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USDA-AMS-NOP
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Washington, DC 20250-0268

Submitted via Regulations.gov.

RE: AMS-NOP-17-0065; NOP-17-02, and/or Regulatory Information Number (RIN) 0581-AD09
Strengthening Organic Enforcement Proposed Rule

Dear Dr. Tucker,

MOSA Certified Organic appreciates the opportunity to provide comments to the National Organic Program regarding the proposed rule for strengthening organic enforcement. MOSA was established in 1999 before the National Organic Standards were yet developed and was among the very first USDA-accredited certification agencies. Today, with a staff of 36 located in five states and over 50 independent inspectors nationwide, we certify approximately 2200 operations throughout the United States representing a broad spectrum of stakeholders in the organic industry.

MOSA strongly supports the intent of strengthening organic enforcement through the proposed rule changes. We have often offered comments to USDA noting how strong enforcement makes for a strong, viable and financially successful organic label. However, the impact of this rulemaking on our organization and client stakeholders is significant and we believe the NOP has grossly underestimated the financial impact it will have on certifiers, independent inspectors, certified operations, the NOP itself, and ultimately organic consumers. Comments below detail areas of support, question and concern.

In addition to the questions following each topic below, 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?

The significance of the proposed regulatory requirements makes it difficult to answer this question. There are many requirements that are crystal clear that we already have implemented or support, but there are also many requirements that are not clear and need further clarification or revision in order for us to readily determine how to comply. These are noted below in our comments on each section of the proposed rule.

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).

One year for full implementation of the proposed changes is not sufficient. We recommend a phased in approach that spreads requirements out over a two or three year period. We think the proposed regulatory changes will certainly impose a cost to MOSA of *greater than 1%* of our annual revenues. To help mitigate some of the costs associated, we propose the following implementation period based on the topics and relative ease of implementation.

Suggested items for one-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 two - three year implementation period:

- 20 hour training programs + inspector qualifications
- Generating certificates in OID
- Certification for all operations that are no longer exempt/excluded
- Supply chain traceability/fraud prevention
- Maintaining current list of operations in OID
- Labeling of non-retail containers (label use-up for some clients)

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.

After evaluating the full Economic Impact Analysis, we were dismayed to find that, in our own analysis, it almost universally underestimates the cost and time burden of implementation and operationalization of these measures for MOSA. Since we are working with a 60-day turnaround to submit our comments we do not have the capacity to run calculations for every new process, but with the work we have done, we have found that **AMS has underestimated costs by over $252,000**. Our full response to the economic and human capital impact to SOE can be found in MOSA's SOE Information Collection and Recordkeeping requirements comments, but some examples of the more egregious underestimates we have found are underlined, **bolded**, and in **red**, below:

- Under "Costs for Reading and Comprehension of Rule section of the Economic Impact Analysis", page 53, we note that the AMS has estimated 4.54 hours (or $208.43) to be spent by certifying agents to read and comprehend the proposed rule. We disagree;

MOSA *conservatively* estimates that six Certification Services Managers have spent at least 250 hours reading, analyzing, discussing, and preparing these comments, which translates to nearly **$11,478** - without implementing a single thing. This is more than the AMS estimate by $11,269.57, and we will need to repeat this process if/when the final rule is published.

- On Federal Register page 47578 #6, AMS estimates one hour ($45.91) to document fraud prevention procedures. Documenting procedures is a small part of the process. By our analysis, the one hour assigned by AMS has been underestimated by 1807 hours (**$83,005**), as implementing fraud prevention procedures is more than just documentation; it also includes:
    - Updating OSP forms (eight hours = **$367**)
    - Training certification review staff (one hour x 15 staff = **$6887**)
    - Communicating to and receiving information from clients (30 minutes x 2200 clients = **$50,501**)
    - Certification review for approval (15 minutes x 2200 clients = **$25,251**)

- Currently, our first-time estimate of an upload to INTEGRITY, which by necessity will be performed by IT staff is 10 minutes x 2200 files= **$16,834**. AMS estimates this work could be done by lower-paid administrative staff, but because of issues with INTEGRITY's capabilities (detailed below) MOSA requires IT staff to complete this work. The difference is $23,511.

- Federal Register page 47579 #12 speaks to 20 hours of training for all personnel. AMS does not seem to recognize due to labor laws certifiers are not able to provide independent inspectors with training. The cost burden of training will fall on the inspectors themselves; twenty hours of training translates to $1300 per year per person; for MOSA's 50 independent inspectors, that comes to **$65,000**, which is magnified when you include all US-based independent inspectors. Inspectors will be spending their training time without reimbursement. We believe the cost they incur will ultimately be passed along in increased inspection fees.

- Federal Register page 47582 discusses the annual paperwork impact and calculates it to be $948.43. We recognize that the pay rate of $28.45 is based on Occupational Employment Statistics group 45-2011, Agricultural Inspectors. However, that is much lower than the rate for the inspectors with which we work; although the rate of independent contractors varies, and we are not able to pay an hourly rate due to labor laws, our calculated average is approximately $65/hour.

  Using the AMS estimate of 33.34 labor hours, the annual paperwork impact per inspector would be $2167 and for staff it would be $1530. For MOSA's 50 independent inspectors and 12 staff inspectors, that comes to **$126,710 annually**.

- Federal Register page 47587 #4. No cost was assigned by AMS to certifiers regarding the

proposed changes to nonretail labels, but we feel this is an error and changes would have a significant financial impact. We anticipate this would add an additional 30 minutes of inspection and review time for clients with nonretail labels. Our clients in total have approximately 1220 nonretail labels and if half of those (610) have to be reconfigured, that will be **$14,006**.

- No cost was assigned by AMS to the section on calculating the percentage of organic ingredients. Depending on the clarification that is intended, revisions could have potential impacts on how our clients calculate the percentage of organic ingredients they use. The organic eligibility of some products may be impacted, requiring label changes to be made. Impact to clients and certifiers may be significant if calculation methods change.

- One final thought on the impact of SOE; no new rule ever simplifies the processes of certifiers, inspectors, or certified operations. Increased regulatory burdens on certifiers lead to increased costs for organic operations and ultimately consumers. With this rule, we can categorically state that the additional financial and time burdens would be significant.

  The burden is felt throughout our entire organization; the burnout felt by reviewers as their work becomes increasingly detail-obsessed, the burden of MOSA as we stay in alignment with the NOP in our systems, paperwork, IT, and training, the burden felt by our inspectors who are spending an increasing amount of time on paperwork, the burden felt by certified operations who are spending more time recordkeeping, documenting, and tracking paperwork, and who are paying more for certification because the certifier and the inspector are trying to remain profitable.

  Strengthening organic enforcement is important, but we are asking for respite, too.

4. Are there alternatives to regulations, or less stringent requirements, that could achieve the same objectives as this proposed rule?

Moving guidance documents out of draft, and use of NOP oversight to assess adequacy of certifiers' audit processes are two examples of alternatives to regulation. For example, instead of adding a specific number of trace-back audits to the regulation, the NOP could review certifiers' processes for identifying high-risk and other operations requiring a track-back audit. In general, we'd recommend that NOP bolster audit procedures and practices to ensure that certifiers are performing the job that is expected.

Alternatives to Federal Register regulation could include improving NOP Program Handbook documents, which are regarded by certifiers as NOP's interpretation of the NOS. We ensure that we follow Program Handbook documents, and the NOP evaluates our compliance with regard to the various applicable documents. We appreciate this system and encourage that it continues, and becomes more robust. Guidance documents and instructions provide the benefit of more

explanation, bringing clarity to the nuances. Such detail may not be practical to add to regulatory text. A few documents that could be evaluated and revised are listed below, but the Handbook sections B through to the end could be evaluated and revised as applicable. Many of the topics covered in this rule are covered in the various guidance documents, instructions and policy memos.
NOP 5031 - Certification Requirements for Handling Unpackaged Organic Products
PM 11-10 - Certification of Grower Groups
NOP 5037 - Calculating the Percentage of Organic Ingredients in Multi-Ingredient Products: Draft Guidance
NOP 2601 - The Organic Certification Process
NOP 2000 - General Accreditation Policies and Procedures

ACA Best Practices documents on related topics could also be revised and "approved" by the NOP in a more formal way, or developed into additional NOP Program Handbook documents.

As we consider the breadth of these proposed requirements, we wonder what, if anything, can we let go of? We want increased organic integrity but that also must be practical. For example, we wonder whether the reference to "production unit" in current §205.403(a)(1) can/should now be viewed in the context of the new proposed definition for Grower group production units. We have been interpreting this to require annual inspection of each field (NOP2601 The Organic Certification Process), but often that only adds time to the inspection without the benefit of improved compliance assessment. Through the use of risk-based assessment tools, can we remove the requirement of seeing every field every year, specifically for updating clients? As we are asked to add more layers to the certification process, we wonder what role risk assessment can play in lightening burdens in other areas. Clients and certifiers alike feel that organic certification becomes more complex, time consuming, and costly each year and this does not necessarily result in greater organic integrity.

5. How will certifying agents cover the costs of additional actions required under this rule, such as the required unannounced inspections and the issuing of NOP Import Certificates? Will certifying agents charge fees that are consistent for expanded handlers, brokers, importers and exporters?

Recognizing that many of our clients are in a capital deficient economy, we acknowledge that our clients will likely struggle to absorb the full costs of implementing the changes proposed in this rule. MOSA will continue to review our internal processes, looking for efficiencies through technology and other resources to bridge the gap. We are not making the assumption that brokers, importers or exporters would have a simpler certification review process, so we wouldn't expect to establish a special fee structure for these clients, or charge less than we would for other handlers. Also, we want to charge adequate fees (as noted by the NOP) and would not subsidize certification of these clients.

