at §205.2 for clarity.
 - *i.* Virtual Transaction. Any form of transaction that does not occur in person (e.g., telephone, mail-order, and/or online sales)

II. Standards:

- a. **§205.101(b)-** We concur that retail operations, not warehouses that cull, label, repackage, or otherwise process agricultural products for retail operations, should be exempt.
- b. §205.101(c)- The proposed language at §205.101(c) exempts "A retail operation or portion of a retail operation that *processes* agricultural products" (emphasis added). The ACA interprets this to mean that retail operations that *handle* certain products, including combining, containerizing, storing, receiving, loading, etc., will now be required to be certified, as these operations' activities are outside of the definition of processing. It may be unclear whether the proposed language at §205.101(c) applies to distribution centers, which is a warehouse or other specialized building from which products are redistributed to retailers, to wholesalers, or directly to consumers. We strongly support distribution centers requiring certification, as most distributors of fresh, ready to eat organic products destined for retailers likely have procedures that require receiving personnel to perform quality checks on the product (i.e. opening boxes, etc.), and/or after receiving in storage to ensure the product meets quality standards before delivery. Activities such as these should require certification.

We also support the continued inclusion of the requirement to follow the labeling requirements at §205.310. We agree that the labeling requirements at §205.308 and §205.309 do not apply to operations exempted under §205.101(c), although the ACA is concerned that this is unclear and that exempt operations are labeling products as certified organic and/or displaying the USDA organic seal. In addition, some certifiers currently permit processors to purchase ingredients from uncertified retailers; although this is currently prohibited under §205.310, the proposed language more clearly prohibits this allowance. While we do not think that retailers with bulk bins should require certification, we do want to acknowledge the risk to organic integrity at the retail level due to activities such as consolidating organic products in bulk bins, repackaging, and handling meat at deli counters, for example.

c. **§205.101(e)-** The ACA agrees that the exemption from certification at 205.101(e) should be limited to operations that are storing and loading products and do not take ownership of said products. However, we are concerned that the proposed language may allow for more exemptions than intended. The preamble states that 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. The ACA requests that these actions be specifically called out in the



exemption at this section. We also propose adding "packaged in sealed, impermeable, and tamper evident containers" to the regulation to note that the exclusions apply only to packaged products. Operations storing, receiving, and/or loading unpackaged agricultural products should be required to be certified, as the risk for commingling and contamination is increased. We also agree that records should be maintained by these exempt operations as also required for subparagraphs (c)-(d). Thus, we request amending the proposed language to include record requirements for exempt operations. The preamble also states that multiple types of handling activities performed at ports, such as loading, unloading, or transfer of packaged, unpackaged, or bulk organic product, would now be required to be certified, but these activities appear to be exempt from certification in this section. To address this, we have recommended replacing the word "load" with the word "ship," to remove some activities at port from the exemption.

The ACA agrees that licensed commodity dealers/brokers are considered brokers and therefore fall under the definition of "handle" proposed at §205.2. We also support the language in this section, which we agree does not exempt licensed commodity dealers/brokers from certification. However, it may be unclear, and some operations may argue that licensed commodity dealers/brokers act only as warehouses, and are therefore exempt from certification. We request explicit language stating that licensed commodity dealers/brokers are not exempt under this section. Furthermore, we agree that cold storage facilities, and refrigerated transport should be exempt and instead covered under the organic system plan of the certified operation.

We acknowledge the impact that tightening this exemption will have on currently certified operations in third countries where the contractors they work with may choose not to become certified. However, the ACA supports a requirement for certification of these operations, but we request a 2-year implementation period to allow for either the certification of these operations of the development of new relationships with certified contractors.

- *i.* An operation that only stores, receives, and/or loads ships agricultural products packaged in sealed, impermeable, and tamper resistant containers, but does not process, own, label/relabel, combine, split, containerize, pack/repack, treat, sort, open, enclose, or otherwise alter or handle such agricultural products. Such operations must maintain records sufficient to: (1) prove that agricultural products identified as organic were organically produced and handled; and (2) Verify quantities stored, received and/or loaded of such agricultural products.
- d. **§205.101 (f)-** We suggest changing the record retention requirement to 5 years for consistency. Also, we suggest changing the subparagraphs to include (a)-(e) Finally we suggest using the language in (c)-(d) and incorporating it into this section.
 - i. Records described in subparagraphs (a)–(d)(e) of this section must be maintained for no less than 3 5 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.

III. Answers to AMS 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)?

The ACA recommends the following activities and types of operations that should require certification:

Activities:

• Opening, packaging, sorting, treating, closing, enclosing, relabeling, splitting, private labeling, transloading

Types of Operations:

- Warehouses that cull, label, repackage, or otherwise process agricultural products for retail operations
- Retail distribution centers
- Meal Kit Company (e.g. Hello Fresh)
 - The final consumer cannot retrieve these products from an onsite location where processing occurred.
 - Makes own ingredients (e.g. sauce)
 - Only compiling previously certified organic ingredients selling online
- Amazon
 - Does not meet the definition of retail operation because independent retailers sell products through their distribution centers and Amazon isn't themselves the retailer in all product sales.
 - They have warehouses/distribution centers
- Retail operations that process agricultural products onsite and label the final product as certified "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or use the USDA organic seal on labels or signage.
 - E.g. opens bulk bags of organic flour, transfers it to an in-store bulk bin, and adds a product information label to the bin including company info they bought the flour from, "certified organic" designation and the USDA organic seal.

2. Are there any activities in the proposed definition of handle that should be exempt from certification?

We agree that customs brokers, or private individuals, partnerships, associations or corporations licensed, regulated and empowered by U.S. Customs and Border Protection (CBP) to assist importers and exporters in meeting Federal requirements governing imports and exports, should be exempt and are not considered to be



facilitating sale or trade. These may be interpreted to be covered under the term "broker" in the proposed definition.

We also agree that milk haulers (transport) should not need to be certified themselves, although these operators combine milk from multiple producers, which falls under the proposed definition of handle. We agree that activities of milk haulers should be covered under the certification of the handler of the milk. Furthermore, we agree that products in cold storage facilities and refrigerated transport that are already chilled or frozen are not chilled or frozen by the facility or transport itself, and therefore are exempt from certification under §205.101(e).

3. Are there specific activities not included in the proposed rule that you believe should be exempt from organic certification?

The ACA agrees that restaurants with delivery services, as well as independent delivery services (such as UberEATS and Instacart) should be exempt.

4. Are there additional requirements that exempt handlers described in this proposed rule should follow?

Exempt handlers at §205.101(e) should be required to maintain records as proposed above.

5. 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?

Transloading, or the process of transferring a shipment from one mode of transportation to another, is an activity commonly occurring at ports and it encompasses grain elevators, and we request that this term is included in the definition of the term "handle". It is also not apparent in the proposed rule that loading, unloading, or transfer of packaged, unpackaged, or bulk organic product at the port would require certification; these activities may fall under the proposed exemptions at §205.105(e).



