



October 5, 2020

Jenny Tucker, Ph.D.
Deputy Administrator
National Organic Program
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642—So., Ag Stop 0268
Washington, DC 20250-0268

Docket Number: AMS-NOP-17-0065

RE: National Organic Program's (NOP) Strengthening Organic Enforcement Proposed Rule

Dear Dr. Tucker,

Thank you for this opportunity to provide feedback on the Agricultural Marketing Service (AMS) National Organic Program's (NOP) Strengthening Organic Enforcement (SOE) Proposed Rule. We welcome the opportunity to comment on the largest single piece of rulemaking since the implementation of NOP in 2002.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Organic Integrity is the lifeblood of the organic industry

The organic industry is one of a very few bright spots in the U.S. agricultural economy. In the thirty years since the Organic Foods Production Act was enacted, organic has grown from \$1 billion to a bustling \$55 billion in U.S. consumer sales. It is now possible to purchase an organic food product in nearly every category in the grocery store. The U.S. Department of Agriculture (USDA) Organic label is highly trusted by over 75% of families. Organic products are in the kitchens of more than 82% of American households. But this trust comes as a result of consumers' belief in the veracity of the organic seal. Strong standards reinforce trust that products bearing the USDA Organic label are held to a high-quality, definable, measurable set of standards with robust oversight and enforcement. The ongoing work of NOP to strengthen the enforcement of the organic standards and to deepen the rigor of oversight across the supply chain is critical to protecting organic integrity, ensuring a level playing field for all organic market participants – in the U.S. and abroad – and bolstering consumer trust in the organic label. The integrity of the organic certification process from farm to table is the lifeblood of the organic industry.

Preventing the Organic Fraud Opportunity

Food fraud, or the act of defrauding buyers of food or ingredients for economic gain, has plagued the food industry throughout history. Although the act of adulterating food for economic gain dates back to at least the Middle Ages, its presence in the global organic supply chain is more recent, and poses a significant threat to the integrity of the organic brand. Simply put, fraud cannot be tolerated in the organic system, inside or

outside of the United States. Anytime there is fraud, it takes value out of the organic chain, and hurts organic farmers wherever they farm.

For the past three years, OTA has prioritized significant time and resources into actions that will help mitigate and prevent organic fraud. Our work ranges from our successful legislative efforts in the 2018 Farm Bill that authorized key provisions of this proposed rule, to our work with National Organic Standards Board (NOSB) and our member task force to help inform this proposed rule, to our major private-sector initiative that has evolved into an industry-wide fraud prevention program, called *Organic Fraud Prevention Solutions*. The program provides businesses with a systematic approach for carrying out a fraud vulnerability assessment and developing an Organic Fraud Prevention Plan. OTA thanks NOP for recognizing our program in the SOE as a private sector initiative that will help operations develop best practices to detect and prevent organic fraud. Certified operations, in fact, do have first-hand knowledge of their supply chains, and are often better able to detect and prevent organic fraud than a third party. OTA remains committed to proactively confronting the fraud challenge with effective solutions, and doing our part as leaders of the organic industry to prevent the organic fraud opportunity.

OTA Positions and Recommendations

OTA maintains its position that everyone plays a role in preventing organic fraud. We applaud NOP for its major undertaking in drafting this proposed rule and for placing emphasis on strengthening supply chain traceability systems and organic fraud prevention plans. We also thank NOP for constructing a proposed rule that embraces shared responsibility across all entities in the supply chain, and for building in the use of risk-assessment to guide supply chain audits. Establishing new requirements for data reporting will create comprehensive data transparency tools for better understanding organic production and trade dynamics. The new grower group standards will finally provide sound and consistent certification practices for millions of organic farmers worldwide. The Strengthening Organic Enforcement Proposed Rule will undoubtedly have significant and far-reaching impacts on the organic sector. Our focus now must be on swiftly moving to a final rule, and providing the support and resources needed to ensure successful implementation.

NOP General Questions

OTA is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including this cover letter. In addition to answering the questions NOP is asking on each topic, we offer the following responses to the general questions NOP is asking.

- 1. The clarity of the proposed requirements. Can certified operations, handlers, and certifying agents readily determine how to comply with the proposed regulations?** No, not in several cases. OTA finds the preamble to be mostly clear in explaining the intent and requirements of the proposed rule. However, the intent and meaning are not adequately translated in the proposed rule text itself. We are concerned in many cases that certified operations and certifying agents will not be able to readily determine how to comply with the regulations without the assistance of the preamble. In some cases, both the preamble and the proposed rule require clarification. We have addressed these instances and provided recommended solutions in our comments on each topic.
- 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).** OTA supports implementation of the Strengthening Organic

Enforcement Proposed Rule at the earliest feasible opportunity. In most cases, NOP's proposed one-year timeframe after publication of the final rule is suitable based on our assessment. However, certain sections of the Proposed Rule will require significant preparation in systems and resources for operations and certifiers to be in compliance. We identify our recommended implementation timeframes in our comments on each topic, and also provide a summary in our comment titled 'Implementation Timeframe.'

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.** OTA was not able to fully analyze the Regulatory Impact Analysis and Regulatory Flexibility Analysis due to the short comment period and the substantive content of the proposed rule. OTA strongly agrees that the benefits of this Proposed Rule far outweigh the costs. To support operations in taking on the costs that will be needed to come into compliance with the rule, we urge USDA to continue offering the Organic Certification Cost Share Program. As certification costs have increased over the years and may rise due to the requirements of the proposed rule, it is critical that USDA provide cost share assistance at the maximum amount allowed by federal law which is currently 75% or \$750 per scope for certified operations.
4. **Are there alternatives to regulations, or less stringent requirements, that could achieve the same objectives as this proposed rule?** Yes, in many cases additional detail or explanation is needed that would best be addressed in Guidance. Given the broad diversity of the organic supply chain, it is critical that the NOP regulations are uniform in nature to ensure organic integrity while, at the same time, flexible enough to work for various organic operations up and down the supply chain. In our analysis of the proposed requirements, we continued to find that the risk of fraud and/or the risk to organic integrity can be very different (low- to high-risk) depending on where in the supply chain the handling is taking place (e.g. lower, middle or upper echelon), the type of commodity being traded (e.g. produce vs. dairy), whether the product is packaged or unpackaged and the nature of the packaging (open tote vs. tamper-proof final packaging). In some cases, a "one-size-fits-all" approach does not make sense to meet the end goal - traceability, fraud prevention and organic integrity. Accordingly, we have provided recommendations, per topic, on where Guidance can serve as a supplementary tool to support compliance with the regulations.
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?** OTA appreciates these extremely important questions and refers to certifying agents themselves for the answers, as we recognize that each agent has their own fee structure. We also refer to our comments on cost-share certification and the importance of continued congressional support for the National Organic Program. OTA does not take lightly the magnitude of this rule and the tremendous amount of energy and resources it will take to not only implement the rule but maintain it in the foreseeable future.

Continued Congressional Support for the National Organic Program

Given the tremendous growth rate of the organic industry over the past several years, accurate data for the production, pricing and marketing of organic products is essential to maintaining stable markets, identifying fraud, creating risk management tools, tracking production trends, and increasing exports. Investments in

technology and access to data to improve tracking of international organic trade will provide the necessary information to ensure a transparent marketplace. OTA has consistently worked with Congress to advocate for increased funding for the National Organic Program to collect data, as well as make important investments in technology to ensure the data is accessible. In both the 2014 and 2018 Farm Bills, OTA successfully advocated for Congress to include \$5 million in mandatory funding to support technology upgrades at NOP. The funding was used to create the Organic Integrity Database (OID) and recent funding included in the 2018 Farm Bill was provided for NOP to make upgrades and maintain OID while also investing in technology to set up a tracking system for electronic import certificates through the U.S. Customs and Border Protection's Automated Commercial Environment (CBP-ACE) system.

NOP's annual budget is provided by Congress through discretionary appropriations. Over the past five years, NOP funding has increased by more than 30% due to OTA's advocacy and in the 2018 Farm Bill. OTA also secured an authorization to increase NOP's budget by 10% per year to keep pace with market growth. Continued Congressional support for NOP funding is vital to ensure that the requirements of the proposed rule related to data collection are achievable, and the federally operated databases upon which the SOE Rule relies (OID & CBP-ACE) can continue to provide the critical functionality and data that the industry requires.

Continuous Improvement in Advancing Organic Standards

We commend NOP for incorporating many outstanding recommendations of the NOSB into this Strengthening Organic Enforcement Proposed Rule that had not been previously implemented. Advancing these recommendations through rulemaking is critical for ensuring uniform and robust standards, a healthy market for organic products, and credibility of the USDA Organic label. There is still more work to do, as there are 20 NOSB recommendations from the past 10 years that have yet to be implemented that would address areas of the organic regulation where clarity and uniform implementation are critically needed, such as animal welfare, apiculture, and greenhouse production standards. Continuous improvement in advancing organic standards is essential for building consumer and industry trust in the USDA Organic label. We look forward to working with USDA to strengthen the public-private partnership, and ensure success of the USDA Organic label into the future.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks USDA and the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs



Johanna Miranda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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Date: October 5, 2020

Docket: AMS-NOP-17-0065

At-A-Glance Summary of OTA's Positions and Recommendations

The Organic Trade Association is submitting individual comments on each topic in Strengthening Organic Enforcement (SOE) Proposed Rule. Below is an at-a-glance summary of our positions and recommendations on each topic with Section numbers that correspond to text of the proposed rule. Please refer to our full comments on each topic for complete, comprehensive and authoritative information on OTA's positions and recommendations.

Exemptions from Certification – Section #1

OTA supports:

- Amending the regulations to clarify the applicability of the regulations and limit the types of operations exempt from organic certification.
- Full organic supply chain certification. The opportunity to be exempt from certification should be very limited, clearly defined, and based on activities that pose little or no risk to traceability and organic integrity.
- The proposed requirement that intermediate market actors such as brokers, traders and importers and other entities that facilitate the sale or trade of NOP certified products, such as traders and importers, should be certified, even if they do not take physical or financial possession or ownership of the product they represent.
- Bringing operations that do not need to get certified under the single term of “exempt,” and eliminating the term “excluded.” This will simplify terminology and reduce confusion and misinterpretation about who needs to be certified.
- The preamble in clarifying that grain elevators and ports of entry that are loading, unloading and/or transferring unpackaged product must be certified, as well as storage facilities that are splitting, combining and storing lots and loads and/or repackaging or relabeling.
- Modernizing the term and definition for ‘*retail operations*’ to capture in-person and on-line or virtual transactions.

OTA does not support:

- The proposed amendment that eliminates the distinction between ‘packaged’ and ‘unpackaged’ product as it relates to receiving, storing and loading activities that may be exempt. Eliminating this distinction could allow high-risk handling operations receiving and loading unpackaged organic product, such as grain elevators and ports of entry, to be exempt from certification. To reduce the opportunity for organic fraud, handling operations that are storing unpackaged product **MUST** be certified.

OTA recommends the following exemptions from certification, provided the allowance is very restricted and narrowly defined:

- Exemptions may be granted only for transporters, storage operations, customs brokers and freight forwarders and retail operations that meet the following conditions (activities) and can comply with the organic requirements outlined below:
 - **Retail operations that handle, but do not process**
 - Associated distribution centers must meet the conditions of §205.101(e) in order to be exempt
 - **Retail operations** that ‘process’ NOP certified
 - Products that are ‘processed’ by the retail operation must be handled on-site at the point of sale to the final consumer
 - Associated distribution centers must meet the conditions of §205.101(e) in order to be exempt
 - A **handling operation** or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients, or that only identifies organic ingredients on the information panel.
 - **Storage operations** that *only* store, receive, and *ship* NOP certified products that arrive in sealed packages or containers, and do not sell, process, package/repackage, label/relabel or otherwise handle such products while in the control of the operation.
 - **Transporters** that *only* transport certified organic products.
 - **Customs brokers and/or freight forwarders** that *only* act as an intermediary between importers and the government or between shippers and transportation services, but do not take physical or financial possession or otherwise handle the agricultural products.
- The exempt operations described above must comply with the following organic requirements (see details in our comments below):
 - Commingling and Contamination Prevention to protect organic integrity
 - Labeling requirements to ensure products are not misrepresented to the buyer or the consumer
 - Record keeping requirements to prove organic status and verify organic integrity

OTA recommends the following revisions or additions to clearly convey, in the proposed text, the activities that must be certified and the operations and activities that may be exempt:

- Revise the definition of ‘handle’ to better capture the activities in the organic supply chain that must be certified unless specifically exempt
- Revise the definition of ‘handler’ and ‘handling operation’ so they are synonymous and depend on the term ‘handle’
- Add the definition of ‘handle’ to §205.270 (Organic Handling Requirements) of the regulations to formally integrate the new definition and its corresponding activities into the regulation.

- Revise the proposed exemption for operations that only store, receive and/or load NOP certified product to apply only to products that are *sealed in a package or container*. Also replace the term ‘load’ with ‘ship’ because the term ‘load’ implies a bulk or unpackaged product is being handled. The term ‘*ship*’ would not exclude the activity of ‘*loading*,’ it simply infers a different meaning.
- Strike the term ‘alter’ and replace with “or otherwise handle,” or, add the term ‘alter’ and a definition to the regulation.
- Add an exemption for an operation that only *transports* (add as § 205.101(f)) to clarify that transportation is an exempt activity.
- Add an exemption for an operation that only handles the intermediary logistics of shipping agricultural products between importers and the government or between shippers and transportation services, but does not sell or otherwise handle the agricultural products. Examples include customs brokers and freight forwarders. (add as § 205.101(g) and add new § 205.101(h) for record keeping)
- Revise the exemptions for retail operations to make a clear distinction between retail operations that ‘*handle*’ but do not process, and retail operations that *process*.
- Add a term and definition for ‘package’ and ‘packaged product’
- Revise the proposed organic requirements that exempt operations must comply with, so they are better aligned with risk to organic integrity and will better allow for oversight and surveillance activity.
- Revise the regulatory language at § 205.100 and § 205.310 to eliminate the term “excluded.”

OTA further recommends:

- Revisions to the rule that will reinforce and strengthen the relationship and shared responsibility between certified operations and exempt operations. Certified operations must ultimately be responsible for verifying their supply chains and ensuring that exempt operations are protecting organic integrity and maintaining organic product traceability. However, exempt operations should be required to maintain records to verify the status of the organic products they are handling, and the measures they are taking to protect organic integrity.
- Updating existing and/or creating new NOP Guidance to assist certifying agents and certified operations comply with the new requirements.
- Releasing NOP Guidance for Retail Operations to help clarify the exemptions under § 205.101(b) and § 205.101(c) and the labeling requirements exempt retail operations must comply with.
- Increased oversight and surveillance of exempt operations to ensure they are in compliance with the applicable organic requirements.
- A two-year implementation timeframe (after the publication of the final rule) for handling operations that must get certified as a result of this proposed rule.

Imports to the United States (Import Certificates) – Section #2

- OTA supports the expanded use of electronic import certificates to support supply chain traceability and import data transparency.
- OTA recommends that AMS aggregates and reports data from the CBP-ACE system to meet the need for reliable comprehensive data on organic imports that is not currently provided by HTS codes.
- OTA supports the allowance of equivalent data systems to be used as a substitute for NOP Import Certificates provided that the same data is able to be collected and is able to (and required to) be uploaded to the CBP-ACE system.
- OTA recommends that NOP clarify which party is responsible for uploading the Import Certificate (or equivalent) into the CBP-ACE system.
- OTA recommends revisions to the proposed definitions of *organic exporter* to ensure clarity and alignment of the exporter's activities under the definition of *Handle* as proposed in Section #1 of the Proposed Rule.
- OTA does not support the 30-day timeframe for certifiers to issue certificates as written in the proposed rule because it is not tethered to the CBP's deadline for uploading data into the ACE system, nor the importer's responsibilities upon receiving the shipment.
- OTA recommends that certifiers issue valid NOP Import Certificates for compliant shipments as soon as possible, ideally upon arrival of the physical shipment at the U.S. Port of Entry. However, the procedures and deadlines for requesting and issuing NOP Import Certificates need to accommodate various modes of transportation and frequencies of shipments (particularly perishable, high frequency and/or short-notice shipments arriving by ground transportation from Mexico and Canada), balanced with certifier's operational capacity, without impeding legitimate trade flow or compromising organic integrity and enforcement capabilities. We recommend that NOP issue guidance to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates.
- OTA recommends the implementation of this section of the proposed rule (with OTA's requested revisions and guidance) using a phased approach that accommodates the increased resources needed for certain types of imports: two years from publication of final rule for shipments by ground transportation from Mexico and Canada; one year from publication of final rule for all other imports. We also recommend that NOP completes a successful pilot test of the new electronic organic import certificate before the final rule is fully implemented.

Labeling of Nonretail Containers – Section #3

- OTA supports mandatory organic identification on nonretail containers, and recommends the regulations allow flexibility for operators to use alternative abbreviations or indicators of a product's organic status.
- OTA does not support the proposed rule that designates the name of the certified operation as optional. OTA recommends mandatory identification of the certified operation and the certifier on nonretail containers.

- OTA recommends a regulatory revision to improve consistency in identifying which operation and certifier should be displayed on nonretail containers.
- OTA supports the ongoing requirement to display traceability information such as lot numbers on nonretail containers.
- OTA recommends that implementation of these requirements provides flexibility for organic operations in displaying mandatory information on nonretail containers in a manner that is adaptable to the wide variety of nonretail containers while still ensuring that the information is immediately accessible.
- OTA recommends that NOP develop additional guidance to support common understanding and consistent implementation of the requirement that nonretail containers “*must display*” the mandatory information listed in §205.307.
- OTA recommends the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within two years after publication of the final rule.

On-site and Unannounced Inspections – Section #4

- OTA supports mandatory unannounced inspections of a minimum of 5 percent of the operations it certifies.
- OTA recommends that certifiers have procedures for identifying high-risk operations and products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations.
- OTA supports the requirement to only certify operations in areas where the certifier is able to conduct unannounced inspections.
- OTA recommends updating Guidance 2609 to further explain expectations around unannounced inspections.
- OTA supports the proposed requirement for certifying agents to conduct “trace-back” and “mass-balance” audits during inspections.
- OTA recommends including reference, in the regulation, to the common terms “trace-back audits” and “mass-balance audits.”
- OTA recommends that the meaning of the term ‘*source*’ as used in the requirement for supply chain traceability audits be clarified.
- OTA recommends adding as a new term and defining ‘*supply chain traceability*’ in the organic regulations.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

Organic Certificates and Data Reporting – Section #5 & #7

Certificates of Organic Operation

- OTA does not support formalizing ‘INTEGRITY’ as the name of the NOP Organic Integrity Database. We support the proposed definition, but request that the associated term retain the full clause of “Organic INTEGRITY Database” along with its acronym “OID.”
- OTA recommends adding the term ‘*organic integrity*,’ as it is typically used, to the organic regulations to clearly define a core concept that is integral to the purpose of this proposed rule and used throughout this proposed rule.
- OTA supports the use of uniform organic certificates generated through OID, but we have concerns about the time and resources it will realistically take to achieve this goal as a requirement.
- OTA does not support a certificate expiration date. An expiration date is more problematic than it is useful. The goal of ensuring a consistent way of communicating and interpreting the validity and status of an organic certificate can be accomplished other ways.
- OTA recommends a *two-year* implementation period after the publication of the final rule for the proposals in this section.