Proposed Amendments
Our comments below follow the sections and proposed standards, and answer specific requests for input outlined by the NOP within each section. Suggested rule edits are in *italics* and use strikethrough for deletions and underlined blue text for additions. In a separate comment letter (as requested), MOSA is addressing the NOP request for comments concerning the information collection and recordkeeping required as a result of the proposed changes.

1. Applicability and Exemptions from Certification
AMS seeks comment regarding the proposed amendments to §§205.2 and 205.100–101 discussed above, including answers to the following questions:

1. Are there additional activities that should be included in the proposed definition of handle (i.e., are there additional activities that require certification)? Are there any activities in the proposed definition of handle that should be exempt from certification?

We have noted several activities that should be specifically noted in the proposed definition of Handle:

- "Transloading" of bulk commodities should be specified, especially since the proposed new §205.101(e) exempts operations that only "load" but do not alter products.
    - Certifiers have concurred that transloading needs to be certified, but we've heard an argument that transloading is a subset of transport.
- The proposed definition could include "splitting," as opposed to just noting "combining."
- This might also be a place to help clarify whether brand holders (that work with private labelers/copackers) must be certified.
- "Importing" and "exporting" should be included in the definition of handling.

The more robust the definition, the less confusion stakeholders will have.

We support the revised definition as suggested by the Accredited Certifiers Association: *Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitate sale or trade, exporting or importing, brokering, opening, packaging, repackaging, sorting, treating, closing, enclosing, labeling, relabeling, combining, containerizing, splitting, storing, receiving, private labeling, transloading, or loading.*

One activity that should specifically be exempt from certification is milk hauling from multiple dairy operations to a handling facility.

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

We'd suggest a specific exemption for restaurants or retailers with local delivery services, and for independent delivery services, such as Ubereats and Instacart.

3. 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 at §205.101(c)-(d). Also, uncertified retail operations should follow the labeling requirements at §205.310 and §205.308 & §205.309 (including bulk labeling by retailers). And, we'd like to see further clarification that retailers applying the USDA Organic Seal must be certified.

4. Activities at ports may present a threat to the integrity of organic products due to the multiple types of handling activities performed in these locations. It is common for independent operations to perform specific physical handling activities within a port (e.g., loading, unloading, or transfer of packaged, unpackaged, or bulk organic product). The proposed rule would require certification of these operations, who are often contractors. What other activities performed at ports should require certification and why?

See our note regarding improvements to the definition of handler (above), which includes "transloading" and addresses loading, unloading, transfer, combining and splitting. It is not apparent in the proposed rule whether loading, unloading, or transfer of packaged, unpackaged, or bulk organic products at the port would require certification. Some of these activities may fall under the proposed exemptions at §205.105(e).

§205.2 Definitions for Handling, Handler, and Handling Operation

- It is not always clear what scopes on certificates are most appropriate for farms, since most farms are involved in some sort of routine on-farm handling, such as post-harvest preparations for sale of farm products. We recognize that most farms are also handlers, but it does not make sense in most cases to require additional scope-specific organic system plan forms.
- The term "handling operation" is used in the section of the proposed rule which describes exemptions. As such, the last part of the definition for "handling operation," beginning with "except…," can be dropped. We also would suggest combining the definitions for "handler," and "handling operation." One synonymous term may be more clear.
- This revised definition will require brokers and traders who buy and sell organic products to be certified. We support this change, but caution about its impact on existing organic equivalency arrangements, which typically require that products traded under the arrangement be produced or packaged in the US or the other country that's part of the arrangement, making compliance with the terms of the equivalency arrangements not possible for some brokers/traders. However, for supply chain traceability, the broker/trader selling the product should be listed on the export certificate, and that's only possible if the equivalency arrangements allow a broker/trader to export product without country of origin restrictions. This disconnect should be addressed.

§205.2 Definition for Retail Operation - We appreciate this simpler definition but have some questions and concerns, noted below, about the breadth of the certification exemption for retailers.

§205.100(a) For certified organic operations that receive products from uncertified, non-exempt handlers and subsequently label the products as organic, used as feed for organic livestock, or used as ingredients for organic products, the explanatory text says these operations are in violation of the USDA organic regulations, and may be subject to adverse actions and possible civil penalties.

Certifiers will require reasonable guidelines for enforcement, beyond the implementation date or effective date for the final rule. We generally would not expect to issue an adverse action without some sort of intermediate enforcement steps, such as conditions for continued certification or noncompliances identifying violations and enabling correction. Then, if not corrected in a timely manner we would move to adverse action. We suggest an implementation period for all suppliers to come into compliance.

We question whether certification will be able to be completed within the year implementation period for all new types of operations, like exporters, that will be required to be certified.

§205.101 Exemptions from certification - We appreciate the elimination of the similar but confusing dual exemption and excluded terms. We also support the approach of adding introductory paragraphs, as in this section, for better overall understanding of the rule.

In general, we assume that exempt operations can still choose to seek certification, but this does not seem to be specified in the proposed rule.

§205.101(a) - We find it interesting and possibly problematic that the sales exemption remains $5000. We understand this level is rooted in OFPA so can't readily be adjusted. Adjusting this for inflation may enable more organic accessibility for smaller operations, without affecting the strength of the proposed rule. Small operations can be challenging/time consuming to certify and we find that their certification costs are subsidized by certification fees paid by larger operations. In other words, though we certainly appreciate smaller operations' contributions to the organic movement, certifiers may lose money when operations are required to be certified but can't be burdened by average certification fees.

§205.101(b) - We support the change to simpler language in this part of the proposed rule. In part, the current regulatory text noting "raw and ready to eat" has been confusing. This new simplified definition clarifies that the only retail operations exempt from certification are those that do not process, which includes all of the terms identified in the definition of processing. Retailers that split, label, and package products are required to be certified organic.

It's our understanding from the Retail Exemption Flowchart that not all activities that occur in and around a retail setting are exempt. The flowchart helps to clarify some long-standing

questions about which aspects of retail processing (as defined in **§**205.2) might need to be certified. For example, it affirms that a retailer acting as a processor and distributor (other than to the final consumer) must be certified. However, if "virtual transaction" describes any form of transaction that does not occur in person (e.g., telephone, mail-order, and/or online sales), then the proposed rule must be more clear regarding whether virtual retail transactions with a final consumer are exempt or are required to be certified. Consider the implications of this clarification as we see (pandemic aside) more stores/restaurants offering local delivery services to final consumers. Our recommendation is that such activity should NOT categorically require certification. We appreciate when exempt operations choose certification, but we'd note that certification of stores and restaurants can be challenging and oftentimes cost-prohibitive, with variables such as frequently changing menus/products and widely varying activities in different store departments.

§205.101(c) - The language "provided that the products are processed onsite at the point of sale to the final consumer" makes it seem like all virtual sales are required to be certified. The explanatory text says in part, "This means that the products must be processed and sold in the same physical location. An operation processing a product for sale at another site would require certification. This would include retailers that sell virtually; the organic products which they sell, label or represent as organic must have been produced and processed by certified operations." We support what seems to be the intention, that most processed products sold by retailers to buyers at other locations must have that processing be certified, but we request additional clarification. Simple delivery from a brick and mortar retail establishment directly to a final consumer could still be exempt without affecting our organic label. That said, there also seems to be a reasonable line somewhere between local store deliveries and major national direct-to consumer distributors such as Amazon.com. Considerations could include use of third-party transport/distribution to a consumer, or length of a distribution chain. Fairly-direct delivery service like UberEats should be exempt. We'd aim to ensure integrity without inordinately affecting consumer access to organic products. We would additionally note that sometimes small handling operations may purchase ingredients in small quantities from exempt retailers (such as their local grocery store or an online source), and we have found that, while the ingredients are adequately identified as organic on the product labeling, it may not be possible to fully trace back the supply chain for such products back to the source. The phrasing regarding the point of sale to the final consumer should not prevent risk-based assessment.

§205.101(e) - We have some uncertainty about the breadth of this exemption and request that the proposed rule provide more clarity on what is intended. Explanatory text nicely defines transport as, "the movement of products in commerce; any activity that alters an agricultural product during transport would qualify as handling, and would require certification. Other activities that could occur adjacent to transport include, for example, combining, splitting, containerizing, packing/repacking, treating, sorting, opening, enclosing, or labeling/relabeling. These activities are handling and would require certification." But it may not be fully clear what is required to be certified as we're presented with transport scenarios. For example, is a person picking up hay from two neighbor farmers on the same trailer "combining," and therefore required to be certified? The answer may depend on who is managing that activity. If the hay

hauler is a broker, then they would need to be certified. Or, milk haulers "combine" "loads" of milk when they "receive" the farm pickup. So the question here is whether or not milk haulers are exempt. They certainly meet the proposed definition of handler but we recommend they be exempt. For transport scenarios, some explanatory examples may help. These could be similar to the explanation for storage locations, which notes, "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." In this section of the proposed rule, we also would suggest that the text says "process or handle," instead of "process or alter." That would more clearly define a certification requirement for brokers or other activities addressed under the proposed new handler definition.

§205.101(f) - This mentions records required in subparagraphs (a)-(d), but records are only specifically noted in (c) and (d) in the proposed regulations. The same recordkeeping requirement as specified in (c) and (d) should be added to (a), (b) and (e) and (f) revised to include all records in (a)-(e).

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

1. Is the 30-day timeframe for certifying agents to review and issue an NOP Import Certificate appropriate? Why or why not?

We feel that the import certificate should be present with the shipment at the port of entry.

2. How could the mode of transportation and frequency of shipments affect the use of the NOP Import Certificate?

Different modes of transportation move at different speeds, and in some cases (such as produce from Mexico), shipments may be packed and cross into the US in a very short period of time, so the administrative capacity needed to provide an import certificate may not be practically achievable.