Section (2) Imports to the United States

The ACA supports the addition of this new section covering imports to the United States. Processes to properly trace organic products coming from overseas is essential and protects the organic industry in the United States. The ACA supports the addition of definitions for "organic exporter" and "organic importer of record." We also support the use of electronic NOP import certifications, and we support clear procedures for the use of these certificates. The ACA requests clarification on the proposed procedures, which are unclear and contradict what is written in the preamble.

I. Definitions:

- a. §205.2 (Organic exporter and Organic importer of record)- The ACA agrees that organic exporters and organic importers of records should be required to be certified organic. However, these operations may or may not be required to be certified, based on the proposed definitions. An organic exporter that is a "final exporter" but not an owner, and an organic importer of record that is responsible for accepting imported organic products within the United States but is not the owner of the product, may be exempt from certification under §205.101(e). In addition, the organic products within the United States but is not the organic products within the United States. However, multiple companies may be involved in the importing process, and it is not clear in the proposed definition of the organic importer of record is the person physically receiving the product (unloading) or the person taking ownership. We suggest the language be clarified to define the importer as the person who takes ownership and arranges import of the product.
 - *i.* Organic importer of record. The operation responsible for accepting arranging and taking ownership of imported organic products within the United States

II. Standards:

- a. §205.273- This section proposes certain requirements for each shipment of organic products imported into the United States through U.S. Ports of Entry. However, the term "each shipment" is unclear; a shipment may include a single lot or multiple lot of products. This may cause difficulty linking a shipment to a specific lot, because an import certificate may include more than one lot, or one lot may be listed on multiple import certificates. The ACA requests clarification to consistently implement this regulation. Another concern is international virtual orders of organic ingredients for organic processed products from marketplaces like Amazon, for example, which currently are not traceable in the supply chain. Would import certificates be required in this instance? Finally, the reference to an equivalent data source is vague, and the ACA suggests adding "as specified at 205.273(e)" to reference the definition of equivalent data source.
 - *i.* 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 as specified at §205.273(e).

- b. **§205.273(a)-** We suggest removing "(e.g. a third-party export system)" and replacing it with "as specified at 205.273(e)" to reference the definition of equivalent data source.
 - i. 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 thirdparty export system) as specified at §205.273(e).
- c. §205.273(b)- It is unclear when the 30 days will begin when the goods are received or when the request is received. The purpose of the 30-day timeframe is unclear if the import certificate should be available when the product arrives at port per §205.273(d) ("...the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate..."). Furthermore, it is unknown what the repercussions are if the import certificate is not issued within 30 days. In practice, 30 days is too long and certifiers are issuing import certificates much sooner. This also seems contradictory to the requirement in the preamble that the import certificate be uploaded to the ACE system within 10 days. We would ideally like to see the import certificate available with receipt of product at shipment, but acknowledge that this may not be possible for all imports, especially those coming from Mexico and Canada which are imported in extremely high volumes. If it is the goal of the NOP to have the import certificate available with receipt of product at shipment, there needs to be a system in place that will allow certifiers to comply with this requirement without the extraordinary administrative burden that this would require for products coming from Mexico and Canada. Although we did not come to consensus on what the timeframe should be, we agree that 30 days is not appropriate. Also, we suggest adding "as specified at §205.273(e)" to reference the definition of equivalent data source.
 - *i.* 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, as specified at §205.273(e), within 30 calendar days of receipt if the shipment complies with the USDA organic regulations.
- d. **§205.273(c)-** This regulation does not clarify who is responsible for uploading the unique NOP Import Certificate. The preamble states that the exporter is responsible and our recommendation is to add this language to the regulation. We also suggest adding "as specified at §205.273(e)" to reference the definition of equivalent data source.
 - *i.* 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 as specified at §205.273(e), into the U.S. Customs and Border Protection's Automated Commercial Environment system. The organic exporter is responsible for uploading the unique NOP import certificate.

- e. **§205.273(d)-** The preamble and proposed language at §205.273(d) are contradictory. The preamble states that the import certificate needs to be uploaded into the ACE within 10 days and not accompanied with the shipment, while the proposed language states that "the organic importer of record must ensure the shipment is *accompanied by* a verified NOP Import Certificate" (emphasis added). We suggest changing the "accompanied by" to "associated with" in order to be consistent with the preamble. We also suggest adding "as specified at §205.273(e)" to reference the definition of equivalent data source.
 - i. Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by associated with a verified NOP Import Certificate or equivalent as specified at §205.273(e); 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 7 CFR 205.272 or exposure to ionizing radiation pursuant to 7 CFR 205.105, since export.
- f. **§205.273(e)-** The proposed language does not indicate who confirms what is considered an equivalent data source. We request that the NOP make this determination and make the information public for certifiers and operators to use. Thus, we recommend adding "as determined by the USDA" to clarify this.
 - i. 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 as determined by the USDA to the NOP Import Certificate.

Section (3) Labeling of Nonretail Containers

The ACA supports the requirement to label nonretail containers. This is critical for organic integrity and will aid in traceability through the supply chain and reduce fraud. The ACA's suggested changes are as follows.

I. Standards

a. §205.307- Labeling of nonretail containers. The preamble states that §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. Thus, we suggest revising the definition of nonretail container at 205.2 to be specific as to what is meant by nonretail container.



- i. Nonretail container. 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 used to ship or store either packaged or unpackaged organic products may include, but are not limited to, 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. Nonretail containers do not include 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.
- b. §205.307(a)- It is important for traceability purposes for nonretail labels to list the actual product. Therefore, we recommend requiring the generic name of the product in the container. In addition, the ACA agrees that a business name and address should be required on nonretail containers. Therefore, we suggest removing this language from §205.307(b)(3) and adding it to §205.307(a)(4). However, we understand the desire for private labelers to conceal the manufacturers name but by doing so it makes it impossible to trace the product. Thus, in lieu of the business name and address we propose allowing a number identifier for traceability such as the OID number along with the certified by statement of the manufacturer
 - i. 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 generic name of the product in the container (2)(3) The statement, "Certified organic by * * *," 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)(4) The production lot number of the product, shipping identification, or other information needed to ensure traceability. (5) The name or number identifier and contact information of the certified producer of the product, or if processed, the last certified handler that processed or handled the product;
- c. §205.307(b)- We agree that this standard revision will greatly aid in traceability. It is reasonable to have the last certified handler that processed the product displayed on the container; however, the ACA requests that the last certified handler include the operation that has not just processed but also handled the product. This would not include contract handlers or copackers who are packaging products for the certified handler to be the one who sells the product, since "to sell" is included in the definition. Not all handlers process products.