Paperwork Submissions to the Administrator

- OTA agrees that accurate and current data must be reported and maintained in the NOP Organic INTEGRITY Database (OID).
- OTA supports global use of the Organic INTEGRITY Database (OID).
- OTA recommends that grower group operations be identified as such in the OID and identify how many members are in the group.
- OTA recommends that NOP issue a final rule that explicitly requires data reporting by crop type, acreage and location (e.g. state), and number of animals by livestock type and location (e.g. state), on a monthly basis to the OID.
- OTA supports timely updates to maintain accurate data reflecting an operation’s current status.
- OTA recommends that NOP contract with NASS, a federal statistical agency, to analyze and turn mandatory data into a comprehensive, reliable, statistical report. This would be *in addition* to the data NOP makes available through the Organic INTEGRITY database.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

Continuation of Certification – Section #6

- OTA supports revisions to the rule that will eliminate unnecessary paperwork without compromising oversight of organic operations.
- OTA supports the clarification that operations are only required to submit sections of the Organic System Plan that have changed during the annual certification year rather than submitting a full plan every year.

- OTA supports a rule that provides certifying agents with the flexibility needed to adjust the timing of an inspection in circumstances when it is impossible to conduct an on-site inspection.
- OTA supports a requirement to conduct an on-site inspection at least once per year, but some flexibility is needed outside a strict 12-month time period. We recommend specifying that inspections must occur on an annual basis with reduced flexibility from 18 months to 15 months.
- OTA recommends a revision to the organic regulations that will provide an impossibility clause or temporary variance for conducting on-site inspections in the case of a natural disaster or natural emergency as declared by the Secretary or President. Given the unprecedented experience and the lessons learned during COVID-19, it is critical that the regulations include flexibility that allow for certifying agencies to utilize emergency remote inspections when on-site inspections are not possible.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

Personnel Training and Qualifications – Section #8

- OTA supports strengthening certification personnel and inspector training and qualifications requirements.
- OTA recommends an expanded list of required knowledge and skills for inspectors that includes specific references to mass balance and traceability auditing skills.
- OTA supports the required one year minimum experience requirement, and recommends a revision to clarify how to define and measure the proposal for “one year of field-based experience.”
- OTA supports the requirement for qualifications and training to be specific to the scope and scale of operations assigned for certification review or inspection. We recommend that guidance be developed to define and clarify various “scopes” and “scales” for consistently evaluating whether personnel have the appropriate training and qualifications.
- OTA supports the proposed minimum 20-hour training requirement for inspectors and certification personnel.
- OTA supports the minimum requirements for on-site evaluations of inspectors once per three years. We recommend that guidance be developed to help certifiers align on scenarios when more frequent evaluations are warranted.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Oversight of Certification Activities – Section #9

- OTA supports the new term and definition of ‘certification activity.’
- OTA supports the new term and definition of ‘certification office,’ with clarification around the use of a home office.

- OTA supports the proposed requirement that NOP be notified of the opening of new certification offices.
- OTA recommends a notification timeframe of 45 days after certification activities begin.
- OTA does not support the revision to strike “accreditation” from the first part of § 205.640.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

Accepting Foreign Conformity Assessments – Section #10

- OTA supports the use of equivalence determinations as a tool for facilitating international organic trade, and supports the proposed rule to codify AMS’s authorities and baseline procedures in the regulations.
- OTA supports the identification and elevation of the conformity assessment system as equally important as technical requirements in an equivalency determination.
- OTA supports the authority of AMS to describe scope of equivalence determination based on outcomes of AMS’s assessment of a foreign government’s organic program. OTA also recommends that data transparency and communication be addressed as part of AMS’s assessment of a foreign government’s organic program.
- OTA does not support inclusion of specific audit timeframes as written in the proposed rule. OTA recommends regulatory revisions that will allow AMS to negotiate the terms of audit timeframes based on the findings of AMS’s assessment.
- OTA recommends regulatory revisions that will allow AMS to negotiate termination procedures as part of the equivalency determination based on the findings of AMS’s assessment.
- OTA sees increased risks with recognition agreements compared to equivalency arrangements as currently implemented across a number of issues including data transparency, communication, and enforcement.
- OTA asks NOP to clarify whether recognition agreements are intended to be covered by the equivalency determination process described in the proposed rule, and explain what will happen to current recognition agreements as a result of this rulemaking action.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Noncompliance, Mediation and Appeals – Section #11-15

- OTA supports the authority of NOP to investigate and enforce against violators of OFPA including uncertified operations.
- OTA supports consistent clarification that enforcement actions extend to all accountable parties per the existing definition of “responsibly connected.” OTA recommends guidance be developed to clarify procedures for certifier to report responsibly connected parties for operations that they

certify, and for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1).

- OTA supports timely updates in the NOP Organic Integrity Database regarding the certification status of surrendered, suspended or revoked operations.
- OTA supports clear explanations of the mediation process and procedures as proposed in §205.663. OTA recommends guidance be developed to clarify the criteria that should be included in a certifier's internal policies and procedures for acceptance or denial of mediation requests, and to clarify that a third-party mediator is not required per §205.663(c).
- OTA does not support the revision as proposed in §205.681 regarding administrative proceedings, and recommends revisions to clarify and maintain the appellant's right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing.
- OTA supports the clarifications proposed for the general appeals section of the regulations at §205.680 and recommends that NOP staff itself appropriately so that it can respond to appeals in a timely manner.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Grower Group Operations – Section #16

- OTA supports certification of group operations and recommends revisions to the new terms and definitions to clarify that the grower group operation is the legal entity that is tied to the legal definition of "person" in §205.2.
- OTA recommends that group operations are identified as such in the NOP Organic Integrity Database.
- OTA recommends that grower group certification become a separate accreditation scope that certifiers must have in order to certify grower group operations.
- OTA does not support limiting group certification only to producers of crop and wild crop products. OTA recommends scope-neutrality regarding the type of products that can be produced and certified under group certification, and recommends that scope limitations are removed from the rule.
- OTA supports scale-neutrality regarding the size of groups and group members that can be certified under group certification. OTA does not support imposing limits on gross sales or field sizes of individual grower group members, nor limiting the maximum number of members allowed in a grower group operation or in a grower group production unit.
- OTA supports geographic proximity of members, and sees no need for more specific limits to further define geographic proximity.
- OTA supports the allowance for members to also have separate individual certification outside of the group should they want to sell organic products outside of the group if they are certified for such products.

- OTA does not support the current proposal that requires certifiers to inspect high-risk members based on the internal control system's own risk criteria. OTA recommends that certifiers conduct an independent external risk assessment separate from (and in addition to) the internal risk assessment conducted by the internal control system. OTA also recommends that NOP develop guidance to support certifiers in reaching a common understanding of the criteria that should be used to identify high risk group members and to assess risks of groups as a whole.
- OTA supports many of the specific regulatory requirements for the Internal Control System (ICS), and recommends several critical revisions to the proposed rule that will enhance and clarify the ICS's responsibilities for establishing and maintaining strong oversight and enforcement capabilities.
- OTA recommends regulatory clarifications and guidance to ensure sufficient qualifications of ICS personnel.
- OTA recommends regulatory clarifications to ensure that recordkeeping by the ICS is sufficient to demonstrate compliance.
- OTA recommends regulatory clarifications to elevate and enhance ICS requirements for member training to ensure that all group members understand and can comply with the organic regulations.
- OTA recommends regulatory clarifications and guidance to ensure internal inspections conducted by the ICS are robust, clearly understood, and consistently implemented.
- OTA recommends the development of guidance that clarifies the scenarios that would qualify as a conflict of interest in an ICS.
- OTA supports the sampling method for external inspections that requires the certifier to inspect 1.4 times the square root ($1.4\sqrt{}$) of members. We also recommend that NOP explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the $1.4\sqrt{}$ method. We also recommend that NOP provide guidance to certifiers that will help ensure that each production unit is well represented in the overall sample of external inspections.
- OTA recommends a modified requirement for external witness audits that requires the certifier to evaluate *at least 25%* of internal auditors to ensure a representative sample of ICS inspectors are evaluated.
- OTA recommends the development of guidance for certifier's external oversight and enforcement of group operations in a manner that focuses on the assessment of the internal control system.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Calculating Percent Organic Ingredients – Section #17

- OTA supports a revision to the organic regulations to clarify the division method used to calculate the organic percentage of a NOP certified product. The intent of NOP's proposed revisions aligns with OTA's Comments on the corresponding NOSB recommendation.

- OTA supports the proposed revisions with minor adjustments to further clarify that the calculation should be made “at formulation.”
- OTA requests that NOP complete its process and finalize NOP Guidance 5037. Additional clarification on when to exclude water from individual ingredients is greatly needed.
- OTA supports an implementation period of one year after the publication of the final rule.

Supply Chain Traceability and Fraud Prevention – Section #18

- OTA supports adding the new term ‘*organic fraud*’ to the organic regulations to clarify the actions this proposed rule is intended to reduce and to support global communication and overall strategic direction of organic fraud prevention.
- OTA supports the proposed definition of ‘*organic fraud*’ whereas the action taking place is ‘intentional deception’ and the motivation is economic gain. However, OTA recommends that the term ‘illicit’ be removed from and the definition is revised to more clearly encompass the types of fraudulent activities that occur in the organic supply chain.
- OTA supports a requirement to include organic identification on the records maintained by a certified operation.
- OTA supports incorporating the term “audit trail” into the organic regulations at § 205.103(b)(3).
- OTA supports the proposal that certified operations must have procedures and practices to verify suppliers and prevent organic fraud. More specifically, we support a requirement that certified operations develop and implement an organic fraud prevention plan.
- OTA supports a requirement for certifying agents to share information with each other to verify supply chains and conduct investigations.
- OTA recommends adding the term ‘*supply chain traceability*’ to the organic regulations to clearly define a core concept that is integral to the purpose of this proposed rule and used throughout this proposed rule.
- OTA supports the requirement for certifiers to annually conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s). Defining ‘*supply chain traceability*’ will help the clarity of this new requirement.
- OTA supports the proposal that requires certifiers to have criteria and procedures for: (1) identifying high-risk operations and agricultural products to conduct risk-based supply chain audits; and (2) reporting credible evidence of organic fraud to the USDA.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

Technical Corrections – Section #19

- OTA has no concerns with the proposed technical corrections, and recommends that these technical corrections be implemented immediately upon the effective date of the final rule.

Additional Amendments considered but not included in this Proposed Rule – Section #20

- **Packaged Product Labeling** - For private-label packaged products, the certifying agent displayed on the label should be the certifying agent of the certified operation listed on the label. The name of the handler or distributor and its certifying agent should also match the information reported in the Organic Integrity Database. Listing contract manufacturers on labels should not be mandatory.
- **Expiration of Certification** - OTA does not support an amendment that would cause an operation’s certification status to automatically expire on an annual basis if the operation did not submit fees and update its certificate of organic operation.
- **Fees to AMS and Oversight of Certifying Agents’ Fees** - OTA does not support a user fee model. OTA maintains that funding should continue to come from congressional appropriations.

Implementation Timeframe

Topic	OTA’s Recommended Implementation Timeframe (from publication of the final rule)
Exemptions from Certification	2 Years for handling operations that must get certified as a result of this proposed rule
Imports to the United States (Import Certificates)	2 Years for shipments by ground transportation from Mexico and Canada; 1 year from publication of final rule for all other imports
Labeling of Nonretail Containers	2 Years for all nonretail containers
On-site and Unannounced Inspections	1 Year
Organic Certificates & Data Reporting	2 Years for mandatory use of Organic Integrity Database for generating certificates
Continuation of Certification	1 Year
Personnel Training and Qualifications	1 Year
Oversight of Certification Activities	1 Year
Accepting Foreign Conformity Assessments	1 Year
Noncompliance, Mediation and Appeals	1 Year
Grower Group Operations	1 Year
Calculating Percent Organic Ingredients	1 Year
Supply Chain Traceability and Fraud Prevention	1 Year
Technical Corrections	Immediately upon final rule becoming effective

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Exemptions from Certification

Thank you for this opportunity for the Organic Trade Association (OTA) to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter.

This comment addresses Section #1: Applicability and Exemptions from Certification

Summary of the Organic Trade Associations (OTA) Positions and Recommendations

OTA supports:

- Amending the regulations to clarify the applicability of the regulations and limit the types of operations exempt from organic certification.
- Full organic supply chain certification. The opportunity to be exempt from certification should be very limited, clearly defined, and based on activities that pose little or no risk to traceability and organic integrity.
- The proposed requirement that intermediate market actors such as brokers, traders and importers and other entities that facilitate the sale or trade of NOP certified products, such as traders and importers, should be certified, even if they do not take physical or financial possession or ownership of the product they represent.
- Bringing operations that do not need to get certified under the single term of “exempt,” and eliminating the term “excluded.” This will simplify terminology and reduce confusion and misinterpretation about who needs to be certified.
- The preamble in clarifying that grain elevators and ports of entry that are loading, unloading and/or transferring unpackaged product must be certified, as well as storage facilities that are splitting, combining and storing lots and loads and/or repackaging or relabeling.
- Modernizing the term and definition for ‘*retail operations*’ to capture in-person and on-line or virtual transactions.

OTA does not support:

- The proposed amendment that eliminates the distinction between ‘packaged’ and ‘unpacked’ product as it relates to receiving, storing and loading activities that may be exempt. Eliminating this distinction could allow high-risk handling operations receiving and loading unpackaged organic product, such as grain elevators and ports of entry, to be exempt from certification. To reduce the opportunity for organic fraud, handling operations that are storing unpackaged product **MUST** be certified.

OTA recommends the following exemptions from certification, provided the allowance is very restricted and narrowly defined:

- Exemptions may be granted only for **transporters, storage operations, customs brokers and freight forwarders and retail operations** that meet the following conditions (activities) and can comply with the organic requirements outlined below:
 - **Retail operations that handle, but do not process**
 - Associated distribution centers must meet the conditions of §205.101(e) in order to be exempt
 - **Retail operations** that ‘process’ NOP certified
 - Products that are ‘processed’ by the retail operation must be handled on-site at the point of sale to the final consumer
 - Associated distribution centers must meet the conditions of §205.101(e) in order to be exempt
 - Handling operations that only handle agricultural products that contain less than 70 percent organic ingredients, or that only identify organic ingredients on the information panel.
 - **Storage operations** that *only* store, receive, and *ship* NOP certified products that arrive in sealed packages or containers, and do not sell, process, package/repackage, label/relabel or otherwise handle such products while in the control of the operation.
 - **Transporters** that *only* transport certified organic products.
 - **Customs brokers and/or freight forwarders** that *only* act as an intermediary between importers and the government or between shippers and transportation services, but do not take physical or financial possession or otherwise handle the agricultural products.
- The exempt operations described above must comply with the following organic requirements (see details in our comments below):
 - Commingling and Contamination Prevention to protect organic integrity
 - Labeling requirements to ensure products are not misrepresented to the buyer or the consumer
 - Record keeping requirements to prove organic status and verify organic integrity

OTA recommends the following revisions or additions to clearly convey, in the proposed text, the activities that must be certified and the operations and activities that may be exempt:

- Revise the definition of ‘handle’ to better capture the activities in the organic supply chain that must be certified unless specifically exempt
- Revise the definition of ‘handler’ and ‘handling operation’ so they are synonymous and depend on the term ‘handle’
- Add the definition of ‘handle’ to §205.270 (Organic Handling Requirements) of the regulations to formally integrate the new definition and its corresponding activities into the regulation.
- Revise the proposed exemption for operations that only store, receive and/or load NOP certified product to apply only to products that are *sealed in a package or container*. Also replace the term ‘load’ with ‘ship’ because the term ‘load’ implies a bulk or unpackaged product is being handled. The term ‘*ship*’ would not exclude the activity of ‘*loading*,’ it simply infers a different meaning.
- Strike the term ‘alter’ and replace with “or otherwise handle,” or, add the term ‘alter’ and a definition to the regulation.
- Add an exemption for an operation that only *transports* (add as § 205.101(f)) to clarify that transportation is an exempt activity.
- Add an exemption for an operation that only handles the intermediary logistics of shipping agricultural products between importers and the government or between shippers and transportation services, but does not sell or otherwise handle the agricultural products. Examples include customs brokers and freight forwarders. (add as § 205.101(g) and add new § 205.101(h)) for record keeping)
- Revise the exemptions for retail operations to make a clear distinction between retail operations that ‘*handle*’ but do not process, and retail operations that *process*.
- Add a term and definition for ‘package’ and ‘packaged product’
- Revise the proposed organic requirements that exempt operations must comply with, so they are better aligned with risk to organic integrity and will better allow for oversight and surveillance activity.
- Revise the regulatory language at § 205.100 and § 205.310 to eliminate the term “excluded.”

OTA further recommends:

- Revisions to the rule that will reinforce and strengthen the relationship and shared responsibility between certified operations and exempt operations. Certified operations must ultimately be responsible for verifying their supply chains and ensuring that exempt operations are protecting organic integrity and maintaining organic product traceability. However, exempt operations should be required to maintain records to verify the status of the organic products they are handling, and the measures they are taking to protect organic integrity.
- Updating existing and/or creating new NOP Guidance to assist certifying agents and certified operations comply with the new requirements.

- Releasing NOP Guidance for Retail Operations to help clarify the exemptions under § 205.101(b) and § 205.101(c) and the labeling requirements exempt retail operations must comply with.
- Increased oversight and surveillance of exempt operations to ensure they are in compliance with the applicable organic requirements.
- A two-year implementation timeframe (after the publication of the final rule) for handling operations that must get certified as a result of this proposed rule.

NOP 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)?***

Yes, the definition of handle does not include many important activities that are included in the preamble. The definition could be improved to better capture common handling activities that occur as product moves from production source to the retail operation. See our detailed comments below.

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

The reference to ‘facilitating sale or trade’ is problematic. It could apply to individuals and entities that are performing intermediary functions that are administrative and truly do not pose a threat to organic integrity or present a fraud opportunity. Examples include customs brokers and freight forwarders. Another example is a sales broker who functions more like a sales representative for a consumer-packaged goods company. The sales broker helps to facilitate the sale and distribution of finished packaged goods (retail, packaged with final label) directly to retail operations. They do not buy the product from the company, but rather represent the company to contracted retailers for a contracted commission on annual retail sales.

Another important consideration is a distributor, or an agent, that supplies packaged finished retail goods (final packaging and label) to retail establishments. They buy finished retail products and sell to retail outlets, with the consumer as the end purchaser. The product is shipped or picked up from the certified operator’s distribution center, taken to the distributor’s distribution network and then delivered to individual selling locations. The products are enclosed in the final tamper-proof retail package with the final retail label, and then further packaged in secondary and tertiary packaging for storage and distribution. There is no further packaging or labeling while the product is in transit or in storage or before it arrives at the retail outlet where it is sold directly to the consumer. It is not uncommon for one large certified operation to have upwards of 300+ distributors that will sell to thousands of outlets, from large grocery stores to specialty shops, military bases, foodservice and more. The risk to organic integrity and/or the opportunity for fraud would be very low. OTA has not suggested an exemption for this type of distributor. However, as mentioned in our cover letter, this is an example of where a “one-size fits-all” regulation can be problematic. Closing the exemption for an intermediary commodity broker presents a very different fraud opportunity than a distributor at the very end of the supply chain selling a fully packaged and labeled retail product to a retail operation. It also raises the question of whether

closing the exemption on this kind of distributor was intended, and if it was fully factored into the assessment of how many uncertified handlers will need to get certified.

3. **Are there specific activities not included in the proposed rule that you believe should be exempt from organic certification?** Yes. The preamble clearly states that ‘transport’ alone is not a handling activity. However, the proposed change to the definition of ‘handle’ removes the clarification that the definition of ‘handle’ does not include transportation. Since the proposed definition of ‘handle’ includes an ‘open list’ of activities that need to be certified, transportation should be explicitly carved out as an exempt activity under § 205.101 and Guidance should be provided.
4. **Are there additional requirements that exempt handlers described in this proposed rule should follow?** Yes. Storage facilities and transporters should be required to maintain records that can be used to verify the organic status of the products they are handling, and the measures taken to protect organic integrity. These records would ultimately be retained by the responsible certified operations and available for inspection, but there should be a shared responsibility as per the regulations. Retail operations that ‘handle’ should also be required to maintain records to verify organic status of the products they are handling and selling. See our detailed comments below.