There also may be tracking/certificate challenges if shipments are split between transportation vehicles.

Section Title - We have some uncertainty whether this section is appropriately titled. How should requirements within this section be addressed by persons that are certified to the USDA requirements but are located outside of the US?

§205.2 Definitions of Organic exporter, and Organic importer of record. For "importer," the definition should specify "organic handling operation" rather than just "operation," so that it connects to the new Handling operation definition (which, we also

suggest, could be combined with Handler). Also, we wonder whether this definition would impact certification requirements for NOP-certified operations located outside of the US.

We agree that organic exporters and importers of record should be required to be certified. But with proposed definitions organic, it's not clear who needs to be certified. For example, a "final exporter" that is not an owner, or 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, while the organic importer of record is defined as the operation responsible for accepting imported organic products within the United States, multiple persons may be involved in the importing process. 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.

> *§205.2 Organic importer of record. The operation responsible for arranging and taking ownership of imported organic products within the United States.*

As noted in our comments on the exemptions, some case examples would help us to better identify who needs to be certified. Some practical limitations as described below have created some uncertainty about our current policies and what would be expected under the proposed regulations. This may not be a comment on these proposed definitions, but examples below illustrate why boundaries around definitions matter. If an organic grower orders an organic seed packet from a garden center in Spain, perhaps through Amazon, is that grower considered to be the importer? Or, is Amazon the importer? Further, for small purchases like this, the supply chain may not be fully traceable.Would the garden center and/or Amazon be considered to be an exempt retailer? What if there was a similar scenario, but the buyer was ordering olive oil to be used as an ingredient in a processed product? Would that now require certification for the retailer? When would an import certificate be required? If exporters are required to be certified, does every person which sells anything overseas require certification? While MOSA is not currently certifying overseas operations, we are often challenged to determine what documentation is expected and reasonable for small-volume imports. For large, bulk shipments, examples would also help provide clarification. For example, for imported grain, is the feed mill the importer of record, or would that be the port where the grain is received?

§205.273 - We support this section but recognize that this will impact our certification work, simply by requiring more supply chain documentation. This also again raises questions about small shipments. Are some small shipments excluded from CBP reporting requirements? We also note that this is the only proposed standard that references NOP 2110. Perhaps the proposed regulations should also have a definition for NOP Import Certificate.

§205.273(a) - This section requires exporters to request an "NOP Import Certificate, or provide data through an equivalent data source," and proposed section §205.273(e) says "equivalent" refers to electronic data, documents, identification numbers, databases, or other systems verified as an equivalent data source to the NOP Import Certificate. It is not clear who verifies whether other data sources are deemed to be equivalent. We would suggest that section

§205.273(e) be referenced in all other sections that refer to an equivalent data source.

§§205.273(b) and .273(c) - We agree with the Accredited Certifiers Association recommendation and request the NOP strike the 30 day requirement for issuing an import certificate. We are uncertain about how this would dovetail with the statement noting that the NOP Import Certificate, or equivalent data, must be uploaded into the ACE system within 10 calendar days of the shipment entering the United States. We suspect these timelines might conflict in some cases. Since we'll see more import certificates and we do not yet have a reliable measure of how many imported products are received by operations we certify, we do not know what impact proposed rule changes will have on our capacity and how that might impact timelines. However, it seems these timelines would be more impactful to certifiers of overseas operations, whereas we are currently only certifying operations within the US. This is another case where our example of small purchases like a bottle of olive oil is a challenge. We don't know what documentation should reasonably be required nor how long that could take to obtain.

§205.273(d) - This proposed regulation and the explanatory text ("This proposed rule would expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin" for "all imported products intended to be sold, represented, or labeled as organic in the United States") indicates that Import certificates would apply to every import of organic product for sale.

We also would like affirmation that the verification required in the last part of this proposed section "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" is not expected to be on the import certificate, but could be separate, since treatment with prohibited substances could occur after issuing an import certificate, at the port of entry. Please note our comments above regarding examples like small purchases from online retailers. We've found obtaining full supply chain documentation to sometimes be impractical for these examples. Would a purchase of an imported, bottled product from an online retailer require phytosanitary documentation?

Lastly, where this section of the proposed rule says "accompanied by," a change to *"associated with,"* would seem more in line with NOP's intent regarding timelines. ("AMS acknowledges the concern that using NOP Import Certificates may slow the importation of organic product. Therefore, AMS is requiring that organic imports that pass through U.S. Ports of Entry be associated with, but not accompanied by, an NOP Import Certificate. This means that a shipment containing organic products may enter the United States without an NOP Import Certificate at the time of entry. However, the NOP Import Certificate, or equivalent data, must be uploaded into the ACE system within 10 calendar days of the shipment entering the United States.")

§205.273(e) - Also see related comments above under .273(a). We would suggest that examples of, or specifically-identified, equivalent data sources be listed in this section. USDA should be the organization to determine that data sources are equivalent.

§205.300(c) - We interpret that "exported for sale" includes imported products used as ingredients by certified clients. That said, we have noted concerns above with examples like small on-line purchases.

3. Labeling of Nonretail Containers.
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.

MOSA generally supports the proposed changes to §205.307 which simplify and strengthen the standards for nonretail container labeling however, we have several recommended revisions for accuracy and clarity, and a few questions.

§205.307 - Comments make it clear that a nonretail container can be used to ship or store either packaged or unpackaged products and that nonretail containers can include produce boxes, totes, bulk containers, bulk bags, and harvest containers as well as boxes, crates, cartons, and master cases of wholesale packaged products. This clarification resolves a discrepancy among certifiers. We recommend adding the examples given in the preamble for a nonretail container to the definition of nonretail container. We are clear that the nonretail containers do not apply to containers used for bulk transport. But, for full industry clarity, we also recommend adding the exclusions given in the preamble to §205.307.

> *§205.2 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 are used to ship or store either packaged or unpackaged organic products, and 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.*
>
> *§205.307 Labeling of nonretail containers. Section §205.307 does not apply to large nonretail containers that are associated with a mode of transportation or storage, such as trailers, tanks, railcars, shipping containers, grain elevators/silos, vessels, cargo holds, freighters, barges, or other method of bulk transport or storage.*

§205.307(a) - Proposed changes require a necessary strengthening of the organic supply chain. Requiring nonretail containers to display the organic labeling claim (100% organic, organic, and made with organic) to identify the product as well as requiring the "certified organic by" statement increases supply chain integrity. At present, it is not always clear from labels whether nonretail containers even contain organic products. The proposed rule does not make it clear if the name of the product is required on the labeling.

For clarity and to align with the language in other labeling standards, we suggest revising §205.307(a) as follows:

> *§205.307(a) Nonretail containers used to ship or store certified organic product must display the following: (1) The term, "100 percent organic," "organic," or "made with*

organic (specified ingredients or food group(s))," as applicable, to ~~identify~~ modify the name of the product;

§205.307(a)(2), and also in §205.307(b)(3) and (b)(4) - We note a significant change for some handlers.
(a)(2) requires "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;***" [emphasis added]
(b)(3) requires *"The name and contact information of the certified producer of the product, or **if processed, the last certified handler that processed the product;"*** [emphasis added]
(b)(4) requires *"The seal, logo, or other identifying mark of the certifying agent that certified the producer of the product, or **if processed, the last handler that processed the product;"*** [emphasis added]

The last handler may not necessarily have processed the product.

> *Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, labeling, combining, containerizing, storing, receiving, or loading.*
> *Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.*

All processors are handlers, but handlers are not necessarily processors. Since the definition of handle includes "to process", we suggest revising all three standards to remove the references to processing. The certifying agent of the handler certifying the product should be listed on the nonretail label. Sale or facilitating sale or trade is generally the last activity performed by a handler.

> *§205.307(a)(2) ..or, ~~if processed,~~ the certifying agent that certified the last handler ~~that processed~~ of the product*
> *§205.307*(b)(3) *...or ~~if processed,~~ the last certified handler ~~that processed~~ of the product*
> *§205.307*(b)(4) *...or ~~if processed~~, the last handler ~~that processed~~ of the product*

The proposed revised language could be interpreted to require a handler who uses 20 copackers to list the copacking plants and the copacker's respective certifiers on their labels. This does not seem reasonable or transparent since the copacker is contracted by the handler and the handler is responsible for all organic certification documentation for their copackers. This revised language would also cause complications for a vegetable cooperative who aggregates veggies which are not further processed. The vegetable cooperative is often the operation identified on the label, not the individual farmers who grew the vegetables. This new requirement would require some major marketing changes including significant label updates for handlers. Certifiers would also have challenges when trying to link a certified product based on the

labeling back to the owner or responsible operation for the label. Neither the certifier nor the operation named on the product packaging would be responsible for the product contained within if copackers are required to be listed because they are the “last handler that processed" the product.

After revisions are made to the three standards above, we also think that §205.307(b)(3) should be a “must” and added as §205.307(a)(4) and deleted from (b)(3). It seems very odd to *require* a COB but not to require identification of the producer or the handler who is responsible for the product. We agree that other additional certifier information in (b)(4) and (b)(5) (certifier seal use/logo use and certifying agent contact information) is optional, as outlined in the current retail labeling standard. It’s important to maintain consistency with existing standards that are not proposed to be revised. This request for revision also answers the NOP’s request for comment - *AMS seeks comment regarding the proposed amendments to the labeling of nonretail containers, specifically whether or not the certified operation that produced or last processed the product must be listed (i.e., not optional) on all nonretail container labels*. We feel the contact information of the handler should <u>not</u> be optional.

§205.307(a)(3) - The expansion of information needed to ensure traceability and will ensure that nonretail containers maintain transparency throughout the supply chain. This change, in addition to the changes required in NOS §205.103 on supply chain traceability, should ensure that we have a full audit trail from production to end use.