In addition, we request clarification on the term "special handling instructions." Finally, proposed language at §205.307(b)(3) was moved to §205.307(a)(4), and the following section numbers were adjusted accordingly.



i. 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)(3) The seal, logo, or other identifying mark of the certifying agent that certified the producer of the product; or if processed, the product, or if processed, the last handler that processed or handled the product; and/or (5)(4) The business address, website, and/or contact information of the certifying agent.

II. Answers to AMS Questions:

1. 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.

The ACA agrees that it is reasonable to list the last certified handler that processed the product; however, the last handler should be considered the operation that manipulates the product in some way such as processes, packages, and/or labels. Thus, we suggest adding the term "handled" after "processed." Furthermore, requiring the business address should be a must along with the business name. However, we understand the desire for private labelers to conceal the manufacturers name but by doing so it makes it impossible to trace the product. Thus, in lieu of the business name and address we propose allowing a number identifier for traceability such as the OID number along with the certified by statement of the manufacturer.

Section (4) On-Site Inspections

The ACA greatly appreciates the addition of these sections as it codifies best practices that certifiers are currently doing. With that being said, the ACA suggests that a definition for unannounced inspections should be in the standards. Furthermore, some of the proposed language does not include products used in ingredients when conducting mass balance and traceability audits. For these reasons, we suggest the revisions, summarized below.

I. Definition:

- a. **§205.2 (Unannounced Inspection)-** The ACA recommends that a definition for unannounced inspection be included in the regulations. We propose as follows:
 - *i.* Unannounced Inspection. An inspection that is conducted with little or no advanced notice to the operation.

II. Standards:

a. **§205.403(d)(4)-** Not all products are sold or transported so the language should include products used as ingredients such as livestock feed.



- *i.* That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold-or, transported, or used as an ingredient in a "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," product; and
- b. **§205.403(d)(5)-** We suggest rewording the regulation to include products used as ingredients. We also suggest adding the following definition of source to avoid confusion: "point of origin or procurement."
 - *i.* That organic products and ingredients are traceable by the operation from the time of production and/or purchase to the use, sale, or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21).

Section (5) Certificates of Organic Operation

The ACA supports consistency among certifiers and acknowledges the need for updated accessible information for organic certificates and standardization. Summarized below, we discuss challenges and concerns with the proposed regulations on organic certificates as well as provide our recommendations for changes.

- I. Definition:
 - a. **205.2 (INTEGRITY)-** The ACA recommends renaming the definition for the NOP database to 'ORGANIC INTEGRITY DATABASE' or 'OID 'for short. The term "integrity" should be reserved to describe the organic integrity of the supply chain.
 - *i.* ORGANIC INTEGRITY DATABASE (OID). 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.

II. Standards:

- a. §205.404(b)- Without knowing what data will be required, it is difficult to know the administrative burden that this will cause for certifiers. Certifiers may need to modify their databases depending on the data required which may take longer than the proposed implementation period of 1 year. On the one hand, we support the idea of having uniform certificates accessible electronically. However, on the other hand, certifiers can issue standardized certificates without relying on the OID. What if the Organic Integrity Database crashes and certifiers are unable to issue updated certificates? What will be the data burden on certifiers, especially larger certifiers, when the data needs to be entered manually? We suggest either the NOP build an application programming interface (API) for data integration or allow certificate issued by the certificate issued by the certificate in the OID in content and design.
 - *i.* The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from OID or match the



certificate in the ORGANIC INTEGRITY DATABASE (OID), in content and design, and may be provided to certified operations electronically.

- b. §205.404(c)- ACA's concur that having expiration dates on certificates only creates confusion when the certification itself does not expire. The integrity purpose of an expiration date is already served by other updates made to the standard. This will only create a paperwork and administrative burden to update certificates. Instead, there should be uniform instruction to all certifiers as to when to update the certificate. Therefore, we recommended removing (6) altogether.
 - i. 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 DATABASE (OID); (3) A link to USDA ORGANIC INTEGRITY DATABASE (OID) or a link to the certified operation's profile in USDA ORGANIC INTEGRITY DATABASE (OID) or a link to the certified operation's profile in USDA ORGANIC INTEGRITY DATABASE (OID), along with a statement, "You may verify the certification of this operation at USDA ORGANIC INTEGRITY DATABASE (OID)," or a similar statement; (4) Name, address, and contact information of the certifying agent; and, (5) "Addendum issue date,." and (6) "Addendum expiration date," which must not exceed the oxpiration date of the certificate of the operation.

III. Answers to AMS Questions:

1. How frequently should accredited certifying agents update the information in an operation's organic certificate?

Certain information should be updated at least once annually, whereas other information should be updated in real time. For example, if operations change their contact information or when additions are made such as when operations add products or parcels/facilities; this information should be updated in real time. Discontinued items can be updated at annual renewal, whereas items eliminated for compliance reasons should be removed in real time.

2. Should an expiration date be included on all certificates of organic operation? Would this make them more useful?

The ACA is not in favor of including expiration dates on certificates. The ACA concurs that having expiration dates on certificates only creates confusion when the certification itself does not expire. The integrity purpose of an expiration date is already served by other updates made to the standard. This will only create a paperwork and administrative burden to update certificates.



Section (6) Continuation of Certification

The ACA strongly supports the revision at §205.406(a) which adds flexibility and efficiency to the annual update process. We are in favor of removing the need to annually update on the correction of minor noncompliances. We did not come to consensus with the proposed language at §205.406(b) that on-site inspections of the certified operation occur at least once per calendar year. However, we did discuss and agree that under extraordinary circumstances, such as a global pandemic, when onsite inspections are not possible, it is important for the NOP to recognize this and allow flexibility with this requirement. The current regulations as written have allowed for remote inspections until an onsite follow-up inspection is safe to occur; with the proposal to change this standard to "per calendar year" it may no longer allow this flexibility. Certifiers agree that in cases such as these, this should not affect accreditation.

Section (7) Paperwork Submissions to the Administrator

The ACA fully supports removing §205.405(c)(3) and appreciates that the NOP supports lessening the paperwork burden of accredited certifying agents. We also support the maintenance of current and accurate data in the ORGANIC INTEGRITY DATABASE for all certified operations, provided that the NOP clarifies some of the proposed language.

- I. Standards:
 - a. §205.501(a)(15)- We suggest that a complete list of required data fields be provided in order to ensure accurate data is uploaded to the OID; as well as, give certifiers an idea of the time and administrative resources needed to implement this standard. Also, certifiers need to know what data to report in order to ensure consistency. For instance, it is important to be able to track applicants that were denied certification or withdrew with noncompliances or adverse actions.
 - *i.* Maintain current and accurate data in ORGANIC INTEGRITY DATABASE (OID) for each operation which it certifies, and all applicants who were denied certification or withdrew with noncompliances or adverse actions;

Section (8) Personnel Training and Qualifications

The ACA strongly supports the use of highly trained certification reviewers and inspectors. Quality certification staff and inspectors are paramount for detecting unintentional and intentional fraud in the organic industry. However, we are extremely concerned about the specific requirements for personnel training. Specifically, requirements for inspectors are extremely broad and vague, and they will likely shrink the pool of available inspectors. We suggest revisions that will still require the use of trained personnel without having unrealistic training requirements.