OTA’s Positions and Recommendations

OTA supports amending the regulations to clarify the applicability of the regulations and limit the types of operations excluded from certification in the organic supply chain. OTA prioritized several legislative changes for the 2018 Farm Bill to give NOP the tools it needs to prevent fraud. One of our top priorities was to provide AMS with the authority needed to make modifications to the regulations to limit the type of operations that are excluded from certification under 7 CFR §205.101. Uncertified entities in the supply chain that are handling organic products pose a major risk of fraud and threat to organic integrity because they are operating outside of the certification system and accordingly are not subject to annual on-site audits. This results in an interruption or break in an otherwise tightly linked supply chain, and creates an opportunity for unverified activity and ultimately fraudulent behavior. The exclusion from certification under § 205.101(b)(1) is no longer appropriate considering the complexity of today’s organic supply chain and the global scale and growth of the sector.

OTA recognizes that handlers currently conducting business as “excluded operations,” such as commodity brokers, traders and wholesalers, will need to become certified. We believe that fraud in the industry poses a far greater risk to the success of the organic marketplace than any impact this change may have, and acknowledge that a trade-off must be made to ensure organic integrity throughout the supply chain and maintain consumer trust in the label. Where ill-intended actors are involved, certification and the oversight of certifying bodies mitigate risk of fraudulent action and create a more robust paper trail for investigating concerns and holding accountable bad actors.

OTA's comments largely focus on NOP's request for comments around the clarity of the proposed requirements and whether certified operations, handlers and certifying agents can readily determine how to comply with the proposed regulations. Overall, the intent and meaning behind the proposed provisions are explained well in the preamble, and they are fairly consistent with OTA's "pre-rule" comments that were submitted on November 20, 2018. However, NOP's *intent is not clearly conveyed in the proposed rule itself*. As we explain below in detail, several revisions are needed to clarify the proposed requirements and ensure that certified operators and certifying agents can readily determine how to comply with the proposed regulations.

Clarification of applicability

Definition of 'Handle'

OTA agrees that the definition of '**handle**' should be revised to clearly capture all of "the activities that affect the organic status or ownership of an agricultural product, after production, as it moves from production source through a supply chain." We also agree that the activities described in the definition of "handle" must be certified, unless specifically exempted by the rule. However, the proposed rule does not "clearly state which entities, operations, and activities require certification under the USDA organic regulations." For example, the preamble states that the proposed rule would require certification of storage facilities that store and split or combine lots and loads. However, § 205.101(e) provides an exemption to an operation that "only stores, receives, and/or loads agricultural products, but does not process or alter such agricultural products." Under these conditions, a storage facility, grain elevator or entry port could receive bulk grain (unpackaged) and convey or load the grain into multiple storage silos and meet the conditions of § 205.101(e). The definition of 'handle' does not provide clarity because it does not include "splitting" as an activity, the meaning of term 'containerizing' is open to varying interpretation, the term 'alter' is undefined, and the term 'load' implies the handling of a bulk product (to load grain vs. ship packaged product). Further explanation is provided below under '**Exemption for storage of organic agricultural products.**'

- ➔ **Recommendation:** 1) Revise the definition of 'handle' to better capture all activities from production source to consumer that must be certified; 2) revise § 205.101(e) to distinguish between 'packaged' and 'unpackaged' product; and 3) Add a definition for the term "alter," or, eliminate it and replace with "...or otherwise handle such agricultural products." ***See OTA's requested revisions in Table 1.***

Customs Brokers and Freight Forwarders

OTA agrees that brokers, traders and importers selling or trading NOP certified products should be certified, even if they do not take physical possession or financial ownership of the product they represent. We want to ensure however that entities that are only engaged in intermediary shipping logistics, such as **customs brokers** and **freight forwarders**, would not need to get certified since they are simply acting as a service agent in the middle of an organic transaction. They are not selling, trading, receiving or otherwise handling product; instead, they are fulfilling

an administrative role in the transaction process. The phrase “facilitating sale or trade” may imply that certification would be required for this type of activity.

- **Recommendation:** Add a specific exemption to the regulation (§ 205.101(g)) for **customs brokers and freight forwarders** that *only* manage the intermediary logistics of shipping agricultural products between importers and the government or between shippers and transportation services, but do not take physical or financial possession or otherwise handle the agricultural products. *See OTA’s requested revision in Table 1.*

Definitions of ‘Handler’ and ‘Handling Operation’

The proposed rule modifies the definition of ‘*handler*’ and ‘*handling operation*’ with the intention of capturing any ‘person’ or ‘operation’ that handles agricultural products:

- The proposed definition of “*Handler*” is defined as ‘any person engaged in the business of handling agricultural products.’
- The regulation defines ‘*person*’ as an “individual, partnership, corporation, association, cooperative, or other entity.”
- The proposed definition of “*Handling Operation*” is, “Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification.”

OTA agrees with the intent; however, as proposed, the slight differences between the two may lead to confusion and misinterpretation. Furthermore, as proposed, an operation that is exempt from certification would be considered a ‘handling operation,’ but an exempt ‘handler’ would still be de considered a ‘handler.’ A ‘handler’ or ‘handling operation’ that is exempt from certification should be exempt from just that - *certification*. The exemption should be based on the ‘activity’ of any handler or handling operation that may or may not need to be certified. An exempt operation should still be referred to and defined as a ‘handler’ or ‘handling operation,’ just one that is exempt from certification. The regulations at §205.101 adequately specify the operations and activities that are exempt from certification.

- **Recommendation:** 1) Remove unnecessary words from the definition of ‘handle so the two terms are synonymous; and 2) omit the phrase “...except for operations that are exempt from certification” from the definition of ‘handling operation.’ *See OTA’s requested revisions in Table 1*

Clarification of exemptions from certification

The proposed rule modifies § 205.101 by renaming the section “Exemptions from certification,” eliminating the exclusions currently listed at § 205.101(b), and listing (in revised § 205.101) all operations that are **exempt** from organic certification. OTA agrees that this approach will reduce confusion and misinterpretation about who needs to be certified. The distinction between the term “excluded” and “exempt” has been a long-time source of confusion and effectively does not serve a purpose. OTA agrees with the proposal to retain one term - “exempt” - to describe operations that may not need to be certified. However, we are concerned about key language that was eliminated under § 205.101(b)(1) that removes the distinction between ‘packaged’ and ‘unpackaged’ product and inadvertently opens the exemption to operations such as grain elevators and ports. (See more detail under “**Exclusions removed from the proposed rule.**”)

The proposed rule also intends to address stakeholder concerns about clarity and consistent implementation of portions of the organic regulations that exempt operations must comply with. Accordingly, the proposal does in fact clearly state the requirements that exempt operations must follow. However, they are not consistently applied according to risk level (fraud opportunity) and the portions of the regulations that should be followed to maintain and demonstrate organic integrity and prevent misleading organic claims.

See more detail under “**Certified operations’ verification and recordkeeping responsibilities**” and **Appendix A (OTA’s Comparison Chart of Organic Requirements for Exempt Operations).**

Exemptions retained by the proposed rule

The proposed rule retains: 1) the current exemption for operations with less than \$5,000 or less in annual income from organic sales; and 2) the current exemption for operations that handle products with less than 70 percent organic ingredients, or, only identify organic ingredients in the ingredient statement. These exempt handlers are required to comply with the labeling requirements of §§ 205.305 and 205.310, the commingling requirements of § 205.272, and must maintain records that (1) prove that agricultural products identified as organic were organically produced and handled, and (2) verify quantities produced or sold from such agricultural products.

OTA supports the continued retention of these exemptions. However, operations with less than \$5,000 should be required to maintain records to prove that agricultural products identified as organic were organically produced and handled. Please keep in mind that such operations may be producers or handlers.

Additionally, it has been brought to our attention that the exemption from certification for operations that only identify organic ingredients on products labels, has a tendency to lead to the creation and use of misleading labels in the marketplace, particularly for single-ingredient products

and/or small products that utilize a single panel label. The same can occur for products with less than 70 percent organic ingredients. However, it is less likely because a “single-organic ingredient” situation would not occur.

→ **Recommendation:** Clarify in Guidance that the exemption for an operation that “only identifies organic ingredients on the information panel” applies to products that include an information panel that is distinctly different from the Principal Display Panel.

Exclusions removed from the proposed rule

The proposed rule brings all operations that do not need to be certified under the single term, “exempt.” OTA agrees with this simplification.

As for what types of operations should qualify to be exempt, we note that the existing regulations, at § 205.101(b)(1)(i) and (ii), provide that handling operations do not need to be certified if they only sell organic agricultural products that are packaged or otherwise enclosed in a sealed container prior to being received and remain in the same package or container and are not otherwise processed while in the control of the handling operation. There are numerous storage facilities that meet this description and have until now been excluded from the requirement of certification pursuant to § 205.101(b)(1)(i) and (ii). The preamble to the proposed rule indicates that under the proposed rule they would need to obtain certification.

We understand from the preamble that the intent was to bring operations handling packaged products into the fold of certification and improve the traceability and potential mishandling of packaged products by uncertified operations. However, under the exemption proposed under § 205.101(e), the language appears to create a new exemption that excuses from certification any handling operation that **loads unpackaged** product (i.e. open bins of produce, loose grain, etc.). This would include, for example, grain elevators and ports that are receiving, storing and/or loading bulk grain. The result is in stark contrast to stakeholder feedback that informed the proposed rule, it does not fulfill the apparent intent of the proposed rule per the preamble, and it should not be allowed.

Furthermore, storage facilities, distributors, and warehouses receiving, storing and loading **packaged** product could continue to be exempt under the proposed definition of “handle” (NOP’s version does not include ‘treatment’) and the § 205.101(e) exemption. As a result, the broad language of § 205.101(e) would continue to shield handling operations dealing in packaged products from the requirement of certification and open up an exemption for handling operations that are dealing with unpackaged bulk product. This would undercut NOP’s intent as expressed in the preamble.

OTA has continuously maintained that an exclusion or exemption from certification should be very restricted and may be granted only for transporters, storage facilities and retail food establishments that meet certain conditions and comply with appropriate regulatory compliance requirements. For storage facilities (including warehouses, distribution centers, ports or other operations that temporarily store or transfer products) to be exempt from certification, the operation must not sell, process, package, label or otherwise handle the product. The NOP certified product must be received in a sealed package or container and be shipped in that same package or container without any opening or closing or repackaging or relabeling. In order to maintain organic integrity and prevent organic fraud, it is critical that the storing and handling of unpackaged products be conducted with oversight of organic certification.

→ **Recommendation:** Revise the exemption in § 205.101(e) to apply to handling operations that only receive, store and **ship** NOP certified products that arrive in a **package or container** and remain in the same package or container and are not otherwise handled while in the control of the handling operation. The handler or handling operation must not sell, repackage, relabel or otherwise handle the products. In this revision, the term ‘load’ should be replaced with the term ‘ship’ because ‘loading’ is commonly associated with bulk unpackaged products

See OTA’s requested revision in Table 1

→ **Recommendation for Definitions and Guidance:** OTA requests Guidance around the types of labeling that may not need to be certified. The definition of ‘handle’ includes the terms ‘labeling’ and ‘package.’ The terms ‘label’ and ‘labeling’ are defined in the organic regulations, but the term ‘package’ (or ‘packaging’) are not. There are some forms of labeling and packaging that do not reasonably fall within the scope of ‘handling’ and may not require certification because they are extremely low- to no-risk activities and would not impact the organic integrity or traceability of the product being handled. Examples include applying a weight code on a pallet and/or an internal tracking number on a shipping box, shrink-wrapping sealed shipping cartons containing packaged retail products onto a pallet and breaking down a pallet of sealed and labeled shipping cartons that contain packaged retail product and shipping the individual (labeled and sealed) cartons to various locations.

OTA received many member comments and questions around the definitions of ‘labeling’ and ‘packaging,’ and the types of labeling and packaging activities that require certification. We also received many questions around whether ‘packaging’ includes ‘labeling.’ Furthermore, several members felt that the definition of ‘processing’ should include ‘labeling.’ We have identified packaging and labeling as points in the supply chain that both protect organic integrity and present a fraud opportunity. To improve the overall clarity of the activities that must be certified, we recommend adding a definition for ‘packing,’ ‘package,’ and ‘packaging,’ and issuing Guidance. It would be very helpful if reference to a “packaged product” meant that it is a NOP certified product that is

packaged and properly labeled, whether it be a retail or non-retail package or container. As a start, we recommend looking to FDA’s definitions that were established in FSMA (see Appendix B). Please note that FDA categorizes ‘labeling’ as a processing activity.

In general, we believe Guidance will be critical to achieve optimal clarity around the applicability and exemptions from certification and to support consistent implementation of the Final Rule.

Clarification of the retail operation exemption

Retail Operation – New Term and Definition

OTA supports the proposal to rename the term ‘retail food establishment’ as ‘retail operation’ and we support the expansion of the definition to include current modes of direct-to-consumer sales that commonly occur in the modern marketplace, such as on-line or virtual transactions (e-commerce). We support the revised definition because it *generally* captures the full range of direct-to-consumer sales and transactions that may occur as well as the full range of certified organic products (food and non-food) that may be sold in today’s retail marketplace. In order to improve its clarity, we suggest including examples provided in the preamble in the definition itself. This approach is similar to the definition of ‘handle.’”

➔ **Recommendation:** Add the following to the definition of retail operation: Examples of retail operations include but are not limited to restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service stations (e.g., grains, nuts), or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.

See OTA’s requested revision in Table 1.

Exemption for Retail Operations that “Sell” vs. “Handle” vs. “Process”

OTA supports the continued exemptions for retail operations. However, we maintain that GUIDANCE for retail operations is needed, particularly as it relates to distinguishing between ‘handling’ and ‘processing,’ and the labeling requirements of §§205.308 – 205.310. In our Pre-Rule comments submitted to NOP on November 20, 2018, we commented extensively on the areas of the rule that need clarification. We continue to be supportive of an exemption for retail operations. However, this support is contingent on ensuring that retail operations are provided with guidance to further understand their responsibility in the supply chain, and the organic requirements they must comply with. This Proposed Rule does not address many of the concerns that we expressed or our comments, particularly as it relates to labeling.

We are largely concerned about the proposed language in § 205.101(b) and § 205.101(c) and the fact that neither one references ‘handling.’ The first exemption (§205.101(b)) is for a retail operation that merely ‘sells,’ and the second exemption (§205.101(c)) is for a retail operation that

processes on-site at the point of sale to the final consumer. This approach leaves out “handling,” and a myriad of activity that most retail operations perform that is not captured under the definition of ‘*processing*.’

Many retail operations that ‘*sell*,’ but do not ‘*process*,’ will be engaged in various forms of handling activity (e.g. receiving, storing, washing, sorting, combining, splitting, opening and relabeling). For example, a retailer may transfer certified organic avocados or apples from a box to the produce display, or a retailer may transfer certified organic flour from a bulk bag to a bulk bin delivery system. Both activities, and similar activities that occur throughout the produce and bulk section of a retail store, would arguably meet the definition of “handle,” but not the definition of “processing.” Without a clear distinction between ‘*sell*,’ ‘*handle*,’ and ‘*process*,’ the organic requirements will be ambiguous.

The proposed rule retains the exemption for a retail operation that does not ‘*process*,’ however, the term ‘*handle*’ was replaced with the term ‘*sell*.’ In practice, a retail operation will seldom just ‘*sell*’ organically produced products. As discussed above, washing, sorting, combining, splitting, among other activities, would constitute “handling.” Therefore, if a retailer conducts any of these activities, we assume they must determine whether they meet the retail processing exemption under § 205.101(c) and meet the associated organic requirements. We are concerned with this approach and the ability for retail operations to readily determine which exemption they fall under and the organic requirements they must comply with.

It is important that retail operation follow organic requirements that make sense for the activity they are conducting. There are several handling activities that most retail operations conduct on a daily basis that do not warrant all of the organic requirements that are proposed for a retail operation that “processes.” Similarly, there are handling activities under 205.101(b) that warrant labeling and record keeping requirements. Therefore, OTA recommends that the rule be revised to include 1) an exemption for a retail operation that handles, but does not process; and 2) an exemption for a retail operation that processes onsite at the point of sale to the consumer.

- ➔ **Recommendation:** Revise § 205.101(b) to make a clear distinction between a retail operation that ‘*handles*’ but does not ‘*process*’ NOP certified products. This will help clarify and justify the organic requirements this type of retail operation must comply with vs. a retail operation that is processing. Given that most retail operations are engaged in labeling at some level, and given that the definition of ‘*handle*’ includes ‘*labeling*,’ we also recommend expanding the organic requirements to include the labeling provisions of §§205.308 – 205.310 along with record keeping requirements to demonstrate the agricultural products identified as organic were organically produced and handled.
- ➔ **Recommendation:** Further analysis of the labeling provisions under §§205.308 – 205.310 is greatly needed followed by subsequent rulemaking and/or Guidance. OTA believes that all exempt operations are subject to 205.310 of the regulations because of its title. Furthermore, § 205.308 and § 205.309 provide helpful clarification

about how agricultural products in other than packaged form at the point of retail sale may be represented. Both sections include an important distinction for products that are prepared in a certified facility. Overall, the labeling requirements for retail operations continues to be an area of great confusion and Guidance is definitely needed.

- *See OTA's requested revisions in Table 1*
- *See Appendix A for OTA's comparison chart of organic requirements for exempt operations*

§ 205.101(c) - Retail Operations that Process Onsite at Point of Sale to the Consumer

NOP proposes to revise the existing exemption for retail operations that process organically produced agricultural products. The revised exemption would cover:

A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer.

This revision specifies that the products received “were previously labeled for retail sale.” OTA is concerned with term “retail,” and its intended meaning and purpose. Restaurants, bakeries and delicatessens commonly source products that are labeled for food service. Limiting the sourcing supply to products that are only labeled for retail sale would present impractical costs and packaging waste.

→ **Recommendation:** Remove the term “retail” from § 205.101(c)

NOP proposes removing the limitation on the types of organically produced agricultural products that can be processed by retail operations (i.e., processing is no longer limited to raw or ready-to-eat foods), instead emphasizing that the processing has to occur in connection with the final sale to the consumer, i.e., at the point of sale. Several questions are being raised about how this will impact retail operations that are delivering processed products to local customers.

→ **Clarification Requested:** The preamble is clear in saying that products must be processed and sold in the same physical location. However, it is unclear how if the products must be processed, sold and served on-site to the customer, or if the products could be sold and then delivered by services such as Grubhub and Uber Eats. For example, a customer could make a phone purchase and then pick the product up, or the store could deliver. Would the latter require certification if the processed products are represented as organic? OTA requests clarification.

Retail Operations and Distribution Centers

Retail operations commonly contract if not own and operate off-site warehouses, distribution centers and fulfillment centers. Additional clarification is needed for storage facilities that are under the management of a retail operation and for retail operations. The exemption for retail operations presents an opportunity for their associated distribution and fulfillment centers to also be exempt. Clarification is needed to ensure that the exemption applies to the storage facility only if the storing activity meets the conditions of § 205.101(e).

- **Recommendation:** OTA requests that NOP clarify in Guidance that distribution centers operating under the ownership of, or in association with a retail operation must only receive, store and ship packaged NOP product. Unless certified, the distribution center **must not** label/relabel, combine, split, containerize, pack/repack, treat, sort, open, enclose, or otherwise handle the organic products while they are under the operation’s control.