§205.307(b)(1-5) - We request that the NOP give additional guidance on what is meant by “special handling instructions” in (b)(1). We also want to be clear that the list of optional information that a handler can display is not limited to the information outlined in §205.307(b)(1-5). We assume the list is not exclusive.

It would be a significant burden, both financially and for staff capacity, for MOSA to require updates to, and review for compliance, all nonretail labels that are under our purview. We have about 1,220 clients who indicate on their OSP that they sell directly to a bulk buyer. Our data system includes all sales to a bulk buyer, including exempt bulk containers, but we can assume that a good number of the 1,220 use nonretail labels. Almost 200 vegetable operations alone list that they ship to a bulk buyer. We do not believe we have staff capacity to complete all reviews within the year implementation period; MOSA anticipates we would spend an additional half hour on inspection, file review work, and additional client communication. A conservative estimate shows this could have a financial impact of as much as $14,000 on nonretail label review and approval. (1220 total labels/2 (to conservatively estimate half will need to be reconfigured)= 610 labels x .5 (half hour review time)= 305 hours x $45.91 =$14,003).

Clients will need to be informed of the regulatory changes and update their labels, and certification staff must re-review the updated labels for compliance which can be done through the annual review cycle and may not correspond to the year timeframe. Additionally, we wonder if there will be any use up period after the implementation period for use of inventory? If not,

inventory loss would be another cost factor to consider for certified operations in addition to the additional expense of the new and more robust labeling.

4. On-Site Inspections.
AMS seeks comment on the proposed amendments regarding on-site inspections.

MOSA remains in overall support of the proposed rule changes in this section. We wonder about the practicality of requiring on-site inspection for some brokers, brandholders or other situations where we would just be auditing records as opposed to a field or facility with physical organic control points. We also ask for the following revisions and clarifications:

§205.403(b) Regarding unannounced inspections, MOSA currently adheres to the guidelines in Handbook Instruction 2609, including the 4-hour notification window outlined in 4.1.9 to ensure that someone is present. Further clarification is requested to explain the guidelines for conducting unannounced inspections, to ensure alignment with the rules and the Handbook Instruction. Such clarification could be included in a new definition for unannounced inspection. Additionally, unchanged §205.403(f) requires that a receipt for any samples is given to the "authorized representative", however §205.403(c) which is also unchanged, does not require that an authorized representative be present for unannounced on-site inspections. This discrepancy needs additional clarity as well.

§205.403(d)(4) and (d)(5) Traceable products and ingredients should include products purchased and/or produced for sale and transport, as well as purchased and/or produced products that are in "use". MOSA requests the addition of the term "use" to be paired alongside the sales and transportation. Many organic crops are "used" on the farm, as in feed for dairy animals, or as an ingredient in an on-farm processed product.

> *§205.403(d)(4) …from the time of production and/or purchase to use or sale or transport*
> *§205.403(d)(5) …from the time of production and/or purchase to use or sale or transport*

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

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

Certificates should be updated when practical, applicable and compliance has been verified. At MOSA we update certificates at least once during our annual cycle, using the date issued as associated with the annual Final Review. We also have risk-based systems in place to update certificates throughout the annual cycle when a new product can be added through a desk audit; i.e., a client is adding a crop that fits within the scope of their certified production methods and is on land that has been previously inspected and certified. We refer to NOP 2615 Instruction on Organic System Plans, Organic System Plan Updates, and Notification of Changes for additional

guidance on certificate updates related to OSP changes, and when inspection is required. We do not feel placing an arbitrary timeline on certificate updates (such as every 12 months) increases organic integrity or is sound and sensible.

2. Should a minimum reporting frequency (e.g., monthly, quarterly, etc.) be added to the regulations?

If this question is in reference to how frequently certifying agencies should be reporting certified client data to NOPOID, and considering the new proposed requirements for issuing certificates from INTEGRITY, it seems practical that reporting should be required *as applicable* and at least once annually per certified operation. We are not in favor of adding a specific reporting frequency to the standards in this section or in section §205.501(a)(15). MOSA currently reports data to the NOPOID database monthly. See also our comments in Section 7 below.

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

MOSA is in *strong* opposition to adding an expiration date to certificates of organic operations. Our first hand experience with other third-party verification systems requiring expiration dates is that expiration dates cause an unnecessary heightened sense of administrative pressure for our review team which does not result in increased enforcement or integrity. We also anticipate that expiration dates may cause confusion in the marketplace, resulting in the loss of a market due to administrative practices out of the clients' control. Since an expiration date would not affect the standard at §205.404(d), we question what benefit the date would bring. We already list the date the certificate is issued, an annual date reflecting our process of annual review and certification. We see revisions at §205.406(b) - clarification that an on-site inspection of the certified operation occurs at least once per calendar year - as part of the increased oversight AMS may be seeking.

§205.2 INTEGRITY. We recommend changing this term to Organic Integrity Database (OID). The simple term integrity has additional meaning for the organic industry, and NOP is pointing to the database. We recommend a more formal title and replacing the term throughout the proposed standards.

§205.404(b) - It is not clear in the proposed rule language that an expiration date would appear on all certificates generated from INTEGRITY, but we understand this to be the NOP's intent. We do not support this intention for the reasons noted in question #3 above. In general, we are not in favor of requiring certificates to be generated through INTEGRITY without a more defined system for doing so, though we do realize there can be some advantages to using a unified taxonomy and for the organic industry to have a uniform certificate. However, the current data structure of this system does not allow for accurately reporting the complexity and important nuances we see; for example, "hay" falls into the "Other" reporting category, "milk" falls into a handling category. Individual vegetables are not able to be sufficiently listed, and additional detail is not accommodated. We already experience challenges in uploading current

information, performing a behind-the-scenes translation from our certified products language to the NOP taxonomy. This translation is far from perfect, landing a considerable amount of MOSA certified products in the "other" category. Without additions and/or changes to the current taxonomy system we run the risk of *increasing* confusion in the marketplace. Currently, the MOSA certificate is far more robust than the same client's information in NOPOID. In addition to the overall taxonomy challenges that would need to be overcome, further guidance and database development is needed for dealing with double crop systems, specific acreage data, accurately reporting cover crop use, clearly indicating slaughter eligibility of livestock, and reporting annual milk yields. Does this system consider the clients that have/need multiple certificates? We issued more than one certificate for a handful or two of clients in 2019.

§205.404(c) -We do not support the addition of (c) in total. We currently have an addendum in place that we call our certified organic products sheet or COPS. Our addendum lists all information as specified in (c)(1), (4), and (5). We would have no concern with adding the NOPOID client ID number to our certificates and addendum (though doing so may take some time to technologically implement) as covered in (2), and we'd be happy to include a link and phrase directing the user to look up the information in the NOPOID database as specified in (3). We recommend to strike (c)(6) entirely since an expiration date should not be associated with the certificate or the addendum. And we want to ensure that the addendum can include information other than that specified in the proposed standard.

§205.404(d) - We strongly support leaving this standard as is. See further comments in section 20 below on expiration of certification.

In summary, MOSA is not in favor of major changes to our current system of administering certificates and certificate addendums without further information and understanding regarding the details about such changes. We don't want to see MOSA clients' certificates become less specific. We can assume the cost impact to MOSA and to our clients would be significant, and the timeframe to put a new system in place would surely take more than a year. We strongly encourage the NOP to be more clear and concise regarding data reporting that will be required from certifiers.

6. Continuation of Certification.
No specific questions requesting comment.

§205.406(a) - We appreciate the new clarifying language proposed, including the removal of the current regulatory text at §205.406(a)(3) which requires clients to update certifiers on the correction of any minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. Since many certificates and final review letters are not issued until after our deadline to submit updated paperwork, we often hear from clients that they can't provide this information, creating an information gap. We automatically follow up on previous conditions and minor issues as part of our inspection process and annual review cycle. This deletion will reduce the frustration level and paperwork burden for clients.

§205.406(b) - Since unannounced inspections have been added in the new §250.403(b), we recognize that the proposed changes at §205.406(b) do not specify whether the on-site inspection is specific to a full annual on-site inspection or if a limited scope unannounced on-site inspection would meet the requirements of the proposed language. We recommend the NOP specify which sections of §205.403 are applicable. Additionally, we recognize that using the calendar year will at times mean an inspection occurs less than 12 months and sometimes more than 12 months apart, depending on the date of the first inspection. We are concerned that we may lose some of the practicality we currently have to adjust inspection timelines to meet client changes or to view operations at different times of the year. Considering the new language, there may be times when two inspections would need to occur in a very short time frame simply to meet this requirement, resulting in additional costs to clients and increasing the workload of an already capacity-deficient inspection system.

7. Paperwork Submissions to the Administrator.
No specific questions requesting comment.

§205.405(c)(3) - MOSA supports the removal of this standard, since it points to a standard that is incorrect, §205.501(a)(14). It should have pointed to §205.501(a)(15), which is proposed for revision. Maintaining current data for operations certified (in revised §205.501(a)(15)), and for suspended or revoked operations (in added §205.662(e)(3)) is appropriate. We also feel that it would be beneficial to maintain a record of operations that are denied or operations that withdrew with adverse actions would be beneficial as well, but note that such operations are not covered in current revisions. As such, we recommend revisions to §205.662(e)(3) below.

§205.501(a)(15) - We request that the NOP define what is meant by "current". Considering other revisions, we feel that this essentially means in real-time. As stated before, we do not support the generation of certificates from the INTEGRITY database. As indicated in Section 5, we have experienced that the current data structure of INTEGRITY does not sufficiently support the nuances of the systems we certify to provide the useful, accurate information this revised requirement seems to seek. The comments provided by NOP indicate, "AMS believes the availability of complete data on certified operation, including complete information on certified items and acreage, will reduce the time certifying agents and AMS spend responding to inquiries about specific operations." We will only achieve this goal if the data structure is improved to include the ability to report double cropping acreage, cover crops, slaughter eligibility of livestock, milk yields, etc.