I. Standards:

a. **§205.501(a)(4)-** The NOP is proposing specific requirements for inspectors at §205.501(a)(4). While the ACA supports the intent to ensure that all inspectors are



highly trained, we are concerned that the prescriptive nature of these requirements will be burdensome for some certifiers and will further exacerbate the human capital issue that our industry is seeing with inspections. The proposed language requires that inspectors complete 20 hours of training annually. The ACA recommends changing the proposed language to "must demonstrate successful completion of annual training in topics that are relevant to inspection." The requirement for 20 hours of training annually is prescriptive and confusing. It is not clear whether it applies to the job itself or the person. For example, would a person who is both a reviewer and inspector require 40 hours of training or 20 hours of training?

Furthermore, requiring this amount of training will create an unnecessary financial burden for independent inspectors. Another concern some certifiers have is requiring training for contract inspectors and how that opposes state labor laws that prohibit mandating training for contractors. The amount of training necessary for inspectors should be individualized as those conducting fewer inspections may need more training than inspectors with more experience that conduct many inspections annually. Also, we recommend including examples from the preamble for the final rule of organizations NOP would consider "other relevant training providers". Our understanding is that this would include organizations such as IOIA, eOrganic, workshops and short courses offered from universities or at farming conferences, etc. Certifiers appreciate being given this discretion when it comes to offering and determining relevant training for inspectors.

In addition, quality audit skills are essential, but the requirement for inspectors to have one year of field-based experience related to both the scope and scale of operations prior to being assigned inspections seems excessive. In February of 2018, the ACA published Guidance on Organic Inspector Qualifications. These recommendations were based on a draft document produced by the International Organic Inspectors Association (IOIA) for the NOP. The skills specific to each inspection scope were addressed in this guidance as well as areas of expertise and knowledge. This best practice respects the diversity of experience in our guidance and is not as specific to require 1 year of field-based experience related to scope and scale; rather, we recommend the requirement for one-year work place experience in the scope, and we offer examples of specific acceptable experience per scope. For instance, inspectors with experience in inspecting some scopes and scales of operations may be able to be trained on other scopes and scales. More emphasis should be given to audit practices and skills, such as the ability to complete trace back and mass balance audits, as well as communication and report writing aptitude. We suggest removing the requirement for 1 year of experience entirely, and we suggest replacing the language in (a)(4)(i)(C)with the language from (ii) for reviewer personnel and replacing "scope and scale" throughout 205.501(a)(4) with "relevant experience." This will allow flexibility and will help prevent further human capital issues.



Finally, we recommend adding "as applicable" after "investigation techniques, and preparation of technically accurate inspection documents". The updated language would read in the standard as:

- i. 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) Inspector qualifications and training—Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the required knowledge, skills, and relevant 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 (e.g. traceback and mass balance), and skills written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents, as applicable; and (B) Initially and every year thereafter, inspectors must demonstrate successful completion of a minimum of 20 hours of annual 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 all persons who conduct inspections, including staff, volunteers, or contractors, have a minimum of 1 year of field-based experience related to both the scope and scale of the operations they will inspect before assigning inspection responsibilities the knowledge, skills, and relevant experience required to perform inspections of operations assigned and to evaluate compliance with the applicable regulations of this part; (ii) Certification review personnel qualifications and training- Certifying agents must demonstrate that all persons who conduct certification review, including staff, volunteers, or contractors, have the knowledge, skills, and relevant experience required to perform certification review of operations 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 annual 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) Certifving agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.
- b. §205.501(a)(5)- The ACA does not support limiting experience to organic production and handling or fields that directly relate to the inspection assignments. First, it is not clear what is meant by "directly relates" and how this would be determined. For instance, would education or experience in conventional agriculture or natural



resources/ environmental studies directly relate? It seems limiting to the industry to only have inspectors with organic backgrounds. Many other fields of professional experience and/or education that are relevant such as law or accounting may be excellent for auditing. We think that it is more essential for inspectors to have critical thinking and analytic skills. Furthermore, informal field-based training, such as shadowing inspections or volunteering on operations, should be considered experience. As written, this section may be too restrictive and difficult to achieve; especially for the handling scope. Therefore, we suggest removing "formal" and "directly" from this regulation to provide more flexibility for certifiers to determine applicable expertise of personnel.

- *i.* 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, related fields, or relevant organic production and handling that directly relates to assigned duties.
- c. **§205.501(a)(6)-** Certifiers appreciate the ability to share the on-site evaluation report as well as contract with personnel to perform them. Thus, we suggest the following revision to clearly permit this in the regulation.
 - i. 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 or review the report from observation of 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 qualified persons as designated by the 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.

II. Answers to AMS Questions:

1. Is 20 training hours a year an appropriate amount of continuing education for organic inspectors and certification review personnel?

We do not feel that 20 hours should be stipulated in the regulation; instead, annual training should be required.

2. Should organic inspectors be evaluated on-site more frequently than once every three years?



The regulation should not indicate more frequently since it already does clarify that certifiers have the discretion to evaluate more frequently when necessary according to risk.

3. Should any other types of knowledge, skills, and experience be specified?

The <u>ACA Guidance on Organic Inspector Qualifications</u> describes skills and areas of expertise that should be specified. These include observation skills, communication skills (Interviewing, documenting/writing, and active listening), intermediate math skills, organization and time management, information management, investigative skills, sampling procedures, and skills specific to the inspection scope (crops, livestock, and handling). It also includes recommendations for prior experience and training. The ACA supports the skills specified in this guidance document.

Section (9) Oversight of Certification Activities

The ACA supports strengthening NOP oversight and enforcement of certifying agents and our activities. We do not support the revision at §205.640, which is not explained, so the impact of this revision is unclear. We offer minor comments to clarify the proposed language at §205.2 and §205.501(a)(22).

I. Definition:

- a. **§205.2 (Certification Office)-** The ACA requests a revision of the proposed language at §205.2 to exclude remote staff working from home from the definition of certification office if oversight activities are not occurring at these home locations.
 - i. Certification office. Any site or facility where certification activities are conducted, except for home offices and certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.

II. Standards:

- a. **§205.501(a)(22)-** The ACA proposes the addition of the word "satellite" to convey that only satellite certification offices, not main offices, can and should notify AMS no later than 90 calendar days after certification activities begin.
 - *i.* Notify AMS not later than 90 calendar days after certification activities begin in a new satellite 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.
- b. **§205.640-** The ACA does not support the revision to strike "accreditation" from §205.640. This proposed revision is not explained, and therefore, the ACA is concerned about the impact of this change.