Retail Operations and Private-Label Arrangements

In the preamble, under additional amendments considered but not included in this proposed rule, NOP explains that the proposed amendments to §§ 205.2 and 205.100 – 101 would require certification of operations that sell or represent organic products. NOP goes on to say, “This would include operations in “**private-label**” relationships; both the operation that produced/processed the organic product (the “contract manufacturer”), and the operation that sells the product under its own label (the “brand name” or “distributor”), would require certification under this proposed rule.” OTA is concerned that the proposed rule itself does not clearly require certification of an operation that is a private-label brand owner, and as a result, impacted operations may have not been given sufficient notice or time to provide public comment. In addition, it does not appear that the impact of this provision has been assessed in the Economic Analysis of the Proposed Rule, and while associated labeling requirements were considered, NOP did not proceed with any proposed changes. Finally, it is unclear if the proposal would allow retail operations to be exempt from certification. As per § 205.101(b), retail operations that “sell” but do not process are exempt from certification.

- **Recommendation:** Given the lack of clarity around the applicability of this proposed rule to private-label brands (retail operations or otherwise), the significant number of operations that may need to get certified, the lack of sufficient economic analysis, and the labeling amendments that were considered but not included in this Proposed Rule, OTA recommends that NOP address private-label certification in a separate rulemaking process. Additional time and notification are needed to sort out all of the various relationships and arrangements and analyze how such activity may or may not impact organic integrity, transparency and traceability.

Guidance and Increased Oversight of Exempt Retail Operations

OTA supports guidance and increased oversight of exempt retail operations. The organic requirements that exempt retail operations are required to comply with should help maintain organic integrity, even in the absence of certification. Retail operations that handle and/or process certified

organic products are carrying out activities that pose a medium- to high-risk to organic integrity. OTA supports retaining an exemption for retail operations that sell, handle and/or process. However, guidance AND increased USDA oversight are significantly needed to ensure that organic requirements are understood and being met. Requiring exempt operations to meet certain provisions of the organic regulations without guidance and without any oversight or surveillance will not meet the goal of protecting organic integrity.

- **Recommendation:** OTA recommends that NOP release Guidance for retail operations concurrent with the final rule. We also recommend that NOP’s Compliance Department increase its oversight of exempt operations and conduct routine surveillance of exempt retail operations.

Exemption for storage of organic agricultural products

NOP proposes to exempt from organic certification operations that only store agricultural products, but do not “process or alter such agricultural products” (proposed § 205.101(e)). In the preamble, NOP explains that this “exemption would apply to warehouses, storage facilities, and other operations whose only function is the temporary holding or storage of organic products, and the associated receiving and loading of organic products.” NOP goes on to explain that “an operation that processes or alters the organic products they store would not qualify for the exemption and must be certified. Storage operations claiming this exemption must not label/relabel, combine, split, containerize, pack/repack, treat, sort, open, enclose, or otherwise alter the organic products they handle.”

OTA agrees. However, the intent, as explained in the preamble, is not clearly conveyed in the proposed regulatory text. The following terms, and the exemption under § 205.101(e), create ambiguity around the “storing” activities that would qualify for an exemption:

- **‘Storing’** is an activity included in the definition of ‘handle,’ and therefore an activity that requires certification. However, § 205.101(e) exempts an operation that only stores, receives and/or loads, but does not process or alter. The proposed language is problematic because the term ‘load’ is commonly used and associated with the handling of bulk or unpackaged product.
- **‘Alter’** is an important term used to qualify whether a storage facility may be exempt. However, unlike “processing,” the term “alter” is not defined or further qualified in the regulation. In the preamble, NOP explains that an operation that processes or alters the organic products they store would not qualify for the exemption and must be certified. NOP goes on to say that “storage operations claiming this exemption must not label/relabel, combine, split, containerize, pack/repack, treat, sort, open, enclose, or otherwise alter the organic products they handle.” The preamble explanation provides good clarity. However, several example activities in the preamble are not included in the definition of “handle,” and/or the definition or “process.” These include relabel, split, pack, treat, sort, open, and enclose.

The ambiguity is further exacerbated by the proposed elimination of the exclusion for handling operations that only sell products that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation and remain in the same package or container. This elimination opens the exemption to operations that receive, store and load unpackaged product. This could, for example, exempt grain storage facilities, grain elevators and ports if the activity is perceived only as receiving, storing and loading.

Due to risk of organic fraud, the receiving, storing and handling of unpackaged product *should* require certification. As explained above, we do not believe NOP intended to exempt storage facilities, grain elevators and entry ports handling bulk products from organic certification. Such an exemption would be in stark contrast to stakeholder feedback to inform the proposed rule and it should not be exempt because it poses a high-risk to organic integrity and presents a significant opportunity for fraud.

- ➔ **Recommendation Part 1:** Revise the definition of ‘handle’ to clearly capture all of “the activities that affect the organic status or ownership of an agricultural product after production as it moves from production source through a supply chain. This revision should include a general description of full supply chain activity as well as a more complete list of activities that reflect the examples provided in the preamble and suggested in OTA’s comments. *See OTA’s requested revision in Table 1*

- ➔ **Recommendation Part 2:** Revise § 205.101(e) to specify a requirement that product must be packaged prior to being received and remain in the same package and must not be otherwise handled while in control of the exempt handling operation. *See OTA’s requested revision in Table 1*

Transport of organic agricultural products

In the preamble, NOP explains that operations that only transport organic products are not required to be certified. NOP considers transport to be a low-risk activity, and points out that transport, as per the definition of “handle” in OFPA, is not a handling activity.

OTA agrees that transporters may be exempt from certification provided they do not sell, process or package. The activity must be limited to the transport or delivery of certified organic crops or livestock, and in the case of unpackaged product, the certified organic product must be transported from a certified operator (producer or handler) to another certified operator or final retailer. In all instances, the certified operation responsible for the organic product(s) must disclose all activity in the Organic System Plan and maintain compliance with the organic regulations, including records, audit trail and traceability of the product(s). Excellent Guidance on transportation and compliance with the organic regulations is provided in **NOP Guidance 5031**.

OTA is concerned that the proposed change to the definition of ‘handle’ will completely remove the ONLY reference to “transportation” from the organic regulations. Transporters and transportation are discussed in the preamble, but the proposed changes to the rule will completely eliminate the term and specific mention of activity altogether. Eliminating the term from the regulations would leave ‘transporters’ and ‘transportation,’ by name, unaddressed in OFPA and the regulations. Any remaining clarification or interpretation would be entirely based on its *absence* from the definition of “handle,” both in OFPA and the rule. Without the context of the preamble and without any specific mention of the activity in the rule itself, the exempt status of transportation will not be clear. Transportation is a unique activity that does not fall under the proposed § 205.101(e) exemption (store, receive, and/or load) or any other proposed exemption. The definition of ‘handle’ references a number of activities that require certification; however, it is an ‘open list’ of examples (aka “included but not limited to”). Therefore, the exemption for transportation should be explicitly called out in the rule itself.

- **Recommendation:** Add a new designated section (exemption) for transporters. Add as § 205.101(f) and re-designate the proposed (f) on records to § 205.101(e). Revise § 205.101 (Exemptions from certification) to read, “The following operations in subparagraphs (a) – (g) are exempt...”
- **Add new § 205.101(f):** An operation that only transports certified organic products. Such operations must comply with record keeping requirements to (1) demonstrate that the organic integrity of the product is maintained during receiving, storage and loading, and (2) verify both the quantities and the organic status of the product being received, stored and shipped.
 - **Add new § 205.101(f):** An operation that only transports certified organic products. Such operations must prevent commingling and contamination and comply with record-keeping requirements to (1) demonstrate that the organic integrity of the product is maintained during transport and; (2) verify the quality and organic status of the product being transported.
 - **Release updated Guidance (NOP 5031)** to help clarify how the exemption applies to an operation that transports packaged and unpackaged products and the organic requirements they must comply with.
 - **Revise § 205.101** to include subparagraphs (a) – (g) as exempt from certification...but must comply with applicable organic production and handling requirements...including provisions for prevention of commingling and contact of organic products with prohibited substances set forth in § 205.272.
 - **Revise the re-designated § 205.101(e)** to include the new exemption for transportation and a requirement for record keeping.

See OTA’s requested revisions in Table 1

- **Guidance Requested:** OTA requests that NOP 5031 be retained (and updated as necessary) to address exempt transportation as it relates to packaged and unpackaged products. The fraud opportunity and the organic requirements that should apply are not the same and a distinction needs to be considered. OTA supports continued compliance with the following, as it relates to unpackaged products and detailed in the NOP Guidance 5031:
- Under NOP 5031, an operation that transports unpackaged organic product does not need to obtain certification if it does not handle (sell, process, or package) organic products. Examples of operations that do not need to obtain certification include:
 - Transportation companies that move certified organic hay or straw (wrapped or unwrapped) or milk from a certified operation farm to a certified organic buyer or processing facility;
 - Transportation companies that transport certified organic grain from certified operations to a certified handling facility; and
 - Transportation companies that move certified organic livestock from a certified organic farm to a certified organic slaughter facility.
 - The certified organic operation responsible for the organic products that are transported must:
 - Maintain records in sufficient detail as to be readily understood and audited;
 - Maintain the audit trail and traceability of organic products;
 - Prevent commingling and contamination of the certified organic products during transportation;
 - Fully describe the transportation practices in the organic system plan; and
 - Ensure that the transportation records for organic products are available for inspection.

Certified operations' verification and recordkeeping responsibilities

The proposed rule requires exempt operations, including storage operations and transportation, to comply with the commingling and contamination prevention requirements of §205.272. OTA strongly agrees. However, it is important that these exempt operations also comply with record keeping requirements to: (1) demonstrate that the organic integrity of the product is maintained during receiving, storage and loading (verify commingling/contamination prevention), and (2) verify both the quantities and the organic status of the product being received, stored and shipped.

As intended by the proposed revision at § 205.301(a)(3) – (see supply chain traceability and organic fraud prevention), certified operations are required to verify the organic status of products that are handled by exempt operations in a supply chain. NOP is proposing that onus be on

certified operations to have procedures in place that will ensure product integrity and traceability. In the preamble, NOP explains that certified operations should “carefully review the practices and records of operations in their supply chain, including transportation and storage operations.” NOP goes on to say that “certified operations must maintain records to support the verification of organic integrity and facilitate supply chain audits.”

OTA strongly believes that the system will be much more robust and the ability for the responsible certified operator to collect and maintain the required documentation will be greatly strengthened if the exempt operations are **required** to not only prevent commingling and contamination, but also maintain records that verify the practices used to prevent commingling and contamination, and verify organic product status. This would not preclude the requirement for a certified operation to have practices and procedures in place (as described in the OSP) to verify the organic status of products handled by exempt operations as well as maintain records to support the verification of such activity. Requiring exempt operations to maintain records on organic integrity and organic status will simply bolster and validate a shared responsibility between the certified operation and the exempt operation.

→ **Recommendation:** *Revise §§ 205.101(e) and 205.101(f) to require exempt operations to comply with record keeping requirements to (1) demonstrate that the organic integrity of the product is maintained during receiving, storage and loading, and (2) verify the organic status of the product being received, stored and shipped.*

See OTA’s requested revisions in Table 1

Additional revisions that are needed but were not identified in the proposed rule

OTA has identified additional revisions that are needed to either correct the regulations due to the elimination of the term “excluded” or to further integrate NOP’s proposed new requirements or OTA’s recommended revisions:

- ***Technical correction: § 205.100 - What has to be certified.*** This section needs to be revised: “(a) Except for operations exempt or ~~excluded~~ in §205.101, each production or handling operation or specified portion of a production or handling....applicable requirements of this part.”
- ***Technical correction: § 205.310*** (Agricultural products produced on an exempt or excluded operation) needs to be revised to strike the term “excluded operation.”
- ***Labeling requirements for retailers and other exempt operations in general:*** The proposed rule requires retail operations that ‘process’ to comply with the labeling provisions of § 205.310. Retail operations that ‘handle’ (sell, process package, label) should

be required to also comply (as applicable) with the labeling provisions of §§205.308, 205.309 and 305.310. OTA recommends that NOP take a close look at these requirements as they are currently written, and ensure they are applied appropriately to the proposed exemptions as we have suggested. We also recommend guidance and training to ensure they are understood and accurately implemented.

- **Add the activity of ‘handle’ to § 205.270 (Organic Handling Requirements):** Currently, § 205.270 includes a description for “processing,” but does not discuss *Handling*. SOE presents an excellent opportunity to address the differences between ‘handling’ and ‘processing’ and formally integrate the distinction between the two under the § 205.270. This could be done by adding a new 205.270(a) for ‘handling’ and re-designating processing to § 205.270(b):

§205.270 Organic handling requirements.

(a) Except for exempt operations described in 205.101, any operation that handles agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part. Handling includes but is not limited to selling, buying, trading, brokering, facilitating sale or trade, processing, packaging, repackaging, labeling, relabeling, opening, enclosing, packing, repacking, sorting, combining, splitting, consolidating, bundling, treating, containerizing, receiving, storing, transferring, loading and/or otherwise moving an agricultural product from the production source to the consumer.

See OTA’s requested revisions in Table 1 (next page)

Table 1. OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA Positions and improve the quality, clarity and utility of the Proposed Rule.
Revise 205.2	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.	<p>Revision needed: OTA does not support the proposed definition of ‘handle’ because it does not clearly capture all of the activities that affect the organic status or ownership of a certified organic product as it moves from production source through the supply chain.</p> <ul style="list-style-type: none"> ● Include a general description of supply chain activity as well as specific examples (included but not limited to) ● Add example activities from preamble ● Add additional activities that are not in the proposed rule or the preamble
<p>OTA Requested Revision: <i>Handle.</i> To sell, process, package or label agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, <u>relabeling, packing, repacking, opening, enclosing</u>, combining, <u>splitting</u>, sorting, <u>consolidating, bundling, treating</u>, containerizing, receiving, storing, <u>transferring</u>, loading or <u>otherwise moving an agricultural product through the organic supply chain from production source to the final consumer.</u></p>		
Revise 205.2	Handler. Any person engaged in the business of handling agricultural products.	<p>Revision needed: OTA does not support the proposed definition of ‘handler.’</p> <ul style="list-style-type: none"> ● Revise the definition to eliminate unnecessary words that lend to confusion and misinterpretation aka “in the business of”
<p>OTA Requested Revision: <i>Handler.</i> Any person <u>engaged in the business of handling</u> that handles agricultural products.</p>		
Revise 205.2	Handling operation. Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification.	<p>Revisions needed: OTA does not support the proposed definition of ‘handling operation.’</p> <ul style="list-style-type: none"> ● A revision is needed to make the term ‘handling operation’ synonymous with ‘handler.’ ● Handling operations that are exempt from certification will be exempt based on the regulation at § 205.101(a). Striking the

		last part of the proposed definition “except for operations that are exempt from certification,” will eliminate confusion. A handling operation that is exempt from certification will continue to be a ‘handling operation,’ just one that is exempt from certification.
OTA Requested Revision: <i>Handling operation.</i> Any operation or portion of an operation that handles agricultural products., except for operations that are exempt from certification.		
Revise 205.2	Retail operation. An operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions.	Revision needed: OTA supports the proposed definition of retail operation; however, there would be greater clarity if the examples in the preamble were included in the regulatory definition itself.
OTA Requested Revision: An operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions. <u>Examples include but are not limited to restaurants, delicatessens, bakeries, grocery stores, or any retail business with a restaurant, delicatessen, bakery, salad bar, bulk food self-service stations, or other eat-in, carry-out, mail-order, or delivery service of raw or processed agricultural products.</u>		
Revise 205.100(a)	(a) Except for exempt operations or excluded <u>described in</u> §205.101, each production or handling operation or specified portion of an production or handling operation, that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.	Support as written.
Revise 205.101	Exemptions and exclusions from certification.	Support as written.
No change needed; however, the term “exclusions” also needs to be deleted from sections 205.100 and 205.310.		
Add intro Paragraph 205.101	The following operations in subparagraphs (a)–(e) are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must comply with the	Revision needed: <ul style="list-style-type: none"> • Include subparagraph (f) and (g) to accommodate an exemption for transportation and an exemption for customs brokers and freight forwarding. See below.

	<p>applicable organic production and handling requirements of subpart C of this part, including the provisions for prevention of contact of organic products with prohibited substances set forth in §205.272, and the specific additional requirements stipulated below.</p>	<ul style="list-style-type: none"> ● Include reference to ‘commingling’ as well as ‘contact with prohibited substances’ to ensure consistency and full application of § 205.272. ● See “At-A-Glance” comparison chart in Appendix A
<p>Requested Revision: The following operations in subparagraphs (a)–(e) (g) are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, including the provisions for prevention of commingling and contact of organic products with prohibited substances set forth in §205.272, and the specific additional requirements stipulated below.</p>		
<p>Revise 205.101(a)</p>	<p>Exemptions. (1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation. Such operations must comply with the labeling provisions of §205.310.</p>	<p>Revision needed: OTA supports this exemption; however, we suggest striking the following sentence which is redundant to the requirements of § 205.310(b). Including this requirement only at § 205.101(a) could lead one to believe that it does not apply to the other exempt operation that must comply with § 205.310.</p> <p>Delete: “The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation.”</p> <p>IMPORTANT CLARIFICATION NEEDED: OTA interprets §205.310 to apply to any exempt operation that is producing or handling exempt products. In the proposed rule, NOP references § 205.310 for some exemptions but not others. This is an area of long-time confusion that must be clarified in this Rule.</p>
<p>OTA Requested Revision: Exemptions. (1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation. Such operations must comply with the labeling provisions of §205.310.</p>		

<p>Revise 205.101(b)</p>	<p>A retail operation or a portion of a retail operation that sells, but does not process, organically produced agricultural products.</p> <p>Existing NOP language: A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.</p>	<p>Revision needed: OTA does not support NOP’s proposed text as written.</p> <ul style="list-style-type: none"> ● NOP’s proposed language does not distinguish between sell, handle and process. Further, it does not address all of the activity that can occur between receiving and selling, that would not be covered or defined under processing (aka ‘handle’). ● A revision is needed to distinguish between ‘handle’ and ‘process.’ Either a retail operation is only handling organic products, but not processing (one type of exemption w/ organic provisions that apply), or they are handling and processing. OTA recommends that NOP retain the exemption for a retail operation that handles but does not process instead of changing the exemption to a retail operation that ‘sells’ but does not process. ● A revision is needed to clearly and appropriately convey the organic provisions an exempt retail operation must comply with depending on its activity. The requirements for a retail operation that is simply handling certified organic products should not be the same as the requirements for a retail operation or portion of a retail operation, that is processing certified organic product. ● Clarification needed: Distribution Centers and storage warehouses that are associated with retail operations must meet the requirements of §205.101(e) to be exempt from certification.
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OTA Requested Revision: A retail operation or a portion of a retail operation that sells handles, but does not process agricultural products that are labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” ~~organically produced agricultural products.~~ Such operations must comply with the labeling provisions of §§205.308 - 205.310, and must maintain records sufficient to:
Prove that agricultural products identified as organic were organically produced and handled.