MOSA provides a certificate addendum which lists acreage, double cropping, square footage of greenhouse operations, the number of cattle in each livestock group (milking cows and/or replacements heifers), and Private Label information. The addendum is not meant to be public information. It is unclear who will have access to this new mandatory data within INTEGRITY and the ways that it may be used. The NOP comments also indicate "other data fields" may be required. We request additional information about what those other data fields will be and would like the opportunity to provide input or feedback.

Without updates to the taxonomy and the data structure of INTEGRITY, MOSA will either need to maintain additional recordkeeping in-house to preserve the information, or lose some of the specificity our current certificates provide, resulting in increased inquiries from the marketplace.

8. Personnel Training and Qualifications.
AMS seeks comment regarding certifying agent personnel qualifications and training, including answers to the following questions:

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

We acknowledge the importance of continued education and training and recommend against a specific number requirement within the regulations for inspectors specifically. Additionally, the language for inspector qualifications and training at §205.501(a)(4)(i) lists specific training that would meet this new requirement. We are concerned about identifying specific training that would meet the requirements and how these requirements conflict with Labor Laws regarding contract inspectors. Our current understanding is that we cannot require specific training of contractors without blurring the lines between an employee and contractors. We also request clarity regarding the requirements for Certification Reviewers who also conduct inspections - will they be required to complete 40 hours of training annually?

The current pandemic has provided significant obstacles to our independent contractors, leading many to be apprehensive about their safety and the sustainability of their careers. This has already catalyzed premature retirements for several of our contractors. Paired with additional barriers to entry in this profession and extra on-going training costs, we anticipate the pool of qualified inspectors to be diminished. Moving forward with these proposals, the recruitment and retainment of inspectors will be a challenge.

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

We currently perform, and are in continued support of on-site evaluations of organic inspectors once every three years or more frequently if warranted.

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

Yes and no - We do not recommend additional types of knowledge, skills or experience be specified in the rule, but we wish to acknowledge that other backgrounds can be very beneficial to the work we do. See comments below on §205.501(a)(5).

§205.2 Certification review - We recognize that some activities of certification review may blur the lines between the review work and activities typically conducted at an inspection, such as investigative work to verify the OSP information. We suggest that the last sentence of the

definition for this new term be revised to state, *"This does not include performing an on-site or unannounced on-site inspection."*

§205.501(a)(4) - We have significant concern around the phrase "scope and scale" throughout this standard. We recommend replacing this phrase with "relevant experience" in all applicable locations. We maintain that knowledge and skills outlined in (i)(A) be required as only applicable to the inspection assignments. Our recommended revisions eliminate the 20 hours of training requirement for inspectors and revise the requirement for "1 year of field-based experience" to more closely resemble the requirements for certifier reviewer personnel. To require one year of field-based experience from all inspectors in the "scope and scale" of the operations assigned is seemingly extremely limiting. If this language is maintained, additional clarity on what is meant by "field-based" will be necessary. Would an inspector need a full year of on the ground experience in specific categories of livestock production or would a general animal science education plus an internship on a dairy farm and training in the organic standards be sufficient? This part of the standard also seems to prevent additional on the job training or life experiences to expand the capabilities of an inspector. We ensure inspectors are adequately trained to perform the duties that we assign, and we continuously provide training and feedback throughout the time we work with an inspector. We feel this standard will reduce the pool of qualified inspectors, and it is already a challenge to find sufficiently qualified inspectors as it is. Finally, this standard references "other relevant training providers" and we want to ensure that certifiers will have discretion to determine what these are. We are continuously pleased to see many new forums for organic education. Who determines which types of training qualify?

Our recommended revisions are as follows:

> *§205.501(a)(4) Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and persons who conduct certification review, to comply with and implement the USDA organic standards; (i) 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 and skills in 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 all persons that conduct inspections, including staff and contract inspectors have ~~a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect~~*

~~*before assigning inspection responsibilities;*~~ *the knowledge, skills, and relevant experience required to perform inspections of operations assigned. (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 ~~of the scope and scale~~ assigned and to evaluate compliance with the applicable regulations of this part; and (A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned; and (B) Initially and every year thereafter, all persons who conduct certification review activities must demonstrate successful completion of ~~a minimum of 20 hours of~~ 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) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.*

§205.501(a)(5)- MOSA does not support the revisions to this standard. We recommend that no changes from the current rule text be made to this standard, however, if (i) is maintained, we recommend the following revisions. This standard would eliminate staff and inspectors who bring valuable experience from fields unrelated to agriculture or science, such as in the field of law and regulatory work, accounting, education, or communications. Somewhat though not specifically related to agriculture or science are other degree paths such as environmental education or natural resources. To limit the training in production and handling to only *organic* experiences significantly impacts qualification requirements, and then to require that it *directly* relates to assigned duties, doubles down on the impact. For example, we value the experiences that a former private pesticide applicator, a NRCS agent, a conventional farmer, or a conventional food handler can bring to our work in organics. The requirements outlined in this section would be relatively difficult to achieve, and would discourage expansion in the industry.

§205.501(a)(5)-Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned; (i) Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of formal education, training, or professional experience in the fields of agriculture, science, relevant or related fields, or ~~organic~~ production and handling that ~~directly~~ relates to assigned duties.

§205.501(a)(6)- We understand that certifiers will still be able to share the on-site evaluations of inspectors, and we would appreciate the ability to contract with other organizations such as IOIA or with contract inspectors for the on-site evaluation. We are concerned about the language in §205.501(a)(6)(i)(A) which indicates on-site inspector evaluations must be

performed by "certifying agent personnel". This language seems to eliminate our ability to have contract inspectors or agencies such as IOIA conduct on-site observations of contract inspectors. This requirement will increase the cost and complexity of conducting on-site inspector evaluations.
We recommend the following revisions to this standard.

> *§205.501(a)(6)- Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services; (i) On-site evaluation of inspectors—Certifying agents must observe 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 ~~certifying agent personnel who are qualified to evaluate inspectors~~ qualified persons as designated by the certifying agent; (ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and on-site inspector evaluations.*

9. Oversight of Certification Activities.
No specific questions requesting comment.

§205.2 Definition for Certification office - NOP has clarified that home offices for remote staff and independent contractors should not be included in this definition. We assume that instead this relates to "satellite offices" described in NOP 2000 (Program Handbook). This is an important clarification, especially as we have more staff working from remote locations, like home, coffee shops, and hotel rooms. MOSA recommends adding language which excludes remote offices .

> *§205.2 Certification office. Any site or facility where certification activities are conducted, except for locations of remote personnel or the certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.*

§205.640 - We are unclear about the intent and potential impact of this section as related to the additional comment request and the preamble for this section §205.640 does not provide any clarification. Removing the reference to accreditation fees implies changes that we cannot fully interpret. Does this imply assessment of new accreditation fees to certifiers? New direct fees from NOP to certified operations? Is this about reviewing our fee schedules for approval? Without knowing intentions, we do not support the revision of this standard. We recommend that this standard remain unchanged. Regulatory burdens on certifiers lead to increased costs for organic operations and as many certified operations are running on very tight budgets, we would not support fees that could create barriers to certification.

§205.665(a) - We do not have concerns about these changes, which seem to add expansion and clarification to how noncompliances may be identified. However, we don't see that adding (1)(ii) and (iii) are needed. The circumstances defined in (ii) and (iii) are already encompassed

with “An inspection, review, or investigation of an accredited certifying agent by the Program Manager” at (i).

10. Accepting Foreign Conformity Assessment Systems.
AMS seeks comment regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships. Specifically, compared with organic equivalence determinations, are there increased risks associated with recognition agreements where other countries' governments oversee the implementation of NOP certification?

§205.511(a) - The meaning of “equivalence determination” terminology is not clear as to whether it applies to both international equivalence arrangements (two-way), and recognition agreements (one-way). Will the NOP continue to enter into recognition agreements?

§205.511(b) - This refers to “eligibility of product certified.” We think plural *“products”* would be more appropriate.

§205.511(d) - We support the added strength of prescribing re-review timeframes. It’s understood that the spread of the two-year cycle will depend upon the length of the review process. We don’t understand the difference between, or potential interplay, of the two-year cycle and the five-year reassessment for an equivalent program.

11. Compliance—General.
No specific questions requesting comment.

§205.660(c) - We support the new language in this section to say “any person.” It’s a good strengthening of our regulation.

§205.660(e) - We would appreciate examples or clarification on specific delivery services that are acceptable. The “dated return receipts” language has not been clear and is not fully consistent with types of delivery systems that have been approved. “Documented delivery confirmation” would be better. We have found Priority Mail to be effective in tracking delivery, but a receipt is not returned to us, per se, unless availability online is considered to be a return. Registered Email may not be reliable if the recipient does not confirm receipt. Also, if the intent is to ensure that operators are duly informed of steps that could lead to curtailing their certification, we also suggest dropping “noncompliance resolution” from the list of communications that must be sent by a (sometimes expensive) delivery service.

> *§205.660(e) 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 documented delivery confirmation. ~~dated return receipts~~.*

12. Noncompliance Procedure for Certified Operations.
No specific questions requesting comment.

§205.100(c) - We appreciate this change to say "person or responsibly connected person." An "operation," as in the current regulation, can involve multiple "persons." We recognize that adding "responsibly-connected person" can dramatically change the potential penalties for engaging in violations of the regulations. Some certifiers have struggled to identify all responsibly connected persons in organic system plans, and it may take some time to fully gather this information and to keep it current, since responsibly connected persons can frequently change. Further, while certifiers have fairly well been able to perform cross-check with regard to status of certified entities, we do not think we can reasonably compare responsibly connected persons (within each entity) information with that for other certifiers.