Section (10) Accepting Foreign Conformity Assessment Systems

The ACA appreciates that the NOP is proposing to codify the acceptance of foreign conformity assessment systems. We do request clarification on whether the NOP will continue entering into recognition agreements. Also, we would like to acknowledge the need for greater transparency of data in regards to foreign governments with equivalence determinations. These equivalence determinations should include an assessment of the foreign country's system of data collection and reporting. Currently, organic producers and handlers certified to an equivalent foreign country's system do not provide the same level of data transparency as USDA certified organic operations listed in the OID. Information on certified operations (organic certificates) and certifiers (accreditation documents) should be available and comparable to the NOP Organic Integrity Database.

Section (11) Compliance—General

The ACA thanks the NOP for clarifying compliance at §205.660, and we especially appreciate the thorough language at §205.660(c). This specification that an enforcement action can be initiated against any violator of OFPA is important because it conveys that a noncertified status does not protect an operation that commits organic fraud from enforcement action. The proposed language at this section aligns with OFPA and current practices at the NOP. We offer one minor comment on §205.660(e), which was not revised in the proposed rule but could be updated to allow for certifier flexibility:

I. Standards:

- a. **§205.660(e)-** In practice, certifiers are using a combination of certified mail, priority mail, and registered email. We suggest rewording to "documented delivery confirmation" in order to remove the requirement for signatures and allow this flexibility.
 - i. Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts documented delivery confirmation.

Section (12) Noncompliance Procedure for Certified Operations

The proposed changes at §205.100 and §205.662 clarify that it is not only an operation but any person who is responsibly connected to an operation that may be subject to a suspension of certification, civil penalties, or criminal charges if they violate OFPA or the USDA organic regulations. While we support this change, we recognize the difficulty in identifying and tracking every responsibly connected party. In addition, this section proposes changes at §205.662(e), (f), and (g), but the ACA proposes that the language in §205.662(d) also be updated to include responsibly connected persons. Without this change, the rule will not effectively address enforcement.



I. Standards:

- a. §205.100(c)- The ACA has concerns about the difficulty in identifying all responsibly connected persons. Responsibly connected is defined at §205.2 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. Is a consultant that works with many different operations considered responsibly connected persons? They may be performing management activities and/or making management decisions. Identifying and tracking all responsibly connected persons will take a lot of additional time. We do not have this data tracked currently, and it is not currently easily searchable in the Organic Integrity Database. In addition, the current practice of removing operations from the Organic Integrity Database could present issues in the future any data on persons responsibility connected to an operation that is removed from this database will be lost.
- b. **§205.662(d)-** The ACA proposes a revision to the language in §205.662(d), which would include responsibly connected persons. Without this change, the rule will not effectively address enforcement. This change is meant to clarify that a responsibly connected person sent a notice of proposed suspension or revocation may have other certifications revoked, if they are responsibly connected to multiple organic operations.
 - i. Willful violations. Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation or a person responsibly connected with an operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation or the person responsibly connected with the operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.
- c. **§205.662(e)(3)-** While we agree that the Organic Integrity Database should be updated quickly in the event of a notification of suspension or revocation, the ACA is concerned that such a short amount of time will create an unnecessary burden for certifiers, and will lead to a focus on getting things done in the time frame rather than verifying that proper procedures were being followed. Certifiers have seen this first hand with COR accreditation audits that have similar requirements. The ACA requests that the requirement to update ORGANIC INTEGRITY DATABASE be lengthened to 10 business days.
 - *i.* Within 3 10 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 ORGANIC INTEGRITY DATABASE (OID).
- d. **§205.662(f)(1)-** The phrase "or submit a request for eligibility to be certified" is not explained in the preamble. The ACA is understanding this clause to refer to a responsibly connected person who is starting a new operation; in this case, he or she



may need to submit a request to determine whether he or she can start the new operation with or without requesting reinstatement. If this interpretation is correct, we request that it is stated in the regulation. Furthermore, it is not clear who is determining eligibility or what procedures are used to determine this. We suggest revising NOP 2605: Reinstating Suspended Operations to include this process.

Historically, we have also seen an inconsistency between reinstatements for suspensions, and revocations; when certification is revoked, the person who was connected to a revoked operation is ineligible for certification for a period of 5 years, but when certification is suspended, a responsibly connected person may create a new legal entity to certify immediately. It is not clear if the person responsibly connected to a suspended operation has to request reinstatement of certification if they were to start a new legal entity for certification. We suggest addressing this scenario in the regulations.

- i. A certified operation or a person responsibly connected with an operation whose certification has been suspended under this section 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 if a responsibly connected person requests certification of a new entity. 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.
- e. §205.662(g)(1)- The reference to (xxxvii) is incorrect; §205.662(g)(1) should reference (xxxvi): "Civil penalty for knowingly labeling or selling a product as organic except in accordance with the Organic Foods Production Act of 1990, codified at 7 U.S.C. 6519(c), has a maximum of \$18,730." We suggest simply referencing 3.91(b)(1) rather than (xxxvi) in case this reference changes.
 - 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.

Section (13) Mediation

The ACA appreciates the updated language on mediation at §205.663; we agree that it is more readable and that it more clearly explains how mediation may be used in noncompliance procedures. The preamble discusses informal mediation, and the ACA agrees that the regulation or separate NOP guidance should allow for this and include a process for conducting informal mediation. We also make two minor suggested edits below.

I. Standards:

a. **§205.663-** The proposed language requires that a request for mediation must be submitted within "30 calendar days of receipt of the notice…", but it also requires that a rejection must include the right to request an appeal within 30 calendar days of the



date of the written notification. The ACA suggests a revision to align these two timelines and avoid confusion. We also suggest replacing "a mediation session" with "mediation."

i. (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 after the date issued 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.

Section (14) Adverse Action Appeal Process—General

The ACA supports the expedited appeals process that results from the changes proposed at §205.680 and §205.681. We suggest a minor revision to language regarding the delivery service used to send communications during an appeal preceding, and we suggest a timeline in which NOP should be required to make a decision on an appeal to allow for due process.



I. Standards:

- a. §205.680(f)- Currently, the proposed language requires that all written communications between parties involved in an appeal proceeding must be sent via a delivery service that provides dated return receipts. We suggest replacing the requirement for dated return receipts with "documented delivery confirmation," to allow flexibility in using different delivery methods.
 - *i.* 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 documented delivery confirmation.
- b. **§205.680(g)-** We suggest that the NOP have a 60-90-day deadline to make decisions on appeals. It is critical that appealed decisions are made in a timely manner so that certifiers are aware of the decision. It becomes an integrity issue when appeals are ongoing for extended periods of time and products which may not be in compliance are continued to be produced and sold.

Section (15) Adverse Action Appeals Process—Appeals

The ACA appreciates revisions to §205.681 that revise and clarify appeal procedures. We support the revisions themselves and support that they will facilitate quicker appeals process for the NOP. We suggest one minor revision below.