<p>Revise 205.101(c)</p>	<p>A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer.</p> <p>Such operations must comply with the labeling provisions of §205.310, and must maintain records sufficient to: Prove that agricultural products identified as organic were organically produced and handled; and Verify quantities produced or sold from such agricultural products.</p>	<p>Revision needed: OTA requests that the term ‘<i>retail</i>’ be removed from this provision. OTA is concerned with term “retail,” and its intended meaning and purpose. Restaurants, bakeries and delicatessens commonly source products that are labeled for food service. Limiting the sourcing supply to products that are only labeled for retail sale would present impractical costs and packaging waste.</p> <p>Guidance needed: Retail operations will need guidance to further distinguish between ‘handle’ and ‘process,’ and to understand the organic labeling requirements they must comply with. The labeling requirements that were not amended in this proposed rule are ambiguous.</p>
<p>OTA Requested Revision: A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer.</p> <p>Such operations must comply with the labeling provisions of §§205.308 - 205.310, and must maintain records sufficient to: Prove that agricultural products identified as organic were organically produced and handled; and Verify quantities produced or sold from such agricultural products.</p>		
<p>Add 205.101(d)</p>	<p>A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in §205.301(d)), or that only identifies organic ingredients on the information panel. Such operations must comply with the labeling provisions of §§205.305 and 205.310 and must maintain records sufficient to: Prove that agricultural products identified as organic were organically produced and handled; and Verify quantities produced or sold from such agricultural products.</p>	<p>Support the language as proposed.</p> <p>Guidance needed: Clarify in Guidance that the exemption for an operation that “only identifies organic ingredients on the information panel” applies to products that include an information panel that is distinctly different from the Principal Display Panel.</p>
<p>Suggested Revision: None – Guidance Requested</p>		

<p>Add 205.101(e)</p>	<p>An operation that only stores, receives, and/or loads agricultural products, but does not process or alter such agricultural products.</p>	<p>Revision needed: OTA does not support the proposal as written.</p> <ul style="list-style-type: none"> • This exemption should apply to operations that are only receiving, storing and shipping <i>packaged</i> products. • Revise the proposed exemption for operations that only store, receive and/or load to apply to <i>packaged</i> product only. Also eliminate the term ‘load’ because this infers application to bulk or unpackaged product. • Refer to a ‘handling operation’ rather than an ‘operation’ • Strike the term ‘alter’ and replace with “or otherwise handle,” or, add the term ‘alter’ and a definition to the regulation
<p>OTA Requested Revision: § 205.101(e) An <u>handling</u> operation that only receives, stores and ships agricultural products that are enclosed in a sealed package or container prior to being received and remain in the same package or container, but does not <u>sell</u>, process, <u>repackage, relabel</u> or otherwise <u>alter-handle</u> such products.</p> <p>Such operations must maintain records sufficient to: <u>(1) demonstrate that the organic integrity of the product is maintained during receiving, storage and loading, and (2) verify both the quantities and the organic status of the product being received, stored and loaded.</u></p>		
<p>Add (new) 205.101(f)</p>	<p>205.101(f) A handling operation that only transports certified organic products from a certified producer, handler or handling operation to another certified producer, handler or handling operation or final retail operation. Such operations must comply with record keeping requirements to (1) demonstrate that the organic integrity of the product is maintained during transport, and (2) verify both the quantities and the organic status of the product being transported.</p> <p>NEW: <u>§ 205.101(f) A handling operation that only transports certified organic products, but does not sell, process, repackage, relabel or otherwise handle such products. Such operations must comply with record-keeping</u></p>	<p>Additional exemption requested: OTA supports the addition of a new section that specifically provides an exemption for transportation.</p> <p>Guidance requested: OTA requests that NOP update and release NOP Guidance 5031 concurrent with the final rule. The Guidance can help specify the organic requirements a transporter must comply with depending on whether they are transporting packaged or unpackaged product.</p>

	<u>requirements to (1) demonstrate that the organic integrity of the product is maintained transport, and (2) verify both the quantities and the organic status of the product being transported.</u>	
	<u>NEW: § 205.101(g) Customs brokers and/or freight forwarders that <i>only</i> act as an intermediary between importers and the government or between shippers and transportation services, but do not take physical or financial possession or otherwise handle the agricultural products.</u>	Additional exemption requested: OTA supports the addition of a new section that specifically provides an exemption for customs brokers and freight forwarders.
Redesignate proposed 205.101(f) to 205.101(h)	Records described in subparagraphs (a)–(d) of this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs’ governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.	Revision needed: Support the requirement for records that are maintained for no less than 3 years, but revise the text to include subparagraphs (e) and (f).
Suggested revision: Records described in subparagraphs (a)– (d) (f) of this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs’ governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.		

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
 Vice President, Regulatory and Technical Affairs



Johanna Miranda
 Farm Policy Director

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Appendix A - Comparison chart for the organic requirements exempt operations must comply with:

Exempt operation	Existing Requirements	Proposed Requirements	OTA recommendation
Gross less than \$5000	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of **310 • Must not be used as ingredients identified as OG in processed products produced by another handling operation 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of **310 • Must not be used as ingredients identified as OG in processed products produced by another handling operation 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of **310 • Must not be used as ingredients identified as OG in processed products produced by another handling operation
Retailer that handles but does not process	None	<ul style="list-style-type: none"> • Commingling/contamination prevention 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of ***308, 309, 310 • Records to prove Organic status • Maintain records for 3 years
Retailer that processes on-site at the point of sale	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of 310 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of **310 • Records to prove Organic status and verify quantities sold • Maintain records for 3 years 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of ***308, 309, 310 • Records to prove Organic status and verify quantities sold • Maintain records for 3 years
70% organic or ingredient statement only	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of *305 and **310 • Records to prove Organic status and verify quantities sold • Maintain records for 3 years 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of *305 and **310 • Records to prove Organic status and verify quantities sold • Maintain records for 3 years 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Labeling provisions of *305 and **310 • Records to prove Organic status and verify quantities sold • Maintain records for 3 years
Stores (receives, ships)	<ul style="list-style-type: none"> • Commingling/contamination prevention 	<ul style="list-style-type: none"> • Commingling/contamination prevention 	<ul style="list-style-type: none"> • Commingling/contamination prevention • Records to prove Organic status • Records to support verification of organic integrity • Maintain records for 3 years
Transports	N/A – not called out as an exemption, however Guidance in place	NA – not called out as an exemption	Add as an exemption and require the following:

			<ul style="list-style-type: none"> • Commingling/contamination prevention • Records to prove Organic status • Records to support verification of organic integrity • Maintain records for 3 years
Customs Brokers and Freight Forwarders	N/A – not called out as an exemption	NA – not called out as an exemption	

***§205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients.**

- (a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:
- (1) Identifying each organically produced ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and
 - (2) If the organically produced ingredients are identified in the ingredient statement, displaying the product's percentage of organic contents on the information panel.
- (b) Agricultural products with less than 70 percent organically produced ingredients must not display:
- (1) The USDA seal; and
 - (2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

****§205.310 Agricultural products produced on an exempt or excluded operation.**

- (a) An agricultural product organically produced or handled on an exempt or excluded operation must not:
- (1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or
 - (2) Be represented as a certified organic product or certified organic ingredient to any buyer.
- (b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.
- (c) Such product is subject to requirements specified in paragraph (a) of §205.300, and paragraphs (f)(1) through (f)(7) of §205.301.

*****§205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic.”**

- (a) Agricultural products in other than packaged form may use the term, “100 percent organic” or “organic,” as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided*, That, the term, “organic,” is used to identify the organic ingredients listed in the ingredient statement.
- (b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:
- (1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

*****§205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”**

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, “made with organic (specified ingredients or food group(s)),” to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product's ingredient statement, the organic ingredients are identified as “organic.”

(b) If prepared in a certified facility, such agricultural products labeled as “made with organic (specified ingredients or food group(s))” in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

Appendix B: FDA Definitions for FSMA

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or-repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Note that FDA’s definitions distinguish between “packing” and “packaging.” The first key distinction is that they use the term “packaging” to mean placing food into a container that directly contacts the food and that the consumer receives, but they use the term “packing” when food is placed into containers that are not consumer containers. For example, placing strawberries into consumer containers that directly contact the food (e.g., plastic “clamshells”) is “packaging,” but placing apples into boxes and sending them to distribution centers or retailers is “packing.”

The second key distinction is that we classify “packaging” as a manufacturing/processing activity, but we do not classify “packing” as a “manufacturing/processing” activity.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, **labeling**, milling, mixing, **packaging** (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, **packing**, or holding.

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Imports to the United States (Import Certificates)

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting comments on each individual topic separately to help NOP in its process of finding and navigating our positions and recommendations. We have submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #2: Imports to the United States.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports the expanded use of electronic import certificates to support supply chain traceability and import data transparency.
- OTA recommends that AMS aggregates and reports data from the CBP-ACE system to meet the need for reliable comprehensive data on organic imports that is not currently provided by HTS codes.
- OTA supports the allowance of equivalent data systems to be used as a substitute for NOP Import Certificates provided that the same data is able to be collected and is able to (and required to) be uploaded to the CBP-ACE system.
- OTA recommends that NOP clarify which party is responsible for uploading the Import Certificate (or equivalent) into the CBP-ACE system.
- OTA recommends revisions to the proposed definitions of *organic exporter* to ensure clarity and alignment of the exporter’s activities under the definition of *Handle* as proposed in Section #1 of the Proposed Rule.
- OTA does not support the 30-day timeframe for certifiers to issue certificates as written in the proposed rule because it is not tethered to the CBP’s deadline for uploading data into the ACE system, nor the importer’s responsibilities upon receiving the shipment.
- OTA recommends that certifiers issue valid NOP Import Certificates for compliant shipments as soon as possible, ideally upon arrival of the physical shipment at the U.S. Port of Entry. However, the procedures and deadlines for requesting and issuing NOP Import Certificates need to accommodate various modes of transportation and frequencies of shipments (particularly perishable, high frequency and/or short-notice shipments arriving by ground transportation from Mexico and Canada), balanced with certifier’s operational capacity, without impeding legitimate trade flow or compromising organic integrity and enforcement capabilities. We recommend that NOP issue guidance to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates.

- OTA recommends the implementation of this section of the proposed rule (with OTA’s requested revisions and guidance) using a phased approach that accommodates the increased resources needed for certain types of imports: two years from publication of final rule for shipments by ground transportation from Mexico and Canada; one year from publication of final rule for all other imports. We also recommend that NOP completes a successful pilot test of the new electronic organic import certificate before the final rule is fully implemented.

Background

Organic import certificates are a type of transaction certificate that contain detailed information about the quantity, origin, and organic status of imported products. The purpose has been to provide trackable and auditable documentation to demonstrate organic compliance and to support investigations of misrepresented product. Currently, NOP only requires organic import certificates for certain countries of origin as required by equivalency arrangements such as EU, Switzerland, Japan, South Korea, and Taiwan. NOP’s current import certificate form¹ and instructions² are available in the NOP Handbook.

This provision of the Strengthening Organic Enforcement Proposed Rule is specifically mandated by the 2018 Farm Bill. In preparation for implementation, NOP developed and launched a new electronic system³ in April 2020 for filing organic import certificates as a voluntary option for through the U.S. Customs and Border Protection’s Automated Commercial Environment (CBP-ACE) system. This system would become mandatory upon implementation of the Strengthening Organic Enforcement final rule.

¹ <https://www.ams.usda.gov/sites/default/files/media/NOP%20Import%20Certificate.pdf>

² <https://www.ams.usda.gov/sites/default/files/media/NOP%20Instructions%20for%20completing%20import%20certificate.pdf>

³ <https://www.ams.usda.gov/services/organic-certification/international-trade/Electronic-Organic-Import-Certificates>

NOP Questions

1. *Is the 30-day timeframe for certifying agents to review and issue an NOP Import Certificate appropriate?*

No. This timeframe is not tethered to the CBP’s deadline for uploading data into the ACE system (within 10 calendar days after shipment physically enters the U.S.), nor the time when the importer needs to conduct its responsibilities (upon receiving a shipment with organic products). For more information, see OTA’s Positions & Recommendations below.

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

NOP currently requires import certificates to accompany imports from some countries of origin. However, the new dynamic of using imports certificates for shipments arriving by ground transportation from Mexico and Canada is very different in comparison to imports arriving from countries that currently use NOP Import Certificates. For more information, see OTA’s Positions & Recommendations below.

OTA’s Positions and Recommendations

- **OTA supports the expanded use of electronic NOP Import Certificates to support supply chain traceability and import data transparency.** The proposed rule is effective to implement the provisions of the 2018 Farm Bill and address findings from the USDA Office of Inspector General in 2017 Audit Report⁴ relevant to the topic of import certificates (Finding #2 – NOP Organic Import Documents Were Not Verified At U.S. Ports of Entry; Finding #3 – Controls Over Organic Products Fumigated at U.S. Ports of Entry were Inadequate).
- **OTA recommends that AMS aggregates and reports data from the CBP-ACE system to meet the need for reliable comprehensive data on organic imports that is not currently provided by HTS codes.** The U.S. is the largest organic market in the world, yet our current data tracking systems only account for a fraction of total imported organic products. The USDA Global Agricultural Trade System (GATS) covers trade data, and organic products are only tracked if the product has an organic-specific Harmonized Tariff System (HTS) code. Each of these codes is established in response to a formal submission request to the U.S. International Trade Commissions. The Organic Trade Association has submitted all applications for organic HTS codes in existence. To date, there are very few (less than 47) HTS codes for

⁴ <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>

organic-specific products⁵. Although this data can help understand some import trends for some organic products, it is not sufficient for a complete understanding of organic trade. Global organic trade is expanding, and our industry needs reliable and consistent information about which organic products are entering the U.S. and from which countries. The data collected from NOP Import Certificates through the CBP-ACE system has the potential to finally provide comprehensive data transparency on the full spectrum of imported organic products. The 2018 Farm Bill enables AMS to access information available in CBP-ACE system. We encourage AMS to access, aggregate and publically report data on organic imports. This information is critical to understanding global organic trade and setting baselines for accurate accounting of volumes and origins of imported organic products.

- **OTA supports the allowance of equivalent data systems to be used as a substitute for NOP Import Certificates provided that the same data is able to be collected and is able to (and required to) be uploaded to the CBP-ACE system.** To avoid inconsistency in which systems are deemed equivalent, USDA should be the sole deciding party about which systems are equivalent. This decision should not be left to individual certifiers. In determining equivalent data systems, USDA must ensure that equivalent data sources are able to be aggregated with NOP Import Certificate data to support our recommendation (see above) that AMS aggregates and reports data on organic imports. Comprehensive datasets aren't possible if equivalent data systems are excluded from the data aggregation and reporting.

→ **Recommendation:** Revise §205.273 to identify USDA as decision maker regarding data sources that are equivalent.

As a point of clarification, OTA also recommends non-substantive revisions to consolidate the examples of equivalent data sources to make it easier and clearer to understand the regulatory provision for determining what an equivalent data source is.

→ **Recommendation:** Implement revisions to consolidate the examples of equivalent data sources to make it easier and clearer to understand what an equivalent data source is. *See OTA's requested revisions in Table 2 below.*

⁵ https://ota.com/sites/default/files/indexed_files/OTATradeReport_10-30-2017.pdf

- **OTA recommends that NOP clarify which party is responsible for uploading the NOP Import Certificate data (or equivalent) into the CBP ACE System.** The proposed rule text does not specify which party is responsible for uploading data to CBP-ACE. The preamble states (emphasis added) that *“the organic exporter must provide the data associated with the NOP Import Certificate to CBP by uploading the data into the ACE system as an electronic record.”* The NOP Fact Sheet⁶ on Import Certificates says that U.S. Importers and Customs Brokers will file entries in ACE using Organic Import Certificate. The NOP Insider⁷ states that U.S. importers may begin requesting the NOP Import Certificate from exporters to include in their import filings at any time.

➔ **Recommendation:** Provide clarification of which party is responsible for uploading the NOP Import Certificate data (or equivalent) into the CBP-ACE System.

- **OTA recommends revisions to the proposed definition of *organic exporter* to ensure clarity and alignment of the exporter’s activities under the definition of *Handle* as proposed in Section #1 of the Proposed Rule.** According to the Preamble, the exporter and importer are both intended to be certified under this proposed rule for exemptions from certification. (Preamble: Preamble: *An organic exporter must be certified organic by certifying agents accredited by the USDA or certifying agents authorized by a trade arrangement, and must maintain records required under § 205.103. Organic exporters may be the final physical handler of organic products within a foreign country or they may be the entities that facilitate, sell, or arrange the sale of organic products shipped to the United States.*) However, the proposed definition of *Handle* in Section #1 of the proposed rule (Applicability and Exemptions from Certification) does not directly cover all of the activities included in the proposed definition of *organic exporter*. Also, the proposed definition of *organic exporter* as written in the proposed rule includes activities (*“consigns, or arranges for the transport/shipping”*) which are not specifically addressed in the proposed rule’s definition of *Handle*. This discrepancy will create an opportunity for confusion about whether the exporter is required to be certified as a handler.

We recommend that the definition of *organic exporter* be revised so that it clearly and directly ties back to the definition of *Handler*. Certifiers can then use the definition of *Handler* to evaluate whether the exporter’s activities are subject to certification. Exporters or importers that *Handle* and do not fall under an exemption from certification should be required to be certified. We also recognize there may be exporters or importers that are handlers but may qualify under an exemption under the proposed rule. These exemptions may be impacted by future revisions to the proposed rule based on public comment. For example, OTA is recommending a revision to include an exemption for

⁶ <https://www.ams.usda.gov/sites/default/files/media/FactSheetImportCertsLaunch.pdf>

⁷ <https://content.govdelivery.com/accounts/USDAAMS/bulletins/29a22e5>

customs brokers and/or freight forwarders that only act as an intermediary between importers and the government or between shippers and transportation services, but do not take physical or financial possession or otherwise handle the agricultural products (*See OTA's Comments on Exemptions from Certification.*)

→ **Recommendation:** Revise definition of *organic exporter* in §205.2 to ensure clarity and alignment of the exporter's activities under the definition of *Handle* in Section #1 of the Proposed Rule: Applicability and Exemptions from Certification. **See OTA's requested revisions in Table 2 below.**

- **OTA does not support the 30-day timeframe for certifiers to review and issue an NOP Import Certificate as written in the proposed rule.** The proposed rule requires that the certifier must review and issue import certificates for compliant shipments within 30 days of receiving the request for the import certificate. According to the proposed rule (emphasis added): “*The certifying agent must review an NOP Import Certificate request, determine whether the shipment complies with the USDA organic regulations, and issue the NOP Import Certificate or equivalent within 30 calendar days of receipt if the shipment complies with the USDA organic regulations.*” The certifier’s responsibility during this time (according to the Preamble, emphasis added) is to verify that: “(1) the information submitted on the NOP Import Certificate, or equivalent, is accurate, including confirmation of the organic status of each product listed on the NOP Import Certificate; and (2) the final handler has the capacity to produce or handle the quantity of organic product to be exported.”

The certifier’s 30-day timeframe is not tethered to physical movement of the product, nor to the deadline for uploading the data to the CBP-ACE system. The intent described in the preamble is that the data from the valid Import Certificate or equivalent is uploaded to the CBP database within 10 calendar days after the shipment physically entering the U.S. As stated in the Preamble (emphasis added), “*the NOP Import Certificate, or equivalent data, must be uploaded into the ACE system within 10 calendar days of the shipment entering the United States. This is consistent with existing trade filing timeframes in ACE using the Entry Summary process.*” In order to upload the data to the CBP-ACE system, the valid certificate needs to have been issued.

The certifier’s 30-day timeframe is also not tethered to the importer’s responsibilities to verify accuracy of the import certificate. The Proposed Rule requires that the importer perform certain activities upon receiving the shipment, and two of these activities are contingent upon having the valid NOP Import Certificate. From the proposed rule (Emphasis added): “*Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to 7 CFR 205.272 or exposure to ionizing radiation pursuant*”

to 7 CFR 205.105, since export.” In order to complete these tasks as written in the proposed rule, the valid certificate needs to have been issued.

Because the 30-day timeframe is not tethered to the deadline for uploading data in to the CBP-ACE system nor the importer’s receiving of a shipment, the 30-day timeline for certifiers could be overridden by these other steps in the procedure and is therefore not useful or appropriate to retain in the regulations. For example: If an exporter requests a Import Certificate on Day 1, and the shipment arrives at the US Port of Entry on Day 5, then the data would need to be uploaded to CBP by Day 15. This means that the certifiers need to have issued the importer certificate by Day 15 (not Day 30) so that the appropriate data is available for uploading to CBP. Furthermore, if the importer of record is ready to accept the product on the day of arrival (Day 5, from the previous example), then the importer needs to have access to the valid Import Certificate on that day. This means that that the certifier needs to have issued the import certificate by Day 5 (not Day 30) for the importer to carry out its responsibilities per the regulations to verify the physical shipment against the data in the import certificate.