§205.662(f)(1) - Clarification is needed regarding the difference between submission of a request of eligibility to be certified and a request for reinstatement. Without more context, this could be interpreted as a weakening of enforcement, enabling an operation that had its certification suspended to circumvent the reinstatement process. We also request clarification as to why "or a person responsibly connected with an operation" is added here. Does this imply that a person responsibly connected with an operation is ineligible for certification if the operation's certification is suspended? Currently, we recognize a eligibility difference between suspension and revocation, in that revocation also affects responsibly connected persons.

§205.662(g)(1) - The specific regulatory citation is incorrect. While the proposed regulatory text now says (xxxvii) and the preamble notes a maximum civil penalty figure of $17,952, the Current Federal Register §3.91(b)(1)(xxxvi) cites a current maximum civil penalty of $18,730. We recommend a general description as in the current regulation *" the amount specified in §3.91(b)(1) of this title."* This would continue to accommodate specific section changes as civil penalties for other areas are added or revised.

13. Mediation

No specific questions requesting comment.

§205.663 - We appreciate this new regulatory clarification that mediation and settlement agreements do not require a third-party mediator. In general, we appreciate some flexibility in the mediation process. Since we came to the understanding several years ago, through NOP trainings for certifiers, that mediation could be a less formal process than is specified in the current regulation, we have used mediation far more often to bring operations into compliance or to facilitate their quicker and procedurally-appropriate exit from the Program. Sometimes, we've found that a phone call to discuss the mediation process just leads to an agreement. In these and other cases with successful and mutually-acceptable outcomes, we have proposed settlement agreements without having had a formal, planned mediation session. For practicality and efficiency, we also have used some reasonable discretion regarding the deadline in the "must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days…" requirement, leading to a more efficient conclusion. With regard to "following a mediation session" in part (e), sometimes we find mediation can take several sessions or ongoing communication in different forms, and we have

found it difficult to determine when a mediation has concluded and the 30-day clock has begun. We would suggest changing " following a mediation session" in part (e) to just say *"following mediation."*

14. Adverse Action Appeal Process—General.
No specific questions requesting comment.

§205.680(f) - See our comments above (section §205.660(e)) regarding "dated return receipts" and suggestion that this be changed to *"documented delivery confirmation."*

§205.680(g)- We strongly recommend that the NOP have a 60-90 day deadline for decisions on appeals. We understand that NOP has been receiving many appeals, but excessive delay is an organic integrity problem. Potentially noncompliant products may continue to be produced and sold as the appeal process occurs, and that creates a communication challenge if consumers inquire whether such operations' certifications are in good standing.

15. Adverse Action Appeal Process—Appeals.
No specific questions requesting comment.

§205.681(c) - While our comments regarding mediation (above) support an allowance for reasonable grace (although that does not need to be codified) regarding the 30-day mediation request deadline, for appeals we support this "must" and a hard 30 day deadline. Appeal will often have proceeded through the due process including the mediation option, or may be the result of the certifier not being willing to engage in mediation because it does not seem to be a reasonable route to bringing operations into compliance.

16. Grower Group Operations.
AMS seeks public comment regarding the certification of grower group operations, including answers to the following questions:
1. Should there be limits on gross sales or field sizes of individual grower group members? If yes, please describe these limits.

We give a nod to comments submitted by IFOAM International for wisdom related to grower group certification, and encourage maximum harmonization with the international organic community for grower group certification. IFOAM's comment reminds that group certification is a common tool in the global organic sector, used for approximately 2.6 million organic small-scale producers worldwide. We do not support sales or field sizes as being a limiting factor for group membership. Rather, if larger farms are a part of a group, they should require annual external inspection. Excluding larger farms from group certification would have a negative financial impact on many entities currently exporting to the U.S, and will not boost integrity. Excluding strong members weakens the whole group, and would become a disincentive for smaller producers becoming more economically viable.

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.

A limit on the number of members allowed either in the grower group or in the production unit would help resolve our concern about the diminishing inspection requirements as the scale of the operation increases (see comments below in §205.403(a)(2)). However, we would also point to IFOAM International's comments on this question, which offers alternate methods to solving this and other concerns regarding very large groups, including introducing a clustered approach with possible de-certification or suspension of specific clusters, and the introduction of additional requirements for the re-inspection rate.

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.

Overall we see geographical limits are needed because of concerns around inspection logistics and travel to remote locations, and the ability to conduct unannounced inspections on any and all groups and production units, but we are unsure what limits make the most sense, and whether geographic proximity could be defined with world-wide applicability. We are wary of developing overly prescriptive rules on geographical proximity of group members.

As a general comment, we'll note that we appreciate the attention to codifying the grower group certification scheme. This has been a gap in our standards for quite a long time, even as we've recognized that many products important to consumers in the US are grown and certified under the grower group construct. We appreciate how this allows organic market access for many

small farmers around the world. This enables our standards to better harmonize with the global organic community and have impacts on social justice.

We also agree with the comments of the Accredited Certifiers Association, which call for accreditation specific to certification of grower groups. In our limited experience with these types of operations, we have seen the potential for weakening of the standards, if oversight is not sound, or if Internal Control Systems are weak. We recognize that the NOP is referencing certification schemes outside of the United States in the grower group section of the preamble. However, since it is not specifically stipulated that grower groups apply to "small-scale farms in developing countries entering the global organic market," we request further clarification regarding the intended geographical regions that the scheme would apply to. The NOP went on to say, "This method of certification gives small growers or gatherers organized into grower groups access to organic markets while expanding consumer choices. Grower group certification supports U.S. consumer demand for organic products that are not produced in the United States, such as coffee, cacao, and bananas." This leads us to believe that grower groups are not intended for US-based production. We feel that to use grower groups in the US would undermine the current system we've developed, where each operation is certified individually and each parcel of land is inspected. To allow for a grower group scenario in the US again would negate the intention of "who has to be certified."

§205.2 Definition for Grower group member - In this definition, "person" seems to mean "individual" grower. Unless a member could also be another type of entity from the wider definition of "person," we'd suggest changing this to state "individual," rather than "person," to avoid confusion. Also, this definition could be interpreted as only enabling groups to handle a single crop and to exclude a multi-crop system. We suggest the following change:

> *§205.2 Grower group member. ~~A person~~ An individual engaged in the activity of growing or gathering ~~a~~ crops and/or wild crops as a member of a grower group operation.*

Also, we find that livestock scope is not included in this definition nor in the definition for grower group operation. See our comment on livestock, below.

§205.2 Definition for Grower group operation - In this definition, we suggest removing a "single producer" and replacing it with "person" to be consistent with the current definition for "person." We also recommend including production units in the definition, to ensure that geographic proximity criteria applies to individual members and/or grower group members within a production unit. Operations may have multiple production units distributed over a large distance. But, geographic proximity to the established production unit - the unit of ICS control - is key. We also advise adding" as approved by the certifier" after geographical proximity because this is not clearly defined. We would like guidance or a list of criteria to help determine geographical proximity. And, as in the grower group member definition, we'd suggest a change to enable the operation to include multi-crop systems.

> *§205.2 Grower group operation. 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 production and handling operation for crops and/or wild crops ~~production and handling operation~~.

The exclusion of livestock from this definition, and also from the definition for "Grower group member," could exclude honey production from the grower group model. We have found that poultry production can be certified under one "person" using an internal control system model (with all locations inspected, in this US-based example). We also have certified multi-site vegetable production under an internal control system model (again with all locations inspected), and because of our experiences we recommend against using the grower group model to allow for US-based vegetable production. The success of this type of system relies on a strong ICS with strong oversight.

§205.2 Definition for Grower group production unit - In this definition, use of the word "similar" is too vague. We think that a key concept is that the group shares practices and resources (as specified in §205.201(c)(5)), as well as certifier approval of the geographical proximity and the Organic System Plan. We suggest the following revisions:

§205.2 Grower group production unit. 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 shared ~~similar~~ practices and ~~shared~~ resources to grow or gather crops and/or wild crops listed in the Organic System Plan.

§205.201(c) - We generally support these Internal Control System criteria. They seem robust and consistent with current grower group certification practice. We request further clarification regarding the conflict of interest expectation for internal auditors, since in some cases, familial conflicts of interest may be unavoidable or it may be impractical to hire internal auditors without some ties to the group. Also, more guidance is needed on reporting noncompliances to the certifying agent. We would expect that minor non-compliances are addressed by the ICS and verified by the inspector on site, while major non-compliances must be reported to the certifier. We also question how certifiers should provide consistent enforcement to insure that Internal Control Systems are effective. At what point do noncompliances by group members indicate that the ICS is not effective, that there is a systemic issue? Compared to typical certification practices where there is not ICS, it seems like the ICS protects grower group members from direct consequences to their certification. While group certification schemes appear to be necessary for some geographical regions and some types of crops, we would like to see this construct used only when necessary. While we appreciate that specific standards are being offered, we would not want grower groups to be used opportunistically, where they are not necessary, where it is practical and possible for each individual within a group to be certified and inspected annually. If that door of opportunity is opened, we would consider that to be an unnecessary weakening of our standards.