I. Standards:

- a. **§205.681(c)-** We recommend replacing "receipt" to "date issued" for clarity and consistency with our suggested language at §205.663.
 - *i.* Filing period. An appeal must be filed in writing within the time period provided in the letter of notification or within 30 calendar days from receipt date issued 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.

Section (16) Grower Group Operations

The ACA recommends that certifiers be accredited to specifically offer Grower Group certification. Auditing an internal control system requires specific skills and guidance. Regulatory language should clearly state the internal control system is inspected in lieu of inspecting individual operations in order to be certified as a grower group. The ACA has concerns about the proposed language and questions about its limitations. For instance, would grower group certification be limited to countries outside the USA? If grower groups are permitted in the United States, could this allow for corporate grower groups or subcontractors? Certifiers have concerns that this could allow large corporate growers in the USA to apply for grower group certification when they can afford individual certification; which would pose a risk to organic



integrity. If allowed, it would negate the original intent of grower groups being restricted to developing countries. Thus, what authority would certifiers have to reject certification of grower group applications deemed inappropriate? While we did not come to consensus if any specific limitations should be imposed on scale, we acknowledge that operations that have the resources to obtain their own certification should not be permitted to seek certification as a grower group. Furthermore, while we did not come to consensus on whether to restrict the grower group certification to the crop/wild crops scopes, we do want to acknowledge the potential impacts of excluding livestock. For instance, excluding livestock will exclude beekeepers and honey as there are no apiculture specific standards, but we recognize that the publication of apiculture standards is needed before we consider certification will negatively impact currently certified honey producer grower groups. Below we summarize our recommendations and requested clarifications for each definition and standard within this section.

I. Definitions:

- a. **§205.2 (Grower group member)-** The definition may be misinterpreted as a single crop and/or wild crop instead of a multi-crop system. Therefore, we recommend rewording the standard for clarification. Also, we suggest replacing "person" with "individual" to prevent confusion with the defined term of person.
 - *i.* Grower group member. <u>A person An individual engaged in the activity of</u> growing or gathering a crops and/or wild crops as a member of a grower group operation.
- b. **§205.2 (Grower group operation)-** We suggest removing a "single producer" and replacing it with "person" to be in line with the definition of person. We also recommend indicating production units in the definition to ensure that geographic proximity criteria apply to individual members and/or grower group members within a production unit. Operations may have multiple production units distributed over a large distance, where geographic proximity to the established production unit (the unit of ICS control) is possible and not necessarily to the ICS central office. This aligns with the grower group production unit definition and what is set forth by §205.201(c). We also advise adding "as approved by the certifier" after geographical proximity because this is not clearly defined. Certifiers would like guidance or a list of criteria to help determine geographical proximity. Finally, we recommend revising the wording to make it clear that a grower group operation can include multi-crop systems.
 - *i.* A single producer person consisting of grower group members and grower group production units composed of members within geographical proximity as approved by the certifier, governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation for crops and/or wild crops.
- c. **§205.2 (Grower group production unit)-** We advise revising the language in this regulation to ensure consistent implementation. Using the term "similar" is vague and



grower group operations should be using "shared" practices and resources to grow crops and/or wild crops as approved in their organic system plan.

i. A defined subgroup of grower group members in geographical proximity as approved by the certifier as a part of a single grower group operation that uses similar shared practices and resources to grow or gather crops and/or wild crops listed in the Organic System Plan

II. Standards:

- a. **§205.201(c)-** Further clarification is needed about internal auditors and conflict of interest. For instance, some auditors may have family members within the grower group and may not have the resources to hire outside auditors to ensure no conflicts within the entire group. Also, more guidance is needed on reporting noncompliances to the certifying agent. Generally, minor non-compliances are addressed by the ICS and verified by the inspector on site, whereas major non-compliances are reported to the certifier.
- b. §205.400(g)- We suggest rewording (1) and (2) for added clarity. Also, we recommend that the term "inspector" be changed to "auditor." The definition of inspector per §205.2 is "Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations." Internal inspectors should have training to conduct organic inspections as required for managing an internal control system.
 - i. In addition to paragraphs (a) through (f) of this section, a grower group operation must: (1) Be a single producer Grower group members organized as a person; (2) Sell, label, or represent only the scopes of 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.

- c. §205.403(a)(2)- More clarification is needed about conducting audits of the ICS and the ICS inspectors. The regulation should indicate the minimum number of audits required. The focus should be on witnessing the internal auditors which is key to a functioning ICS. At least 25% should be witnessed especially because of turnover. Moreover, since a production unit could have hundreds of individual members, the production unit should be the unit that is sampled rather than the entire grower group. That will ensure that the sample is more representative and distributed throughout the grower group. Also, the certifier, not the ICS, should determine what members are considered high risk (§205.201(c)(4)). This is consistent with the EU standards which expect certifiers to determine risk of members and perform these assessments. More guidance and clarification are also needed for determining risk which is listed in the preamble but not in the regulation.
 - Initial and annual on-site inspections of a grower group operation as defined in i. §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(q)(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 per production unit. This must include an inspection of all grower group members determined to be high risk according to criteria in §205.201(c)(4) as determined by the certifying agent. The certifying agent should also select members from across the risk spectrum—including lowerrisk 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). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.

III. Answers to AMS Questions:

1. Should there be limits on gross sales or field sizes of individual grower group members? If yes, please describe these limits.

The ACA was unable to reach consensus on what, if any, limit should be placed on gross sales or field sizes of individual grower group members. While we did not come to consensus if any specific limitations should be imposed, we acknowledge that operations that have the resources to obtain their own certification should not be permitted to seek certification as a grower group; such that would allow for corporate grower groups or subcontractors especially in the USA.



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.

The ACA was unable to reach consensus on what, if any, limit to the maximum number of members should be allowed in grower group operations or in a grower group production unit.

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.

The ACA was unable to reach consensus on what, if any, limit to geographical distribution of members should be, thus we request guidance on this.

Section (17) Calculating the Percentage of Organically Produced Ingredients

The ACA appreciates the added clarification at §205.302(a)(2) regarding calculation of concentrates and reconstitution. We also appreciate the intent of the NOP to clarify §205.302(a). Current language at this section of the regulations is unclear regarding whether water and salt are to be excluded from each ingredient in the formulation when calculating organic percentage, or only when added as ingredients to the final formulation. However, the ACA agrees that the proposed language does not adequately clarify this question. In addition, the proposed language does not seem to match the intent expressed in the preamble, which states that "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 to the final formulation are excluded when calculating the percentage of organically produced ingredients. However, the proposed language may be interpreted to require exclusion of water and salt within each ingredient. The ACA requests clearer language addressing the exclusion of water and salt from each individual ingredient to aid in consistent interpretation.