➔ **Recommendation:** Revise §205.273(b) to remove the 30-day timeframe. *See OTA’s requested revisions in Table 2 below.*

- **OTA recommends that certifiers issue valid NOP Import Certificates for compliant shipments as soon as possible, ideally upon arrival of the physical shipment at the U.S. Port of Entry. However, the procedures and deadlines for requesting and issuing NOP Import Certificates need to accommodate various modes of transportation and frequencies of shipments (particularly perishable, high frequency and/or short-notice shipments arriving by ground transportation from Mexico and Canada), balanced with certifier’s operational capacity, without impeding legitimate trade flow or compromising organic integrity and enforcement capabilities.**

The NOP Import Certificate requirements need to be flexible enough to support all forms of international trade. Thousands of shipments of organic products arrive in the U.S. every year, entering numerous Ports of Entry, and arriving via plane, truck, vessel, and railcar. Shipments are entering 365 days per year at all hours of the day and night. Many organic products are perishable products that are distributed and sold to end consumers within days of entry into the U.S.

Benefits of issuing import certificates as soon as possible

It is beneficial to minimize the window of time between the physical shipment of organic product arriving at the U.S. Port of Entry and the certifier issuing a valid NOP Import Certificate for compliant shipments. Importers can be assured that the certifier has completed its responsibility to review and verify the information on the NOP Import Certificate by the time the importer is ready to accept the product at the U.S. Port of Entry. The Proposed Rule requires that the importer perform certain activities upon receiving the shipment, and two of these activities are contingent upon having the valid NOP Import Certificate. From the proposed rule (Emphasis added): *“Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to 7 CFR 205.272 or exposure to ionizing radiation pursuant to 7 CFR 205.105, since export.”* In order to complete these tasks as written in the proposed rule, the valid certificate needs to have been issued.

Timely issuance of NOP Import Certificates can minimize importer’s risk of accepting product without a valid certificate or need to hold product waiting for a valid certificate. NOP is clear in the Preamble that the NOP Import Certificate requirements are not meant to impede trade, and a shipment containing organic products may enter the United States without an NOP Import Certificate at the time of entry. NOP explains in the preamble (emphasis added) *“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, allowing a time-lag after the shipment arrives until the certifier determines if the certificate is valid may not necessarily lead to unimpeded flow of trade as NOP intends. There is a burden for some importers who may be hesitant to accept and move imported products throughout their supply chains if they have not yet received a valid organic import certificate. Downstream certified organic handlers may be unwilling to buy a product that does not yet have a valid organic import certificate. For some importers, there is an unacceptable level of risk in accepting a not-yet-approved organic shipment and selling it to a buyer, or combining it with other approved organic product. To manage their risk, importers may choose to hold a product at the port while they are waiting for the valid import certificate, which leads to increased storage fees, and loss of valuable shelf-time for perishable products.

Avoiding impediment of legitimate trade flow or compromising organic integrity and enforcement capabilities

The NOP Import Certificate requirements should not negatively impact the ability of legitimate organic products from entering the U.S. market. An NOP Import Certificate, in and of itself, should not serve -- and is not intended to serve -- as a singular or exclusive tool for guaranteeing real-time organic compliance of imported products as received at the U.S. Port of Entry. Organic integrity of exports and imports can and should be verified through an operation's recordkeeping, monitoring practices, procedures and other systems for maintaining organic integrity (and the certifier's oversight thereof) as required by the current NOP regulations, and new strengthened regulations proposed in the Strengthening Organic Enforcement Proposed Rule. According to NOP Instruction 4013 Maintaining Integrity of Organic Imports⁸, audit trail documentation that should already be in use by organic operations to ensure compliance includes: Organic certificates for each product with the name of the certified operation and their certifier; Purchase and receiving records with information identifying the specific product(s), lot numbers, quantities, and supply chain entities; Shipping records with information such as lot numbers, product volume, handling instructions and the name of the last certified organic operation; Weigh tickets, receipts, and tags; Clean truck/container affidavits for bulk product verifying that truck/container was thoroughly cleaned and poses no risk of contact with prohibited substances; Phytosanitary certificates from the last country of export; and more. The SOE Proposed Rule adds additional requirements such as having supply chain traceability, fraud prevention plans, and organic identification on nonretail containers. The import or exporter describes its plans for using these tools and practices to verify and ensure compliance of organic exports and imports, and the certifier reviews and verifies the plans through annual inspections, periodic residue testing, and other oversight measures. These tools and practices are not directly tied to issuance of the NOP Import Certificate yet still must be carried out even if the NOP Import Certificate is not available at the time of entry at the U.S. Port of Entry. Provided that these systems for maintaining organic integrity are in place, there will be no need for imported shipments to be required to be held at U.S. Port of Entry waiting on the issuance of an NOP Import Certificate in order to confirm organic compliance.

Verifying compliance based on these tools and systems can be more effective than relying only on an NOP Import Certificate to guarantee real-time organic compliance verification at the U.S. Port of Entry. If used as a singular or exclusive tool to guarantee real-time organic compliance, the NOP Import Certificate could become a fraud opportunity and distract from other organic integrity verification systems. Rather, the NOP Import Certificate is one *of many* elements in a system of maintaining and verifying integrity of organic imports. NOP Import Certificates also provide additional value in terms of strengthening supply chain traceability and import data transparency.

⁸ <https://www.ams.usda.gov/sites/default/files/media/NOP4013IntegrityOrganicImports.pdf>

Accommodations for various modes of transportation and frequencies of shipments

The procedures and timeframes for requesting and issuing import certificates need to accommodate various modes of transportation and frequencies of shipments. NOP currently requires import certificates to accompany imports from some countries of origin under equivalency arrangements, but none of those countries are accessible by ground transportation. For product arriving by ocean freight, it will likely be possible for the certificates to be available at the time the shipment arrives. However, the new dynamic of using imports certificates for shipments arriving by ground transportation from Mexico and Canada is very different in comparison to imports arriving from countries that currently use NOP Import Certificates. Mexico and Canada are contiguous to the U.S., making import possible at much shorter timeframes at much higher frequencies. This means a higher volume of import certificates will need to be issued, with shorter notice of the products being declared on the import certificate. The significance of this new dynamic must be taken in to consideration when developing requirements for NOP Import Certificates. The requirements need to accommodate high frequency, short-notice, and/or perishable shipments of organic products arriving by ground transportation from Mexico and Canada.

Perishable produce imported from Mexico is perhaps the most significant trade dynamic that needs to be considered. Hundreds of shipments per day are imported across the Mexico border on a constant basis, many within just a few hours of the produce being harvested. Perishable produce arrives most commonly by truck. A single truck may contain multiple product types, pack-sizes, varieties, from multiple growers and pack-houses. Several certificate-holders may contribute product to a single truck. A single exporter may arrange multiple trucks in a single day. In their peak season, a single produce exporter can have up to 100 shipments (trucks) per day from Mexico. This exact contents and quantities of products are confirmed once the truck is finished loading, which can be as three hours prior to the truck arriving at a U.S. Port of Entry. Trucks may be arriving at any hour of the day including overnight and weekends, year round.

Shipments by ground transportation from Canada can impose similar time constraints even for nonperishable products. Trucks or railcars of grain can be loaded in as little as 12 hours before arriving at a U.S. Port of Entry. Air-freight transportation can also have significantly shorter windows between loading and arrival in the U.S. compared to longer travel times of imports arriving by ocean-freight.

Operational capacity of certification agencies

The NOP Import Certificate requirements need take into account the operational capacity (e.g. staffing) of certification agencies responsible for reviewing and issuing NOP Import Certificates for every physical shipment of imported organic product. The new requirements for certifiers to issue import certificates for every physical shipment will impose significant new demands on certifiers, especially considering the high-volume and short-notice demands for import certificates for shipments arriving by ground transportation from Mexico and Canada. As already described above, shipments can be loaded on the same day or overnight or with as little as three hours prior to arrival at the U.S. Port of Entry. Final shipment data (e.g. exact weights, volumes, and container identification numbers) may not be known until the truck or railcar is loaded and ready for shipment, leaving a very small window for certificate request, review, and approval. This dynamic creates significant stress and time pressures for certifiers and certified operations to prepare data and issue certificates in a timely manner.

At this time, there is no evidence that a requirement for certificates to be available at time of arrival in the U.S. could be realistic to implement. Certifiers would need to be staffed twenty-four hours per day, including weekends and holidays, year round, to keep up with the constant influx of organic imports. Lessons learned from the 2016 attempt to require NOP Import Certificates to accompany shipments from Mexico revealed extreme logistical and operational capacity challenges for certification agencies to overcome in order to be staffed appropriately for this type of work. Considering that NOP Import Certificates are one *of many* elements in a system of maintaining and verifying integrity of organic imports, such significant investments in 24/7 staffing for this sole purpose may not be warranted.

- **NOP should issue guidance to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates.**

Given the magnitude and dynamics of organic imports to the U.S., OTA does not recommend that the regulations specify a one-size-fits-all requirement for exactly when the certifier must issue a NOP Import Certificate for valid shipments. Rather, we recommend that NOP provide details and instructions through guidance. Guidance is an appropriate mechanism for explaining the procedures for requesting and issuing NOP Import Certificates, and establishing the ideal deadline as being available by the time the physical shipment arrives in the U.S. Additionally, the guidance can explain the circumstances under which a NOP Import Certificate can be issued after the shipment arrives provided that strong organic integrity verification systems are in place. This will allow flexibility where needed, such as high frequency, short-notice, and/or perishable shipments of organic products. Guidance should also provide a clear definition on how to identify and define a single “physical shipment” for various modes of transportation.

The foundation of the NOP Import Certificate procedure should be grounded in the Organic System Plan, developed by the operation and approved by the certifier. Each exporter and importer's Organic System Plan should describe its plan for requesting and/or tracking and receiving NOP Import Certificates. Through the Organic System Plan development and approval process, operators and certifiers can agree to a system and timeline that can accommodate all parties. This process allows for timelines to be established that account for each unique import scenario and various combinations of product type, origin, destination, perishability, mode of transportation, time of year (peak, off peak), etc. The agreed-upon timeline should balance the capacity of the exporter and certifier, while meeting the needs of the importer for receiving the shipment and having access to the NOP Import Certificates.

We encourage exporters, importers, and their certifiers to work together to implement procedures for requesting and issuing NOP Import Certificates as soon as possible, ideally upon arrival of the physical shipment at the U.S. Port of Entry. There are systems and procedures that could begin to be established now that could help work towards the ideal deadline. Operators need to develop efficient systems to ensure that they are collecting and submitting complete information to the certifier so that certificates can be issued quickly and no information is missing or inadequate. Certifiers can work on developing internal systems and procedures that increase efficiencies of receiving, reviewing, and issuing certificates. For example, certifiers should explore the role of pre-shipment notifications that would require exporters to provide information about shipments in advance and let the certifier complete parts of the verification as appropriate. Recognizing that some data points of the import certificate cannot be confirmed until the shipment is loaded (e.g. exact weight or volume), pre-shipment notification still could help minimize the amount of verification that is needed in the short timeframe between loading the shipment and arrival at the U.S. Port of Entry. Certifiers could also explore the role of multi-shipment certificates, such as those used by the Global Organic Textiles Standard. Also certifiers can explore opportunities where expedited review and issuance procedures can be employed for some import/export arrangements, such as operations that are exporting and importing between their own subsidiaries.

In cases where logistical or operational capacity prevents the issuance of valid certificates upon time of entry of product in the U.S. (e.g. such as high frequency, short-notice, and/or perishable shipments of organic products), the certifier may approve an alternative system that allows a certain number of extra days after shipment arrival for the certifier to issue the NOP Import Certificate for compliant shipments. Alternative systems should only be approved in cases where the operation is in good standing and has strong organic integrity verification measures in place. The operation and certifier must agree that the data submitted for the NOP Import Certificate is audited within the agreed-upon timeframe. The certifier should issue valid NOP Import Certificates for compliant shipments no later than 10 calendar days after shipment arrival. As stated in the Preamble (emphasis added), *"the NOP Import Certificate, or equivalent data, must be uploaded into the ACE system within 10 calendar days of the shipment entering the United States. This is consistent with existing trade filing timeframes in ACE using the Entry Summary process."* In order to upload the data to the CBP-ACE system, the valid certificate needs to have been issued. The 10-day maximum will ensure that the valid certificate is – at the very least – issued in time for its data to be uploaded in to the CBP-ACE system.

In all cases, the systems must comply with other regulatory requirements that are not directly tied to issuance of the NOP Import Certificate, such as the product being declared as “organic” to U.S Customs and Border Protection upon entry into the U.S and the importer being responsible for verifying compliance of the received shipment. As much information as is readily available should be uploaded to the CBP-ACE system. Additionally, the certifier may impose stronger controls or more frequent risk-based traceability and mass balance audits of NOP Import Certificates to ensure that the system that was approved in Organic System Plan is effective or needs improvement. NOP Import Certificates should also become a standard element of onsite inspector verification like verification of other organic recordkeeping requirements.

→ **Recommendation:** Develop guidance to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates.

- **We recommend that these provisions of the proposed rule (with OTA requested revisions and recommendations for guidance) described above are implemented using a phased approach that accommodates the increased resources needed for certain types of imports.** We recommend **two years** from publication of final rule for shipments by ground transportation from Mexico and Canada; **one year** from publication for all other imports. Shipments by ground transportation from Mexico and Canada will require additional time to come into compliance due to the shorter timeframes and higher frequencies of shipments from these countries via these modes of transportation. Certifiers, importers, and exports all need time to develop and implement systems for managing import certificate requests, reviews, and approvals at significantly higher frequencies than are currently experienced. The extended implementation period for ground shipments from Mexico and Canada will allow certifiers to start collecting data about the volumes, timing and frequencies of these import events and gauge the resources needed to accommodate import certificate requests and issuance procedures. The additional time can also be used for certifiers to identify and resolve any technological issues with issuing electronic import certificates so that the procedures can be executed seamlessly by the time the requirement becomes mandatory.

We also recommend that NOP completes a successful pilot test of the new electronic organic import certificate before the final rule is fully implemented. NOP has developed and launched the new electronic system and plans to begin a pilot program in fall 2020. As with any new technology, testing will be critical for success of the system, and the system must be successful for global organic trade to rely on it for every individual shipment of imported organic product. We strongly encourage NOP to work with industry members to pilot the new system and resolve any technological barriers prior to implementation of this rule provision.

Table 2: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.2 Add new term	<i>Organic exporter.</i> The owner or final exporter of the organic product who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic product from a foreign country.	Revision needed to ensure clarity and alignment of the exporter’s activities under the definition of <i>Handle</i> in Section #1 of the Proposed Rule: Applicability and Exemptions from Certification. <i>(See also OTA’s Comments on Exempt Operations)</i>
OTA Requested Revision: <i>Organic exporter.</i> The handler owner or final exporter of the organic product who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic product from a foreign country.		
205.2 Add new term	<i>Organic importer of record.</i> The operation responsible for accepting imported organic products within the United States.	Revision needed to clarify that the importer is responsible for accepting organic products “at a U.S. port of entry” to avoid confusion with other recipients elsewhere in the supply chain. <ul style="list-style-type: none"> • Add “at a U.S. Port of Entry”
OTA Requested Revision: The operation responsible for accepting imported organic products within the United States <u>at a U.S. Port of Entry</u> .		
205.273 Add new section	Imports to the United States.	

205.273 Add	Each shipment of organic products imported into the United States through U.S. Ports of Entry must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with a valid NOP Import Certificate (Form NOP 2110-1) or equivalent data source.	
205.273(a) Add	Persons exporting organic products to the United States must request an NOP Import Certificate, or provide data through an equivalent data source, from a certifying agent, for each physical shipment of certified organic products prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement may issue an NOP Import Certificate or approve a listing in an equivalent data source (e.g., a third-party export system).	<p>Revision needed to use consistent terminology throughout the rulemaking action. The SOE Proposed Rule on Foreign Conformity Assessment Systems proposed a new system of “equivalence determinations” which should be used instead of trade arrangement in 205.273(a). (See SOE Section #10: Accepting Foreign Conformity Assessment Systems).</p> <ul style="list-style-type: none"> • Replace “trade arrangement” with “equivalence determination” <p>Revision needed to move the example of equivalent data sources to 205.273(e) to consolidate the regulatory provision for determining what an equivalent data source is. See OTA Position on <u>equivalent data sources</u>.</p> <ul style="list-style-type: none"> • Remove “e.g. a third party export system” <p>Guidance is needed to explain the procedures and ideal deadlines for requesting and issuing NOP Import Certificates. See OTA’s Recommendation above.</p>
<p>OTA Requested Revision: Persons exporting organic products to the United States must request an NOP Import Certificate, or provide data through an equivalent data source, from a certifying agent, for each physical shipment of certified organic products prior to their export. Only certifying agents accredited by the</p>		

USDA or foreign certifying agents authorized under an organic ~~trade arrangement~~ equivalence determination may issue an NOP Import Certificate or approve a listing in an equivalent data source ~~(e.g., a third-party export system)~~.

205.273(b)
Add

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

Revision needed to implement OTA Position on the **30-day timeframe** for certifiers to issue certificates.

- Remove 30-day timeframe.

Revision needed to accommodate shipments that are imported under an equivalence determination. This clarification is explained by the preamble (emphasis added): *The organic exporter’s certifying agent would issue the NOP Import Certificate, or equivalent, provided it has verified that the shipment complies with the USDA organic regulations or an equivalent standard.*

- Add “or the terms of an equivalence determination”

OTA Requested Revision:

The certifying agent must review an NOP Import Certificate request, determine whether the shipment complies with the USDA organic regulations or the terms of an equivalence determination, and issue the NOP Import Certificate or equivalent ~~within 30 calendar days of receipt~~ if the shipment is compliant ~~complies with the USDA organic regulations~~.

205.273(c)
Add

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

Clarification is needed about which party is responsible for uploading the Import Certificate data (or equivalent) into the CBP ACE System.

<p>205.273(d) Add</p>	<p>Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to 7 CFR 205.272 or exposure to ionizing radiation pursuant to 7 CFR 205.105, since export.</p>	<p>Revision needed to correct the proposed rule text to align with the text in 205.273 above which states (emphasis added): <i>Each shipment of organic products imported into the United States through U.S. Ports of Entry must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be <u>associated with</u> a valid NOP Import Certificate (Form NOP 2110-1) or equivalent data source.</i> This correction is also needed to align with the preamble (emphasis added): <i>“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 <u>associated with</u>, but not accompanied by, an NOP Import Certificate.”</i></p> <ul style="list-style-type: none"> • Replace “accompanied by” with “associated with” <p>Revise needed to clarify the reference to a “valid” import certificate that has been issued by a certifier in accordance with 205.273(b), which states (emphasis added), <i>“associated with a <u>valid</u> NOP Import Certificate.”</i></p> <ul style="list-style-type: none"> • Replace “valid” with “verified” in the phrase “verified NOP Import Certificate or equivalent”
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OTA Requested Revision: Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is ~~accompanied by~~ associated with a ~~verified~~ valid NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to 7 CFR 205.272 or exposure to ionizing radiation pursuant to 7 CFR 205.105, since export.