§205.400(g) - We suggest rewording (1) and (2) for added clarity. Also, we recommend that the term "inspector" be changed to "auditor," since in the proposed grower group regulations, this person is hired and overseen by the certified entity, not the certifying agent as noted in the current regulatory definition for "inspector." We strongly believe that internal auditors should

maintain the same qualifications put forth for organic inspectors. After all, they are conducting the organic inspection for the internal members, and inspection is a defined term, *"Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part"* which clearly indicates examining and evaluation of organic compliance. We suggest these changes:

> *§205.400(g)-In addition to paragraphs (a) through (f) of this section, a grower group operation must: (1)* ~~*Be a single producer*~~ *Consist of grower group members that are organized as a person; (2) Sell, label, or represent only the scopes of crops and/or wild crops as organic; …(8) Conduct internal inspections of each grower group member, at least annually, by internal* ~~*inspectors*~~ *auditors, 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…*

Also, we would interpret that individual group members, or the group as a whole, would be allowed to sell some products as nonorganic, without affecting certification for the individual or the group.

§205.403(a)(2) - More clarification is needed regarding conducting audits of the ICS and the ICS auditors. The regulation should indicate the minimum number of audits required, with focus on witnessing the internal auditors. Also, the certifier, not the ICS, should determine which members are considered high risk (§205.201(c)(4)). More guidance and clarification is also needed for determining risk, also including assessment of compliance for lower-risk members. In the preamble, the NOP gave several factors for helping to determine which grower group members to inspect, and included best practices for the inspection of the ICS. We recommend that the factors and the best practices be added to the regulation or a guidance document. We also have some concern that the calculation method in (iii) may give some advantages (fewer inspections by percentage) for groups or production units with more members. To help resolve our concern, we suggest calculating based on grower group members *per production unit* instead of on total group members. Or instead, requiring a simple annual re-inspection percentage rate, which is also suggested in IFOAM's comments, would align with other inspection requirements for certifiers (unannounced inspections and residue testing) and would resolve our concern about the sliding scale for larger groups. As noted in our answers to NOP questions above, we recommend a limit on the number of members and production units. We suggest the following revisions:

> *§205.403(a)(2) Initial and annual on-site inspections of a grower group operation as defined in §205.2 must: (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system. (ii) Conduct witness audits of internal control system* ~~*inspectors*~~ *auditors 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) and as determined by the certifying agent. The certifying agent should also select members*

from across the risk spectrum—including lower-risk members. This may require a sample size larger than the minimum required by the proposed regulation (i.e., more than 1.4 times the square root of the number of grower group members). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.

17. Calculating the Percentage of Organically Produced Ingredients.
No specific questions requesting comment.

MOSA supports a clear standard for calculating the percentage of organically produced ingredients. We ensure that manufacturers remove salt and water added as ingredients to the final formulation from the final formulation. The preamble notes 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 are excluded from the calculation*" [emphasis added]. Draft guidance NOP 5037 did not provide sufficiently clear guidance as evidenced by comments submitted by various groups. This proposed rule change does not clear up the confusion. The placement of the parenthetical phrase "(excluding water and salt)" varies between the three standards making it confusing and will continue to result in varied interpretations among certifiers and manufacturers.

We recommend the following revisions be made to the three standards to clarify that manufacturers need to exclude from calculations water and salt added as individual ingredients in their final formulation.

§205.302(a)(1) Dividing the total net weight ~~(excluding water and salt)~~ of combined organic ingredients at formulation by the total weight ~~(excluding water and salt)~~ of all ingredients (excluding water and salt added as individual ingredients to the final formulation).

§205.302(a)(2) Dividing the fluid volume of all organic ingredients ~~(excluding water and salt)~~ at formulation by the fluid volume of all ingredients (excluding water and salt added as individual 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.

§205.302(a)(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid organic ingredients and the weight of the liquid organic ingredients ~~(excluding water and salt)~~ at formulation by the total weight ~~(excluding water and salt)~~ of all ingredients (excluding water and salt added as individual ingredients to the final formulation).

If the NOP intends that water and salt content be removed from each ingredient and also the water and salt added as ingredients to the final formulation are removed from the calculation, it

would be a disruption in the organic industry and a significant expense for certifiers and manufacturers.

18. Supply Chain Traceability and Organic Fraud Prevention.
AMS seeks comment from the public and organic stakeholders regarding the proposed amendments to address supply chain traceability and organic fraud, including answers to the following questions:
1. Does the proposed definition of organic fraud encompass the types of fraudulent activities you witness in the organic supply chain?

We have only witnessed the fraud that has made the news. We are not aware of fraudulent activities among our certified clients. MOSA recommends the word "illicit" be removed from the definition, acknowledging that not all fraud is illicit. Referencing the definition of fraud as "wrongful or criminal deception intended to result in financial or personal gain," we suggest the following edits:

> *§205.2 Organic fraud. Intentional deception for ~~illicit~~ economic and/or personal gain, where nonorganic products are labeled, sold or represented as "100 percent organic, " "organic," or "made with organic (specified ingredients or food groups(s))."*

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

MOSA is not in favor of adding a required minimum number of trace-back audits each year to the standards. Instead, certifying agents should have sound, auditable processes for determining when and why full supply chain trace-back audits are conducted and NOP audits of certifiers should verify that processes are sufficient.

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

No, we do not have any additional suggestions. We do encourage continued robust certification and accreditation oversight by certifiers and the NOP as a measure to prevent fraud in the organic industry.

§205.103(b)(2) - We support the intention of having products organic status identified in records. We note, however, that the openness to abbreviations or indicators of a product's organic status on nonretail labels or other recordkeeping, as noted in the explanatory text, does not align with the proposed regulatory text, which specifies explicit organic status terminology consistent with organic labeling categories. Also, we'd note that producer (as opposed to handler) certificates do not typically identify labeling categories. If this standard is only referring to external systems, then adding "transaction" before "records" would not limit internal system flexibility. We concur with the Accredited Certifiers Association's proposed revision:

> ***§****205.103(b)(2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, including identification in*

transaction records of products as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," ***as applicable;***

§205.103(b)(3) - This specificity may add some clarity regarding recordkeeping expectations, but audit trial documentation may already be adequately covered by proposed text at section 205.103(b)(2), and the addition of this (b)(3) may not be necessary.

§205.201(a)(3) - The revisions to this standard require a plan for supply chain oversight and fraud prevention. Comments from the NOP included expectations on what such a plan would include. Those expectations should be developed into a NOP Program Handbook document.

§§205.501(a)(10) and 205.501(a)(13) - We appreciate the clarity regarding information sharing between certifiers at §205.501(a)(10)(ii) and (iii), and §205.501(a)(13). Sometimes we've found that other certifiers are hesitant to provide information needed to aid enforcement, because of unfounded concerns regarding protecting confidentiality.

§205.501(a)(21) - We assume that "back to the source" requires auditing the supply chain all the way back to original producers. That will result in certifiers that are conducting audits placing unforeseen information-sharing burden on other certifiers involved in the same supply chain. We are concerned that this will not enable us to project our workloads. The addition of the "traceability" to all references of "supply chain audits" would help clarify the requirement to fully trace a product from origin to destination. This phrase is found in §205.504(b)(7) as well.

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

§205.504(b)(4) and (b)(7) - MOSA participated in the working groups for the development of guidance in the ACA best practice documents for cross agency investigations, verifying traceability in the supply chain and for risk assessment and follow-up.
We'd like the NOP and ACA to collaborate to finalize these documents for incorporation into the NOP Program Handbook.

19. Technical Corrections.
No specific questions requesting comment.

We have the following comments on the technical corrections proposed, and we have a few of our own requests for technical corrections. Our suggestions come with the general request to maintain consistency when using the same word or phrase. Our staff relies greatly on our ability to search the National Organic Standards; when there is variation in terminology, searches return unreliable results.

The changes to §205.301(f)(2) and (3) align the rule with the way we've applied the rule to excluded methods verification required. We verify that *crop derived* materials on §205.606 are not *produced* using sewage sludge as a crop input during the production of the crop the material was derived from, i.e. sewage sludge was not a crop input for the celery crop the celery powder is

derived from. Verification that materials were not produced using sewage sludge as a crop input is not applicable to nonsynthetic or synthetic §205.605 materials. We verify that ionizing radiation was not used in *processed* products which are outlined in Food and Drug Administration regulation, 21 CFR 179.26, which is a rather limited list. In general ionizing radiation applies to very few materials we see used in processed products.

We also request that the NOP correct common errors made in the current and proposed regulatory text, as applicable.

- The term *on-site* is used in the current regulation 34 times, and *onsite* is used once, in §205.501(a)(12)(i). In the proposed regulatory changes, *onsite* is used once in §205.101(c). We recommend changing all references to *on-site.*
- As noted in section 12 above, references to civil penalties need to be corrected. We recommend eliminating the specific *accurate* reference (xxxvi).
- The acronym *DMI* should be added to the definition of *dry matter intake* in the current regulation.
- For consistency in style, numbers that are ten or less should be spelled out. Both *3 years* and *three years* and *5 years* and *five years* appear several times in the current regulatory text and in the proposed changes and there are a few other instances of numbers less than ten as well.
- *Percent* should be standardized by using the word *percent* rather than the *%* sign, as in *100 percent* not *100%* as noted in proposed §205.103(b)(2).
- *Wild crop* or *wild-crop*? Most instances of this phrase are wild crop, but the title for section §205.207 is wild-crop and there are a few more instances where the hyphen is used.
- In the current regulation, *feedlot* is used primarily, but there is an instance of *feed lot* in §205.239(d).
- In the current regulation, §205.601(b)(2)(i) and (c) list "newspaper or other recycled paper, without *glossy or colored inks.*" Certifiers uniformly require that newspaper or recycled paper not contain *glossy paper* or *colored inks.*

We appreciate your consideration of our suggestions.

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

Packaged Product Labeling

Although AMS has chosen not to include packaged product labeling amendments in this proposed rule, we seek public comment on the following questions regarding private-labeled organic products. Please explain how your answers could improve organic integrity and transparency, and facilitate the verification and traceability of organic products.