In addition, we would like to note that many certifiers currently only exclude water and salt added as ingredients to the final formulation, not water and salt within each ingredient. Requiring the exclusion of water and salt from each ingredient will have major ramifications on and result in product category changes for currently certified products (products currently labeled as "organic" will need to be relabeled as "made with organic (specified ingredients or food group(s))."). The ACA went into more detail about this matter in our <u>comments on NOP 5037 Draft Guidance Calculating the Percentage of Organic Ingredients in Multi-Ingredient Products and NOP 5037-1 Sample Calculation Worksheet.</u>

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To address these comments, we offer two sets of proposed changes, depending on the intent of NOP. We could not come to complete consensus, but the majority of certifiers support option 1.

I. Standards

Option 1:

- a. **§205.302(a)(1)-** We suggest revising the text to make the exclusion of water and salt added as ingredients clear in the regulation.
 - *i.* Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight of all ingredients (excluding water and salt added as ingredients to the final formulation).
- b. **§205.302(a)(2)-** We suggest language revisions similar to 205.302 (a)(1) to provide clarity.
 - i. 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 added as ingredients to the final formulation) 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.

c. §205.302(a)(3)-

i. 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 of all ingredients (excluding water and salt added as ingredients to the final formulation).

Option 2:

- a. **§205.302(a)(1)-** We suggest revising the text to make the exclusion of water and salt added as ingredients clear in the regulation.
 - *i.* Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight of all ingredients (excluding water and salt within each ingredient and water and salt added as ingredients to the final formulation).
- b. **§205.302(a)(2)-** We suggest language revisions similar to 205.302 (a)(1) to provide clarity.
 - *i.* 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 within each ingredient and water and salt added as ingredients to the final formulation) 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.

c. §205.302 (a)(3)-

i. 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 (oxcluding water and salt) at formulation by the total weight of all ingredients (excluding water and salt within each ingredient and water and salt added as ingredients to the final formulation).

Section (18) Supply Chain Traceability and Organic Fraud Prevention

The ACA appreciates the additions of ii and iii to 205.501(a)(10) which add clarity. We also support 205.501(a)(13) because of the added cooperation among certifiers. However, we have questions about the scope of the supply chain audit, the depth of auditing both certified and uncertified products, the potential administrative burden, and if certifiers have the capacity to do a complete supply chain audit. Furthermore, certifiers agree that the NOP should coordinate these investigations and funding should come from taxpayer money or congressional appropriations. Below we summarize our thoughts and recommendations.

I. Definitions:

- a. **§205.2 (Organic fraud)-** We concur that illicit economic gain should not be a part of the definition because not all fraud is illicit. For instance, marketing can be deceptive but not illicit. Also, fraud is defined as "wrongful or criminal deception intended to result in financial or personal gain." Thus, we recommend replacing "illicit economic" with "financial and personal" gain.
 - *i.* Organic fraud. Intentional deception for *illicit economic* financial and personal gain, where nonorganic products are labeled, sold, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."
- b. **§205.2 (Supply Chain Traceability)-** The ACA proposed to add a definition for Supply Chain Traceability. This term is defined in the preamble but not in the proposed regulations, and codifying it would add clarity. In addition, we request that the NOP clarify the term "source" in this definition. The preamble clarifies that the supply chain is "farm to table," so presumably the source is the "farm," although this may not be clear for some organic products such as yeast.
 - *i.* 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."



- c. **§205.2 (Supply Chain Audit)-** We request a definition for Supply Chain Audit, as specified in the preamble.
 - *i.* Supply Chain Audit. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.

II. Standards:

- a. §205.103 (b)(2)- The preamble and standard do not seem to be in alignment, specifically with the allowance for internal systems to have different language/designations as long as it is covered in their Organic System Plan. We support allowing flexibility for certified operations to use alternative abbreviations of a product's organic status on both non-retail labels and records, including but not limited to "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. Thus, we recommend if this standard is only referring to external systems then adding "transaction" before "records" would clarify this. The ACA does not intend for this addition to limit the types of records that would be required to clarify a product's organic status to transaction records only.
 - *i.* Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, including identification in transaction records of products as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," as applicable;
- b. **§205.201(a)(3)-** In the preamble, 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
 - process for reporting suspected organic fraud to certifying agents and the NOP.

The requirements of the organic fraud prevention plan should be included in the regulation or provided in a separate guidance document.

c. **§205.501(a)(21)-** We request further clarity or guidance on "supply chain" and how many steps removed from a given certified operation.



- d. §205.504(b)(4)- The ACA agrees that certification agencies must share information with one another for the purposes of certification and enforcement. We request more guidance on what our procedures for sharing information must include, such as under what circumstances this sharing of information can occur, and how validity of requests is to be assessed. The ACA created a <u>Best Practice for Cross Agency Investigation</u> earlier this year that outlines procedures for collaborative investigations among certifiers and could be used to develop this guidance to ensure consistency.
- e. §205.504 (b)(7)- The ACA requests further clarity or guidance on "supply chain" and how many steps removed from a given certified operation. We also think a definition of "credible evidence" is needed. Also, a guidance document on supply chain audits and risk would improve consistency. In April of 2018, the ACA revised its <u>Best Practices for Verifying Traceability in the Supply Chain and ACA Guidance for Risk Assessment and Follow-up</u> which could be used to develop this guidance.

III. Answers to AMS Questions:

1. Does the proposed definition of organic fraud encompass the types of fraudulent activities you witness in the organic supply chain?

The ACA does not support a definition of organic fraud that includes the term "illicit economic gain." Not all fraud is illicit; for example, marketing can be deceptive but not illicit. Fraud is commonly defined as "wrongful or criminal deception intended to result in financial or personal gain." Thus, we recommend replacing "illicit economic" with "financial and personal" gain.

2. Should certifying agents be required to perform a minimum number of traceback audits each year?

We do not support establishing a specific metric for the number of annual audits that a certifying agent needs to conduct, because the quantity and types of high-risk operations will vary by certifying agent.

3. Should more specific fraud prevention criteria be included in the regulation?

In the preamble, the 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
- process for reporting suspected organic fraud to certifying agents and the NOP.

The requirements of the organic fraud prevention plan should be included in the regulation or provided in a separate guidance document.

Section (19) Technical Corrections.

The ACA appreciates and supports the revisions to ionizing radiation and sewage sludge at \$205.301(f)(2) and \$205.031(f)(3); and the correct referencing of \$205.201 for standards \$205.400(b) and \$205.401(a).

Section (20) Additional amendments considered but not included in this Proposed Rule

The ACA has summarized our responses to each question below.

I. Packaged Product Labeling

1. For private-label packaged products, which certified operation(s) should be listed on the retail label (brand name/distributor, contract manufacturer, or both)?

The ACA did not reach consensus on which certified operation(s) should be listed on the retail label, but we agree that traceability of products in the marketplace is essential for detecting fraud.