<p>205.273(e) Add</p>	<p>The use of the term equivalent in this section refers to electronic data, documents, identification numbers, databases, or other systems verified as an equivalent data source to the NOP Import Certificate.</p>	<p>Revision needed to clarify that USDA-AMS is the sole decider of which third-party databases/systems are equivalent. See OTA’s Position on <u>equivalent data systems</u>.</p> <ul style="list-style-type: none"> • Add “by the Administrator” <p>Revision needed to integrate relevant examples from 205.273(a) and from the preamble. See OTA’s Position on <u>equivalent data systems</u>. Relevant portion of the Preamble: <i>The use of the term “equivalent” in this section refers to data and systems that are created, issued, or used by the United States or foreign governments to share trade-related information.</i></p> <ul style="list-style-type: none"> • Add examples: data sources and systems that are created, issued, or used by the United States or foreign governments to share trade-related information, third-party export systems
<p>OTA Requested Revision: The use of the term equivalent in this section refers to <u>data sources and systems that are created, issued, or used by the United States or foreign governments to share trade-related information, including but not limited to</u> electronic data, documents, identification numbers, databases, or other systems (<u>e.g., a third-party export system</u>) verified <u>by the Administrator</u> as an equivalent data source to the NOP Import Certificate.</p>		
<p>205.300(c) Revise</p>	<p>Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, and labeled pursuant to this subpart D, and must comply with the requirements in 205.273, Imports to the United States.</p>	<p>Revision needed to accommodate shipments that are imported under an equivalence determination.</p> <ul style="list-style-type: none"> • Add “and the terms of an equivalence determination”
<p>OTA Requested Revision: Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, and labeled pursuant to this subpart D, and must comply with the requirements in 205.273, Imports to the United States, <u>and the terms of an equivalence determination</u>.</p>		



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Johanna Miranda
Farm Policy Director

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Labeling of Nonretail Containers

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #3: Labeling of Nonretail Containers.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports mandatory organic identification on nonretail containers, and recommends the regulations allow flexibility for operators to use alternative abbreviations or indicators of a product’s organic status.
- OTA does not support the proposed rule that designates the name of the certified operation as optional. OTA recommends mandatory identification of the certified operation and the certifier on nonretail containers.
- OTA recommends a regulatory revision to improve consistency in identifying which operation and certifier should be displayed on nonretail containers.
- OTA supports the ongoing requirement to display traceability information such as lot numbers on nonretail containers.
- OTA recommends that implementation of these requirements provides flexibility for organic operations in displaying mandatory information on nonretail containers in a manner that is adaptable to the wide variety of nonretail containers while still ensuring that the information is immediately accessible.
- OTA recommends that NOP develop additional guidance to support common understanding and consistent implementation of the requirement that nonretail containers “*must display*” the mandatory information listed in §205.307.
- OTA recommends the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within two years after publication of the final rule.

Background

Nonretail container is currently defined in the NOP Regulations as “Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.” Nonretail containers are used to ship or store either packaged or unpackaged organic products, and may include the following: produce boxes, totes, bulk containers, bulk bags, flexible bulk containers, harvest crates and bins, boxes, crates, cartons, and master cases of wholesale packaged products. *Labeling* is currently defined in the NOP Regulations as “All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.”

NOP Questions

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

OTA supports mandatory identification of the certified operation on nonretail containers in addition to the name of the operation’s certifier. OTA does not agree with the proposed rule text that designates the operation name as optional. The name of the certifier alone is not sufficient to match the physical product to the corresponding organic certificate and other supporting documentation. Please see OTA Positions below for more information about our position on identification of the certifier and the certified operation on nonretail containers.

OTA’s Positions and Recommendations

- **OTA supports mandatory organic identification on nonretail containers, and recommends the regulations allow flexibility for operators to use alternative abbreviations or indicators of a product’s organic status.** Identification of organic products as organic is essential and should not be optional in any scenario. Organic identification is critical as a baseline requirement for any and all documentation, labels, and other related items for an organic product and its supply chain. (*See also OTA Comments on Supply Chain Traceability & Fraud Prevention*)

Organic identification is important at all steps of the supply chain, but is especially important on nonretail containers used to ship product from a certified operation, given the expectation that such product will be transferred and/or repackaged. Organic identification is currently

optional on nonretail containers, creating challenges to track organic supply chains and connect physical product to corresponding organic certificates and other supporting documentation. Having products that are organic but not labeled as such creates a vulnerability in the organic supply chain that can be addressed through mandatory organic identification requirements. It also creates opportunities for misidentification and mishandling of organic products during transport or other movement throughout the supply chain. As described in the preamble, the NOP's goal for organic products to be immediately identified as organic is to prevent misidentification or mishandling of organic products, to reduce risk of having organic integrity compromised by treatment with a prohibited substance during border crossings or commingling with conventional product during transport, storage, and handling.

The organic identification requirement is needed to meet the goals described above while being practical for operations to implement. As written, the proposed rule would require nonretail labels to display the full text of the organic status of the product: "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," as applicable, to identify the product. However, such level of detail will impose an undue burden on organic operations that is unnecessary to meet the overall goals of immediate organic identification. Lengthy text may not be able to fit on existing containers or labeling materials, and could result in increased costs and resources to adjust labeling information and associated logistics. It would also prevent operations from using generic shipping and storage containers that don't currently contain this level of detail. The proposed rule will already require that full organic identification (with the full text of the organic status of the product) is available on audit trail documentation (See SOE Section #18: Supply Chain Traceability & Fraud Prevention).

The regulations should allow nonretail labels to use alternative abbreviations or indicators of a product's organic status. Many operations are already using short-hand abbreviations (100% OG, OG, and MWO) instead of entire status descriptions, and these abbreviations have proven effective in immediately identifying products as organic. This amount of flexibility will support organic operations in adapting organic identification to their organic systems. Also, this will ensure consistency with SOE Section #18: Supply Chain Traceability & Fraud Prevention, which allows for abbreviations and alternative indicators. The Preamble states (emphasis added): *"This proposed action is not intended to limit an operation's flexibility to use alternative abbreviations or indicators of a product's organic status on nonretail labels or other recordkeeping. This may include use of abbreviations such as "MWO" (i.e., "made with organic"), ORG (i.e., "organic"), color designations, or other tracking systems that are used internally within a certified organic operation to denote a product's organic status."*

The current regulations read "identification of the product as organic." This is the exact text that currently appears in the regulations for nonretail containers. We recommend using this same language, and only moving it from an optional piece of information to a mandatory piece of information. This language should be sufficient to achieve the intended goal of immediate identification of organic. We recommend that guidance is also developed to support consistent implementation of the alternative abbreviations or indicators of a product's organic status that are allowed.

→ **Recommendation:** Revise §205.307(a) to allow flexibility for operators to use alternative abbreviations or indicators of a product’s organic status. Develop guidance that explains the options for how to identify products as certified organic and clarify that such identifications can use alternative abbreviations or indicators of a product’s organic status. **See OTA’s requested revisions in Table 3 below.**

- **OTA does not support the proposed rule that designates the name of the certified operation as optional. OTA recommends mandatory identification of the certified operation and the certifier on nonretail containers.** NOP explains in the preamble that the purpose of identifying the certification agency is to provide a point of contact to verify the organic status of the product. We acknowledge that the additional benefit of identifying the certification agency is to connect physical product to the corresponding organic certificate. Both the operation name and the certifier name are needed to efficiently and successfully match the physical nonretail container of organic products with its corresponding organic certificate and other associated documentation. The name of the certifier alone is not sufficient to match the physical product to the organic certificate because an organic certifier has many operations that they certify. The only way that listing the certifier will have value is if the certifier operation name is also listed. We support flexibility in how the operation name and certifier name are communicated on labeling of nonretail containers, e.g. logos or abbreviations can be sufficient for achieving the goals of providing a point of contact to verify organic status of the product and to match the physical product to its organic certificate.

→ **Recommendation:** Revise §205.307 to designate the operation’s name as mandatory and not optional on nonretail containers. **See OTA’s requested revisions in Table 3 below.**

- **OTA recommends a regulatory revision to improve consistency in identifying which operation and certifier should be displayed on nonretail containers.** The regulations should be clear and consistent in how it describes *which operation and which certifier* need to be identified on the nonretail container. We recognize concerns with referring simply to the “last handler” given the proposed expansion of the definition of handler under SOE Section #1: Applicability and Exemptions from Certification. OTA had made a suggestion in our pre-rule comments in 2018 to identify *the last certified organic operation that handled the product*. However, the proposed rule will require certification of brokers and traders under the revised definition of *Handle*. Therefore, the last certified handler could be the broker who is facilitating trade of the product but is not processing or otherwise taking financial or physical ownership of the product. The broker may or may not be the appropriate point of contact for nonretail containers of organic products.

The proposed rule would require identification 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**. NOP provides these specific examples in the preamble:

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

We have identified concerns with the proposed rule that may present challenges for implementation across all nonretail containers.

- Depending on where in the supply chain the nonretail container is being labeled, it may not be evident if the product has been processed earlier in the supply chain. Certain activities listed in the definition of processing are not readily evident, such as drying, freezing, or chilling. The proposed rule may unintentionally create inconsistencies by dictating labeling requirements based on whether these activities have or have not occurred in the supply chain.
- Handlers that do not process may still have a legitimate reason to be listed on the label as they are the responsible party and/or legal owner of the product, e.g. in the case of contract processing/manufacturing.

We also identify these alternative options that are currently used in the NOP Organic Regulations.

- Current regulations for labeling of nonretail containers at §205.307(a)(1): The name and contact information of the certifying agent which certified **the handler which assembled the final product**
- Current regulations for labeling of nonretail containers at §205.307(a)(5): The seal, logo, or other identifying mark of the certifying agent that certified **the organic production or handling operation that produced or handled the finished product**.
- Current regulations for retail labels at §205.303(b)(2): On the information panel, below the information identifying **the handler or distributor of the product** and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified **the handler of the finished product** and may display the business address, Internet address, or telephone number of the certifying agent in such label.

OTA recommends adopting the current language in §205.303(b)(2) regarding “**the handler or distributor of the product**” for the purposes of identifying a certified operation and its certifier on nonretail containers. This option supports consistency in which the certified operation and certifier are required to be identified on all labeling throughout the supply chain including nonretail containers and retail labels. The choice of either handler or distributor should be determined by whichever entity is the most appropriate point of contact. In all cases, the certifying agent displayed on the nonretail container should be the certifying agent of the certified operation displayed on the nonretail containers. The name of the handler or distributor and its certifying agent should also match the information reported in the Organic Integrity Database. This approach provides a transparent direct route for identifying the appropriate point of contact, connecting the physical product to its organic certificate, and supporting product traceability.

→ **Recommendation:** Revise §205.307 to specify that the handler or distributor of the product and the name of its certifier should be displayed on nonretail containers. *See OTA’s requested revisions in Table 3 below.*

- **OTA supports the ongoing requirement to display traceability information such as lot numbers on nonretail containers.** We agree that this information remains a critical element to identify on organic products to facilitate traceability of the organic productions throughout the supply chain. Organic integrity and fraud prevention are greatly enhanced when traceability data is combined with organic identification, and the name of the certified operation and certifier that connect the physical product to organic certificates and audit trail documents.
- **OTA recommends that implementation of these requirements provides flexibility for organic operations in displaying mandatory information on nonretail containers in a manner that is adaptable to the wide variety of nonretail containers while still ensuring that the information is immediately accessible.** There is a huge variety in the types of nonretail containers that are used for organic products throughout many different organic supply chains worldwide. Every type of container presents unique considerations for how it can be labeled. Each nonretail container will have different considerations for how/where the mandatory information is able to be displayed. It is important that operators are able to display the mandatory information in a manner that is most effective and useful to the parties that will interact with the container at any particular point in the supply chain.

OTA recommends that implementation of the requirement that nonretail containers “*must display*” the mandatory information listed in §205.307 is reflective of the range of NOP regulatory definitions of *label* and *labeling*. It has been current practice for operations to consider this to mean that the mandatory information in §205.307 (currently only lot numbers, if applicable) are displayed directly on the container itself rather than in a document accompanying the container. However, it is notable to consider the range of regulatory definitions for

“labeling” and “label.” **Labeling** is defined as (emphasis added): “*All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.*” **Label** is defined as (emphasis added): “*A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.*” (See also OTA’s comments on Exemptions from Certification regarding a request for guidance on the type of labeling that needs to be certified.).

In order to provide maximum flexibility for a wide range of nonretail containers while staying within the regulatory boundaries, implementation of these requirements must avoid overly prescriptive display requirements, and honor the definition of labeling that includes any material accompanying the product at any time. In many cases, the mandatory information in §205.307 can be displayed on or affixed to the immediate container. In many other cases, the practicalities of labeling or affixing information to nonretail containers may present challenges that are overcome by providing the information on materials accompanying product such that the information is immediately accessible.

The preamble describes scenarios where labeling on certain types of nonretail containers is impractical. In these scenarios, NOP explains that the information can instead be provided in documentation that is associated with and traceable to the container. The Preamble states, (emphasis added): “*Section 205.307 does not apply to large nonretail containers that are associated with a mode of transportation or storage, such as trailers, tanks, railcars, shipping containers, grain elevators/silos, vessels, cargo holds, freighters, barges, or other method of bulk transport or storage. As labeling of these types of large containers may be impractical, they do not need to be labeled with the information described in §205.307. However, this information must be evident in documentation associated with and traceable to the container, to ensure that organic integrity is maintained during transport, storage, and handling.*” Such impracticalities extend to many other types of nonretail containers. For example, individual harvest containers, totes or wagons used to bring produce or grains from the field into the pack house or grain elevator. Individually labeling these short-term or temporary on-farm transportation containers can be impractical. Impracticalities also exist for operations that are labeling nonretail containers that contain only sealed packages of fully labeled final retail products. For example, master cases or shipping cases of labeled packaged organic product wherein the packaged product within the container has all of the required label elements. However, distinguishing regulatory applicability based only on whether an activity is “impractical” would be difficult to implement consistently across operations and certifiers.

- **OTA recommends that NOP develop additional guidance to support common understanding and consistent implementation of the requirement that nonretail containers “*must display*” the mandatory information listed in §205.307.** Guidance is an opportunity to support implementation of regulatory requirements that are not one-size-fits all, because it can explain options for complying with the regulations in situation-specific scenarios. Guidance can support operations in applying the NOP regulations to any scenario of container/product combinations in a manner that the mandatory is readily accessible such that the goals of this SOE Proposed Rule are achieved.

OTA recommends that the guidance specifically address how the nonretail container labeling provisions should apply to containers of packaged versus unpackaged products, or sealed or unsealed containers (*See OTA’s comments on Exemptions from Certification regarding a request for guidance on the definition of “packaged.”*). We also recommend that the guidance include increased flexibility for nonretail containers that are only being used to store or move product on-site within a single certified operation (e.g. containers that are not being shipped or otherwise transferred outside of the operation to another operation in the supply chain). We also recommend that in cases where space is limited on physical containers, the display of organic identification and traceability information are prioritized as the most important labeling elements.

➔ **Recommendation:** Develop guidance to support common understanding and consistent implementation of nonretail container labeling requirements in manner that is adaptable to the wide variety of nonretail containers while still ensuring that mandatory information is immediately accessible.

- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within two years after publication of the final rule. An extended implementation period is necessary to allow operations time to develop and implement new labeling systems for nonretail containers that includes new mandatory information.

Table 3: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text compared with Current Rule Text (strikethrough removed text; underlined new text)	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.307 Revise title	Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”	
205.307(a) Revise	<p>205.307(b)(a) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing certified organic ingredients product must display the following:</p> <p><u>(1) The term, “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable, to identify the product;</u></p> <p><u>(2) The statement, “Certified organic by * * *,” or similar phrase, to identify the name of the certifying agent that certified the producer of the product, or, if processed, the certifying agent that certified the last handler that processed the product; and</u></p> <p><u>(3) The production lot number of the product if applicable, shipping identification, or other information needed to ensure traceability.</u></p>	<p>Revision needed to allow flexibility for operators to use alternative abbreviations or indicators of a product’s organic status. See OTA’s Position on <u>organic identification</u>.</p> <ul style="list-style-type: none"> Revise §205.307(a)(1) to read “identification of the product as organic.” This is the exact text that currently appears in the regulations for nonretail containers. We recommend using this same language and only moving it from an optional piece of information to a mandatory piece of information. <p>Revision needed to designate the operation’s name as mandatory and not optional on nonretail containers. See OTA’s Position on <u>identification of the certified operation</u>.</p> <ul style="list-style-type: none"> Move operation name from paragraph (b) to paragraph (a) so that it becomes mandatory information.

		<p>Revision needed to clarify which operation and certifier must be identified. See OTA’s Position on <u>which operation and certifier</u> should be displayed.</p> <ul style="list-style-type: none"> Revise §205.307 to specify that the handler or distributor of the product and the name of its certifier should be identified on nonretail containers. <p>Guidance needed to explain the options for how to identify products as certified organic and clarify that such identifications can use alternative abbreviations or indicators of a product’s organic status. See OTA’s Position on <u>organic identification</u>.</p> <p>Guidance needed to support common understanding and consistent implementation of the requirement that nonretail containers must display mandatory information in manner that is adaptable to the wide variety of nonretail containers while still ensuring that the information is immediately accessible. See OTA’s Position on <u>flexibility for organic operations</u> in their labeling of nonretail containers with mandatory information.</p>
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OTA Requested Revision:

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

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

(New) The name of the handler or distributor of the product

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

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

205.307(b)
 Revise

~~205.307(a)(b) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing certified organic ingredients~~ product may display the following terms or marks:

~~(1)(3) Special handling instructions needed to maintain the organic integrity of the product;~~

~~(2)(4) The USDA seal. Use of the USDA seal must comply with 205.311~~

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

~~(4)(5) The business address, website, and/or name and contact information of the certifying agent which certified the handler which assembled the final product.~~

~~(2) Identification of the product as organic;~~

Revision needed to designate the operation’s name as mandatory and not optional on nonretail containers. See OTA’s Position on **identification of the certified operation**.

- Move operation name from paragraph (b) to paragraph (a) so that it becomes mandatory information.

Revision needed to clarify which operation and certifier must be identified. See OTA’s Position on **which operation and certifier** should be displayed.

- Revise §205.307 to specify that the handler or distributor of the product and the name of its certifier should be identified on nonretail containers.

OTA Requested Revision:

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



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Johanna Miranda
Farm Policy Director

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – On-Site (Unannounced) Inspections

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter.

This comment addresses Section #4: On-site Inspections

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports mandatory unannounced inspections of a minimum of 5 percent of the operations it certifies.
- OTA recommends that certifiers have procedures for identifying high-risk operations and products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations.
- OTA supports the requirement to only certify operations in areas where the certifier is able to conduct unannounced inspections.
- OTA recommends updating Guidance 2609 to further explain expectations around unannounced inspections.
- OTA supports the proposed requirement for certifying agents to conduct “trace-back” and “mass-balance” audits during inspections.
- OTA recommends including reference, in the regulation, to the common terms “trace-back audits” and “mass-balance audits.”
- OTA recommends that the meaning of the term ‘*source*’ as used in the requirement for supply chain traceability audits be clarified.
- OTA recommends adding as a new term and defining ‘*supply chain traceability*’ in the organic regulations.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

OTA's Positions and Recommendations

Unannounced Inspections

- **§ 205.403(b): OTA supports mandatory unannounced inspections.** Although unannounced inspections are standard practice, we strongly support the proposal that will codify the practice and require a minimum number of unannounced inspections be conducted annually. Unannounced inspections are a critical enforcement tool. The cost of unannounced inspections should be factored into the certifier's fee structure.
- **§ 205.403(b)(1): OTA supports unannounced inspections of a minimum of 5 percent of the operations it certifies.** However, in addition, certifiers must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations. Such a requirement would incorporate a risk-based approach to deciding when it is appropriate to conduct unannounced inspections above and beyond the 5% minimum and it would be consistent with the proposed requirement for Supply Chain Traceability, under § 205.504(b)(7), whereas certifiers must have a copy of the criteria to identify high-risk operations and products. We expect the criteria would be similar and could serve both aspects of the rule. *(See also our comments on Grower Group Operations)*

➔ **Recommendation:** OTA recommends that certifiers be required to have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations. *See OTA's requested revision in Table 4*

§ 205.403(b)(2): OTA supports the requirement to only certify operations in areas where the certifier is able to conduct unannounced inspections. OTA strongly agrees. Unannounced inspections are a critical enforcement tool and being able to utilize this tool on any certified operation, regardless of where the operation is located, should be a basic and fundamental requirement of the organic regulations. In the preamble, NOP explains that certifying agents would be expected to “describe the areas where they operate in written materials they provide to both applicants and certified operations, and review the locations of all operations during the application review or annual review.” OTA agrees. However, it will be important that this expectation is communicated either in the Rule itself or in Guidance. In this case, OTA supports the use of Guidance.