We understand that private labeling companies will be required to be certified and are recommending the addition of "private labeling" to the definition of "handle." Brand holders would also need to be certified under the proposed rule, because they facilitate the sale of products. Currently, MOSA certifies the copacker/private labeler (typically a processor who applies the final retail label) and, if the entity identified on the label is not certified, but MOSA is identified as the certifier of the product on the label, then we require a Private Label

Arrangement form for each private label applied by the certified copacker. Requiring both persons (the entity applying the private label and the different entity identified on the private label) to become certified is a significant change. The implementation timeframe for instituting this change would require careful consideration and we recommended in our comments above that this be a 2-3 year implementation period.

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 operation that is responsible for the product in the marketplace - the brand holder- should be listed on the label. In many instances, the contract manufacturer is proprietary information.

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

Complete transparency of the supply chain for a given product for the consumer is not necessarily possible using information provided on a label, especially in a complex supply chain that may involve multiple contract handlers. If certification is required for brand holders, then it seems reasonable that the certifying agent of the brand holder (responsible for the product in the marketplace) would be listed on the label. One brand holder may contract with multiple copackers/private labelers and having the supply chain information reviewed under one certification (for the brand holder) streamlines the label review processes for the brand holder, and enables the brand holder to shift label supply from one contracted copacking facility to another, if needed. We recommend that brand holders and copackers/private labelers be consulted on this change. If the copacker/private labeler is also listed, their respective certifier should also be listed.

It's common that we certify copackers/private labelers that process and apply labels for brand holders that are already certified by another ACA. In these cases, we do not require a Private Label Arrangement form. However, when MOSA sees another certifier listed on a retail label, we contact that certifier to ensure that the label has been approved, and sometimes this communication has been challenging. Changes to private labeling certification requirements will likely require smoother inter-agency communication regarding label approval. Again, we appreciate the clarity regarding information sharing between certifiers at §§205.501(a)(10)(ii) and (iii), and §205.501(a)(13), and would welcome further guidance on transparent inter-agency label approval processes.

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)?

Currently, we require a Private Label Arrangement form when MOSA is listed as the certifier on a retail label of a brand holder that is not a certified operation (so therefore the certifier and the brand holder listed don't "match" as described above). Our Private Label Arrangement form allows us to match them internally for sufficient traceability. If brand holders must be certified

in the future, it may be simpler for the certifier of the brand holder to be listed on the label. See responses for number 2 in this section for more details.

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

Listing the contract manufacturer (copacker/private labeller) should be optional. We encourage a system that maintains a reasonable level of proprietary information and practicality. Large brands often have multiple contract manufacturers using the same labels. It is impractical and inefficient to require listing these on the labels.

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

"Private labeled" works for us. Whatever terminology is selected should have a clear definition associated with it to ensure shared understanding in the organic industry. MOSA understands "private labeled" to mean that a person other than the brand holder applied retail labels listing the brand holder. We use the term copacker synonymously with private labeler.

6. What terminology should be used to describe the operations involved in packaged product or private labeling (e.g., brand name manufacturer, contract manufacturer, and distributor)?

We are not suggesting terminology, but whatever terminology is determined needs to be defined and clear.

We question how much the changes to private label disclosure and transparency will set organic labeled apart from nonorganic labeled products. Changes to private labeling certification and labeling requirements would come with a significant cost to clients and to certifiers. We certify about 65 clients that have private label arrangements for *retail* labels, and these clients may have multiple private label arrangements. Our database cannot easily provide a report to show how many *nonretail* private labels, nor how many individual retail private label arrangements we oversee, we bill for more than 100 *retail* private label arrangements per year. Many private labelers have arrangements with more than one brand holder. Some of those brand holders are certified organic, but our database does not have a way of finding out how many. The proposed regulations will require many new brand holders to become certified, but the quantitative impact of such regulation is unknown.

Expiration of Certification.

Although AMS has decided not to include annual expiration of certification in this proposed rule, AMS seeks comment on the following questions:

MOSA is <u>strongly</u> opposed to the idea that organic certification may expire automatically. We do not feel that this will increase organic integrity and will decrease our oversight of organic operations. Our answers to AMS questions follow:

1. How might annual expiration of certification improve organic integrity?

MOSA does not feel that organic integrity would be improved. Operations are certified unless suspended, surrendered, or revoked (as specified in the current regulation §204.404(c)). The idea that certification could expire would eliminate this standard, which has been a basis of our annual certification cycle. To think that certification would automatically expire if update paperwork is not received would create a scenario where we'd be required to track individual operations in and out of certification. We issue around 150 noncompliance letters annually to clients who do not submit their paperwork on time. Our process is entirely systematic and trackable, so we know where every client is in the process. MOSA's budget relies on the assurance that most of our clients are going to continue to certify with us. Annual expiration would disrupt this. We support a system (the current system) that encourages certification and maintains marketplace security. We do not favor a system where certification would automatically expire.

2. What are the limitations of requiring expiration of certification?

The current organic certification system is well developed and functions well to maintain organic integrity. Certifiers are able to confirm active status as needed if certificates may appear out of date. Instituting a system that includes annual expiration of certification, or of the annual organic certificates, could cause marketplace disruptions and add additional communication burdens for organic operations and organic certifiers. Furthermore, for organic certificates, administrative tracking of issue and expiration dates would add a layer of complexity (and time and cost burden) for certifiers without increasing organic integrity. That is neither sound nor sensible. MOSA's work with a different certification program, which has certificates that expire, has shown us first hand how challenging this can be.

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

The current system for renewal of certification functions well. Clients must submit annual paperwork updating their organic system plan and fees. If they do not do this, we issue a noncompliance, moving to proposed suspension as needed, and finally suspension. Clients that find themselves suspended would need to resolve all noncompliances prior to requesting reinstatement. Additionally, clients receive an annual inspection and review and compliance with the organic standards is verified through these processes. All of these activities are well documented throughout our process. Updated certificates may be issued at other times throughout the cycle when products are added that fit within the scope of the certified activities and the site where they are produced has been inspected. If we moved to an arbitrary expiration date system, we feel this could adversely affect our annual review and inspection processes.

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

The National Organic Program has instituted a clear process for addressing and working through adverse action proceedings. This ensures that clients have an opportunity for rebuttal, mediation, appeal, and ultimately suspension, revocation, or arriving at a settlement agreement.

While the adverse action process is ongoing, clients may be issued an updated certificate, however, the current system ensures that all issues have been resolved or are being addressed in order to continue certification. This process works and certifiers are able to collaborate to ensure clients' compliance. At times, the appeals process can be ongoing for a long period of time, during which certifiers continue to hold responsibility for assessing clients' compliance. An improvement would be if the National Organic Program were able to work through appeals in a more timely manner (we suggest within 60-90 days above in Section 14. Adverse Action Appeal Process—General.- §205.680(g)).

5. Would a grace period be appropriate for operations that failed to renew by the expiration date? If so, what length grace period would be appropriate?

The current system we have has a grace period built into the timelines, and it's well documented and trackable. Our oversight is maintained. We do not support expiration of certification.

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

We feel the current process of reinstatement works well when certification is suspended or revoked. We do not support expiration of certification; any new process put in place to regain certification due to a late submission of annual update paperwork would be burdensome and expensive for certifiers, clients, and the National Organic Program. If both the overall organic certification could expire if update paperwork is not submitted, and expiration dates were added to certificates, then a conflicting system would be born. MOSA's paperwork deadline is in April, and we issue and update certificates after annual review cycles that sometimes may not conclude until the following year. An operation could receive its certificate in October and their organic certification could expire in April, but the certificate might appear to be current due to the October expiration date though it really wouldn't be if they didn't update their paperwork. Additionally, if certificates were to expire, certifiers would need to adjust their annual workflow to ensure we don't create scenarios where certificates expire through no fault of the client. This would divert staff attention away from more important organic integrity concerns. Whether organic integrity is in question, or when clients are unresponsive to deadlines or other administrative requirements, the current adverse action processes serve us well. We feel that this is the best way to support integrity within the system and we strongly discourage the National Organic Program from instituting expiration of certification or expiration dates on certificates.

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

Our current system of notifications ensures clients are adequately notified of all upcoming deadlines. Since organic certification typically ceases when we issue a final adverse action notification, we will have sent multiple notices before the certification is no longer valid. (Or, the client may voluntarily surrender their certification, so they'd be aware of that.) If certificates also

were to expire, this would place additional administrative burdens on certifiers regarding communication.

Fees to AMS and Oversight of Certifying Agents' Fees

AMS is seeking public comments in this proposed rule on how fees in the NOP could strengthen testing and enforcement across all stakeholders to ensure that the NOP keeps pace with the rapid growth and better serves the industry.

NOP has not explained the intention behind the revisions to standard §205.640 or this request for comments and we are uncertain of the potential impact. Section 9, §205.640 proposed some changes to fees by removing the references to accreditation. We cannot support a revision to §205.640 since the implications of such changes are not clear.

In closing, we would like to express our appreciation for the opportunity to provide comments. MOSA supports the general mission to strengthen organic integrity and we encourage collaborative and creative solutions to rise to the top as comments are evaluated. However,we found that just a little more than sixty days to review, collaborate with other organizations, and frame our comments was not sufficient for a proposed rule of this magnitude. We request that in the future more time be given for review of significant regulations and that the timeframe not overlap with other important requests for comments (i.e., NOSB meeting documents).

We have a concern that the SOE Rule will land with the same result as OLPP - after much time and effort among certifiers to align our thinking and prepare for the rule, it was decided that the financial impact was too great and it was withdrawn. In our opinion, the financial impact of SOE is magnitudes larger.

Thank you for the consideration of our feedback.

Sincerely,

The Certification Services Managers of
MOSA Certified Organic