2. Which certifying agent(s) should be listed?

The certifying agent of the operation that is responsible for the product in the marketplace (the certifier of the brand owner (private label)) should be listed. If the copacker is listed on the label, the certifier of that copacker should also 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)?

The certifying agent should match the operation listed on the label. This is generally a best practice that most certifiers are following. However, some certifiers think that both the private labeler and the contract manufacturer with the certifying agent of each should be listed.



4. Should listing contract manufacturers on labels be mandatory? Should it be optional?

The ACA did not come to consensus on whether listing contract manufacturers on labels should be mandatory. Currently, it is mandatory for some product categories such as meat, poultry, and dairy to have an Establishment Number which can trace back to the facility where it was processed. For other products that are not currently mandated to provide this information it is often considered proprietary, and in some instances, there could be multiple contract manufacturers operating at the direction of the certified company. Listing all contract manufacturers on the label may cause an unnecessary financial burden for certified operations that need to update labels. Finally, many certifiers feel that this would be unnecessary since the list of copackers would be captured in the Organic System Plan and allow traceability within the supply chain. However, there are some certifiers that feel strongly that contract manufacturers in addition to private labelers be listed on the product.

5. What terminology should be used to describe private-labeled organic products?

The ACA does not have a recommendation for terminology, but we do agree that any terminology used needs clear regulatory definitions.

II. Expiration of Certification

1. How might annual expiration of certification improve organic integrity? What are the limitations of requiring expiration of certification?

The ACA does not agree that expiration of certification will improve organic integrity. Currently, certified operations are certified until surrendered, suspended, or revoked. If the US were to follow the EU system and allow certifications to expire without this requirement, this may decrease the number of suspensions and mediations, and operations that do not want to be certified can just let their certificate expire. However, this would be outweighed by the extra paperwork burden of tracking the operations moving in and out of certification. This also presents a potential integrity concern. In our current system, if an operation surrenders the certifier will remind them what issues need resolution which they would need to present to any new certifier if they seek recertification. This would not happen if an operation's certification just expires. Finally, the impacts and unintended consequences of expiration of certification on the marketplace are unknown (i.e. product availability and inventory on hand).

2. What minimum requirements must be met before renewing certification?

The ACA would support a requirement for the submission of annual paperwork prior to certification renewal. We would not support a requirement for an inspection to take



place prior to renewal. That would create an increased burden and not have a significant impact on integrity.

3. Could an operation with unresolved adverse actions renew certification?

Unaddressed adverse actions and noncompliances should prevent renewal, but unresolved adverse actions and noncompliances could mean that the adverse actions or noncompliances are in process and should not affect renewal.

4. 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?

Allowing a grace period for expiration of certification seems to be equivalent to the system we currently have. It would likely result in a similar paperwork burden and the degree to which it would address integrity would not change.

5. What process should exist for an operation to regain organic certification should it allow its certification to expire?

Once expired, the ACA agrees that the operation would need to reapply and go through the entire process. However, there would need to be a way to track any unresolved adverse actions that were present in their previous certification; otherwise, this system could lead to operations switching certifiers to avoid addressing adverse actions.

6. Should certifying agents notify certified operations of their upcoming expiration of certification?

Certifiers feel that is a question of customer service and should not be a regulatory requirement. Most certifiers would do this for the customer service reasons; reminders are common practices in our current system.

III. Fees to AMS and Oversight of Certifying Agents' Fees

It is difficult to address this section, which is extremely vague. If the intent of this is to raise accreditation fees, then the ACA does not support this. We understand and fully support the need for robust funding for the NOP, especially in compliance and enforcement activities, but do not agree that accreditation fees should be the primary source of funding. Since the NOP is a federal program under the USDA, funding should primarily come from congressional appropriations. Certifiers are best suited to handle much of the compliance and enforcement work with regards to investigations and sampling. Increasing accreditation fees will result in higher certification costs. For the same reason, if the intent of this section is for the USDA to charge fees to organic operators directly, we also do not support this, because we do not want inequitable access to organic certification with small



and medium scale operations being pushed out of the industry because of unaffordability. This will have a negative impact on consumer perception of organic agriculture and the industry as a whole.

- IV. 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?

As noted throughout the comment sections, ACA's will need greater clarity in several areas.

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).

The ACA concurs that 1 year is not sufficient time to implement all of the proposed changes. We suggest a phased approach, with a 1-year implementation for some items and 2 years for others. We feel this would be more appropriate and spread the cost over a 2-year time period. However, if the NOP were to accept some of our comments, we may be able to implement the new regulations more quickly.

Suggested items for 1-year implementation period:

- NOP Import Certificates
- Unannounced inspection
- Continuation of certification (OSP update, annual inspection)
- Annual performance evaluations
- Notification of new certification office
- Mediation procedures
- Adverse action appeals

Suggested items for 2-year implementation period:

- 20-hour training programs + inspector qualifications
- Generating certificates in OID
- Maintaining and updating current list of operations in OID for any potentially new data fields (while some updates to the OID may take 1-year, other updates may take 2 years)
- Certification for all operations that are no longer exempt/excluded
- Supply chain traceability. This includes updating OSPs, collecting this information from clients, approving OSPs, etc. for certifiers to conduct full supply chain audits.



- Labeling of non-retail containers (label use-up for some clients). Informing clients of changes, label approvals, updating databases, etc.
- 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.

We feel that the estimated cost to certifiers are extremely low. Proposed changes will affect the following areas, which will increase costs for certifiers:

- Fraud prevention procedures
- 5% unannounced inspections (the analyses suggest that 2.5% of those would satisfy the annual inspection requirement, but this is not the case for all certifiers)
- Certificate implementation
- Inspector evaluation cost
- Training for all personnel inspectors and reviewers
- Finding sufficiently trained inspectors
- Increase in the number of operations that need to be certified
- Supply chain traceability audits will require hiring additional staff in order to complete these. May need staff dedicated to performing these audits in some cases. These audits take a lot of coordination among other certifiers and within the certifier to gather the correct information.
- Additional OID uploads and data management
- 4. 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?

The ACA is in agreement that for most certifiers, the cost of certification would need to be increased. Increasing cost share could help cover those increased certification costs. Generally, sampling and unannounced inspections get wrapped into the overall certification services and are not charged to the individual clients. Some certifiers, however, will charge for the inspection to cover the cost of the investigation if a sample comes back positive. Because certification fees will increase, taking a phased approach may help to spread the costs over years and not have an as significant impact on producers.



The Accredited Certifiers Association greatly appreciates the intensive work that went into creating this proposed rule for Strengthening Organic Enforcement. We strongly support the intent of this rule as it will benefit the organic industry with much needed oversight. As certifiers, we want to uphold the standard and ensure consistent implementation and thus have made the above recommendations and requests for clarification. We appreciate your consideration of our comments.

Sincerely,

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