➔ **Recommendation for Updated Guidance:** OTA recommends that NOP 2609 (Unannounced Inspections) be updated concurrently with this final rule to include the following expectation as expressed in the preamble:

- “To ensure consistency, transparency, and accountability, certifying agents would be expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.”
See OTA’s requested revision in Table 4

Supply chain traceability and mass balance audits

- **§§ 205.403(d)(4) and 205.403(d)(5): OTA strongly supports the proposed requirement for certifying agents to conduct “trace-back” and “mass-balance” audits during inspections.** NOP is proposing that the on-site inspection of an operation must verify that: 1) sufficient quantities of organic products and ingredients are produced or purchased to account for organic product sold or transported; and that 2) organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21). OTA strongly agrees. It would be helpful, however, if the regulatory text specifically referenced “trace-back audits” and “mass-balance audits” as they are referred to in the preamble. It will be easier for both certified operations and certifying agents to quickly and easily identify and understand these new requirements if the common terminology is used. OTA notes that the proposed regulations for Grower Groups, at §205.400(g), specifically reference “mass-balance audits.”

➔ **Recommendation:** OTA recommends revising §§ 205.403(d)(4) and (d)(5) to include reference to “trace-back audits” and “mass-balance audits,” respectively. *See OTA’s requested revision in Table 4*

Supply chain audits, both “trace-back” audits and “mass-balance” audits, are effective verification tools and they are fundamental to organic fraud prevention. A regulatory requirement to conduct such audits is important and it is needed to ensure that NOP can take appropriate action against certifying agents that are not conducting adequate audits during inspections. To ensure effective implementation of an entire supply chain traceability audit, as proposed at § 205.501(a)(21), there must be full participation from all NOP accredited certifying agents around the globe. Everyone must commit to working together and to sharing information in a timely manner. OTA believes that additional NOP support will be needed, including mandatory training and Guidance for all NOP accredited certifiers, domestic and international.

- **§ 205.403(d)(5): OTA recommends that the meaning of the term “source” in reference to traceability audits be clarified.** This proposal requires certifying agents to verify traceability back to the “source.” OTA agrees with this requirement. However, it is unclear in the proposed rule itself what is meant by the term “source.” The preamble clarifies this term to mean “farm,” or the source at “any step in the supply chain.” To improve the clarity of the proposed requirement, we recommend a minor revision that will capture this explanation.

➔ **Recommendation:** OTA recommends a revision at § 205.403(d)(5) to clarify meaning of the term “source” as it is explained in the preamble of this proposed rule. We recommend inserting the clause “at any step in the supply chain” to clarify that

certifying agents may verify traceability back to the source, at any step in the supply chain. We also recommend defining the term ‘*supply chain traceability*’ in the organic regulations. **See OTA’s requested revision in Table 4**

- **OTA recommends adding the term and definition for “supply chain traceability” to the organic regulations.** In the preamble, NOP explains the terminology and objectives of this proposed rule. In addressing terminology, NOP explains that four concepts are used throughout this proposed rule and they are integral to the purpose of this proposed rule. Those concepts are: 1) organic integrity; 2) organic fraud; 3) audit trails; and 4) supply chain traceability. NOP explains each concept upfront to assist reader understanding. Given the importance of these terms and concepts and to improve the clarity of this proposed rule, OTA strongly believes that all four terms should be defined in the organic regulations. Currently, the organic regulations define *audit trail* and NOP is proposing the term ‘*organic fraud*’ be added and defined. OTA requests that ‘*organic integrity*’ and ‘*supply chain traceability*’ be added and defined as well.

➔ **Recommendation:** To further clarify the term ‘source’ as well as the proposed requirement that certifying agents conduct trace-back or supply chain traceability audits, OTA recommends that the term ‘*supply chain traceability*’ be added as a new term to the organic regulations. We recommend using the definition provided in the preamble:

- *Supply Chain Traceability.* The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards” from consumption to source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.

See OTA’s requested revision in Table 4

Table 4: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity and utility of the Proposed Rule
Redesignate 205.403(b) as 205.403(c) and Add new paragraph 205.403(b)	Unannounced inspections. (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. (2) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.	<p>Support with a revision: OTA supports 5% as a minimum. However, in addition, certifiers must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum as needed and in response to complaints and investigations.</p> <p>Updated Guidance (NOP 2609) Requested: The preamble explains that certifiers are expected to describe the areas where they operate in written materials they provide to both applicants and certified operations, and review the locations of all operations during the application review or annual review. OTA agrees; however, it will be important that this expectation is communicated either in the Rule or in Guidance. In this case, OTA supports the use of Guidance and recommends that NOP 2609 (Unannounced Inspections) be updated concurrently with this final rule and revised to include the following:</p> <p>“To ensure consistency, transparency, and accountability, certifying agents would be expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.”</p>
<p>OTA Requested Revision: 205.403(b - Unannounced inspections. (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. <u>(2) A certifying agent must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum as needed and in response to complaints and investigations.</u> (2) (3) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.</p>		
Redesignate 204.403(d)(1)	Verification of information. The on-site inspection of an operation must verify:	Technical correction; no concerns.

<p>– (3); correct 205.200 to 205.201</p>	<p>(1) The operation’s compliance or capability to comply with the Act and the regulations in this part; That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200 205.201, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.</p>	
<p>OTA Requested Revision: None</p>		
<p>Add 205.403(d)(4)</p>	<p>That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported; and</p>	<p>Revision needed: OTA recommends revising §§ 205.403(d)(4) to include reference to “mass-balance audits.” It will be easier for both certified operations and certifying agents to quickly and easily identify and understand this new requirement if the common terminology is used.</p>
<p>OTA Requested Revision: That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported (<u>“mass-balance audits”</u>); and</p>		
<p>Add 205.403(d)(5)</p>	<p>That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21) (<u>“trace-back audits”</u>).</p>	<p>Revision needed: OTA recommends revising §§ 205.403(d)(5) to include reference to “trace-back audits.” It will be easier for both certified operations and certifying agents to quickly and easily identify and understand this new requirement if the common terminology is used.</p> <p>Revision needed: OTA recommends that the meaning of the term “source” in reference to traceability audits be clarified. The preamble clarifies this term to mean “farm,” or the source at “any step in the supply chain.” To improve the clarity of the proposed requirement, we recommend a minor revision that will capture the explanation provided in the preamble.</p>

		<p>Request to add a NEW term and definition to the organic regulations: To further clarify the term ‘source’ and the requirement that certifying agents conduct supply chain traceability audits, OTA recommends that the term, ‘<i>supply chain traceability</i>’ be added as a new term to the organic regulations. We recommend using the definition provided in the preamble. See below.</p> <p>Guidance, Training and Support Requested: For full supply chain audits to be feasible, there must be complete participation from all NOP accredited certifying agents around the globe. Everyone must commit to working together and sharing information in a timely manner. OTA believes that strong NOP support and monitoring will be needed, including training and Guidance.</p>
<p>OTA Requested Revision: § 205.403(d) 5) That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source <u>at any step in the supply chain</u> per §205.501(a)(21).</p> <p>OTA Requested Revision (NEW term – supply chain traceability): Add a new term to §205.2 - <i>Supply Chain Traceability</i>. The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards “from consumption to source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.</p>		

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
 Vice President, Regulatory and Technical Affairs



Johanna Miranda
 Farm Policy Director

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Organic Certificates and Paperwork Submissions (Data Reporting)

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement.

The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #5 (Certificates of Organic Operations) and Section #7 (Paperwork Submissions to the Administrator).

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

Certificates of Organic Operation

- OTA does not support formalizing ‘INTEGRITY’ as the name of the NOP Organic Integrity Database. We support the proposed definition, but request that the associated term retain the full clause of “Organic INTEGRITY Database” along with its acronym “OID.”
- OTA recommends adding the term ‘*organic integrity*,’ as it is typically used, to the organic regulations to clearly define a core concept that is integral to the purpose of this proposed rule and used throughout this proposed rule.
- OTA supports the use of uniform organic certificates generated through OID, but we have concerns about the time and resources it will realistically take to achieve this goal as a requirement.
- OTA does not support a certificate expiration date. An expiration date is more problematic than it is useful. The goal of ensuring a consistent way of communicating and interpreting the validity and status of an organic certificate can be accomplished other ways.
- OTA recommends a *two-year* implementation period after the publication of the final rule for the proposals in this section.

Paperwork Submissions to the Administrator

- OTA agrees that accurate and current data must be reported and maintained in the NOP Organic INTEGRITY Database (OID).
- OTA supports global use of the Organic INTEGRITY Database (OID).
- OTA recommends that grower group operations be identified as such in the OID and identify how many members are in the group.
- OTA recommends that NOP issue a final rule that explicitly requires data reporting by crop type, acreage and location (e.g. state), and number of animals by livestock type and location (e.g. state), on a monthly basis to the OID.

- OTA supports timely updates to maintain accurate data reflecting an operation's current status.
- OTA recommends that NOP contract with NASS, a federal statistical agency, to analyze and turn mandatory data into a comprehensive, reliable, statistical report. This would be *in addition* to the data NOP makes available through the Organic INTEGRITY database.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

NOP Questions:

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

Updates should be made in real time as changes occur. If no changes occur during the year, the certificate should be updated annually to reflect new dates.

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

No. OTA does not support a certificate expiration date. Establishing an expiration date for a physical or electronic document does not serve a beneficial purpose and would create more problems than solutions. See our detailed comments below.

Background

Accurate data for the production, pricing and marketing of organic products is essential to maintaining stable markets, identifying fraud, creating risk management tools, tracking production trends, and increasing exports. Investments in technology and access to data to improve tracking of international organic trade will provide the necessary information to ensure a transparent marketplace. OTA has consistently worked with Congress to advocate for increased funding for the National Organic Program to collect data as well as make important investments in technology to ensure the data is accessible. In both the 2014 and 2018 Farm Bills, OTA successfully advocated for Congress to include \$5 million in mandatory funding to support technology upgrades at NOP. The funding was used to create the Organic Integrity Database (OID) and recent funding included in the 2018 Farm Bill was provided for NOP to make upgrades and maintain OID while also investing in technology to set up a tracking system for electronic import certificates through the U.S. Customs and Border Protection's Automated Commercial Environment (CBP-ACE) system. NOP's annual budget is provided by Congress through discretionary appropriations. Over the past five years, NOP funding has increased by more than 30% due to OTA's advocacy. In the 2018 Farm Bill, OTA secured an authorization to increase NOP's budget by 10% per year to keep pace with market growth. Continued Congressional support for NOP funding is vital to ensure that the requirements of the proposed rule related to data collection are achievable, and the federally operated databases upon which the SOE Rule relies (OID & CBP-ACE) can continue to provide the critical functionality and data that the industry requires.

OTA's Positions and Recommendations

ORGANIC CERTIFICATES

- **OTA does not support formalizing the term INTEGRITY as the name of the NOP Organic Integrity Database.** We support the proposed definition, but request that the associated term (the name of the database) retain the full clause - “Organic INTEGRITY Database.” The word “integrity” is a fundamental term used by the organic sector to describe the “integrity” of an organic product as well as the “integrity” of the organic supply chain. More specifically, the term is used to describe the uncompromised quality of being authentically certified organic. We request that the term ‘organic integrity’ continue to be reserved as a descriptor for organic authenticity rather than become the name of a database.

In the preamble, NOP explains the terminology and objectives of this proposed rule. In addressing terminology, NOP explains that four concepts are used throughout this proposed rule and they are integral to the purpose of this proposed rule. Those concepts are: 1) organic integrity; 2) organic fraud; 3) audit trails; and 4) supply chain traceability. NOP explains each concept upfront to assist reader understanding. Given the importance of the term ‘organic integrity,’ and to improve the clarity of this proposed rule, OTA highly recommends that it be formalized in the organic regulations as a new term and definition and not be conflated with or used as the name of the NOP database.

- ➔ **Recommendation:** Add the new term “Organic INTEGRITY Database” and formalize its acronym as OID:
 - **Organic INTEGRITY Database (OID):** The National Organic Program’s electronic, web- based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors.
- ➔ **Recommendation:** Add a new term and definition to the regulations, “*organic integrity*.” OTA recommends the definition that is used in the preamble:
 - **Organic Integrity:** The unique attributes that make a product organic, and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised. *See OTA's requested revision in Table 5*

§ 205.404(b): OTA supports the use of organic certificates generated through the NOP Organic INTEGRITY Database (OID). We believe that a federated organic certificate can bring many benefits to the organic sector, and we are largely in favor of this direction. However, we have concerns about how the requirement may impact certifiers and the technology systems and databases they have built and invested in over the course of many years and the time and resources it will take to make the transition. We understand that NOP is not

seeking to eliminate “these unique sources of value,” but nonetheless it will require additional time and resources for certifiers to maintain data in two systems. We also have concerns about the potential certification service delays that may arise should the OID be temporarily out of service or functioning less than optimally. OTA believes that the goal of certificate uniformity is extremely important, and we strongly support the OID as **the “go-to” place** to access data and to verify organic certificates and certification status in real-time. We fully support this direction, but also recognize the time and resources that are needed to get there. We are also aware of the heavy reliance this proposed rule places on OID, and again, emphasize the importance of adequate NOP funding to support its functionality into the foreseeable future.

OTA strongly supports mandatory reporting to the NOP Organic INTEGRITY Database and access to real-time (or “modern-time”) electronic information that will support the use of uniform certificates, whether they be electronic or paper-based. We would like to see less reliance on the paper-form of the certificate, and more reliance on using a functional and up-to-date database to verify an organic operation’s status and to access critical data such as crop acreage.

→ **Recommendation:** NOP’s goal is to eliminate the wide variability in the content and style of certifying-agent-generated organic certificates. OTA agrees with this goal and we agree that this variation may increase the chance of alteration and organic fraud. OTA supports moving to the mandatory use of the NOP Organic INTEGRITY Database to generate organic certificates, but we want to ensure that organic certifying agents have the time and resources needed to make the transition. To accommodate a realistic transition and to ensure an efficient and seamless interface, OTA is recommending a two-year implementation time period. We also support exploring an option where certifying agents could retain the ability to issue a certificate as needed, provided it matches the OID certificate and is clearly linked to the OID.

- **OTA does not support a certificate expiration date.** This requirement was a topic of great debate for many years under the corresponding 2006 NOSB recommendation, and certified operators and certifying agents widely disliked and disagreed with the recommendation. Certifying agents have established effective ways to indicate whether an organic certificate is current and valid. Establishing an expiration date for a piece of paper does not serve a beneficial purpose and it would actually create more problems and confusion since it would not have any effect on the operation’s certification status. OTA believes the primary issue that needs to be addressed is the variability and lack of consistency around the terms and dates used to communicate the validity of a certificate. While certifying agents have established ways to indicate whether a certificate is current and valid, the lack of uniformity can be challenging to certified operations trying to assess multiple certificates from multiple certifying agents.

→ **Recommendation:** The goal should be a simple and uniform way for a certifying agent or a certified operation to assess whether a certificate is current. For example, specify the use, meaning and placement (certificate vs. addendum) of 1) NOP effective date; 2) certificate issue date; 3) anniversary date; 4) certificate revision or

signature date; and 5) the ten-digit NOP Operation ID. This is done to some extent in **NOP 2603**. However, further refinement and clarification are needed to achieve consistent interpretation and use by certifying agents.

See OTA's recommended guidance in Table 5

- **OTA supports timely updates to maintain data reflecting an operation's current status.** Accordingly, we support the requirement for certifying agents to update OID within 3 business days of accepting an operation's surrender, or suspending or revoking an operation's certification (see *OTA's comments Noncompliance, Mediation and Appeals*)

PAPERWORK SUBMISSIONS TO THE ADMINISTRATOR (DATA REPORTING)

- **OTA agrees that accurate and current data must be maintained in the Organic INTEGRITY Database.** The organic industry cannot continue to thrive and maintain stable markets without good data collection. A requirement for certifying agents to report production area certified by crop/livestock and location, on an at least an annual basis, to the Organic INTEGRITY Database is one of the most impactful single actions that can be taken to increase the integrity in the global organic control systems. Currently there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis. This hinders the ability of NOP, the State Organic Program, and certifiers to evaluate the total volume of organic product coming from any given region and accordingly detect whether fraud is occurring.
- **OTA supports global use of the Organic INTEGRITY Database.** If global use is not possible, then we recommend investing in developing some additional system that give organic operations and certifying agents access to the same type of information about certified operations around the world that are operating under equivalency arrangements or recognition agreements and selling product into the United States. The system should include operations in equivalent countries eligible to export to the U.S. as organic and operations certified to the USDA regulations by a certifier operating under a recognition agreement. (*See also OTA's comments on Accepting Foreign Conformity Assessment*)
- **OTA recommends that grower group operations be identified as such in the NOP Organic INTEGRITY Database.** Currently, the status of an operation as being a grower group is not visible in the Organic INTEGRITY Database, so it is not possible to determine if an operation is a grower group or how many grower groups are certified to the NOP organic standards. This is an important point of data transparency. Ideally, the OID should identify if an operation is certified as a group operation and identify how many members are in the group. The total certified acreage group operation should already be captured in requirements for operations to report certified acreage to the Administrator, because group operations need to report data just as any other certified operation. (*See also OTA's comments on Grower Group Operations*)

- **OTA does not support the proposed text under § 205.501(a)(15) because it does not clearly or adequately convey what the mandatory data requirements will include.** To accurately calculate organic acreage and/or yield estimates on a country-by-country basis, it is critical that certifying agents be required to submit data by crop type, acreage and location (e.g. state), and number of animals by livestock type and location (e.g. state), at least on a quarterly or biannual basis. OTA is sensitive to confidential business information and therefore expects that NOP will continue its practice of aggregate reporting to the public.
 - ➔ **Recommendation:** OTA recommends that NOP issue a final rule that explicitly requires data reporting to NOP by crop type, acreage and location (e.g. state), and number of animals by livestock type and location (e.g. state), at least on an annual basis to the Organic Integrity Database. Reports to the public will include aggregated acreage and livestock data only. *See OTA's requested revision in Table 5*
- **OTA recommends that NOP contract with the National Agricultural Statistics Service (NASS) to analyze and turn mandatory data into a comprehensive, reliable, statistical report.** Mandatory data reporting is not only essential to identifying fraud, it is also critical for policymakers, farmers, businesses, and crop insurance providers to make sound policy, business, marketing, and risk management decisions as well as identify what sectors are strong, and where there is room for growth. Since 2008, NASS's Organic Survey has become a valuable and essential source of data on health and emerging trends facing organic agriculture. The SOE requirement for certifying agents to maintain updated data in the NOP Organic INTEGRITY Database provides an excellent opportunity for partnership between NOP and NASS, whereas NOP can gather data through mandatory reporting and make that data available through the OID. Additionally (but not in place of), NASS, a federal statistical agency, could turn the reported data into a comprehensive, reliable, statistical report. The data will still have gaps due to confidential screens. However, it will come much closer to a population number than the national producer surveys currently do. Contracting with NASS to produce such a report would be incredibly valuable to the organic sector.
 - ➔ **Recommendation:** In addition to the data NOP makes available through the Organic INTEGRITY Database, OTA recommends that NOP contract with NASS, a federal statistical agency, to analyze and turn mandatory data into a comprehensive, reliable, statistical report.
- **OTA supports timely updates to maintain data reflecting an operation's current status.** The frequency of reporting should be directly related to operational changes, which will be highly variable per operation. Certifying agents should be encouraged to report updates whenever there are changes to the products or activities listed on the organic certificate. OTA recommends requiring data to be reported by certifiers to the OID on a monthly basis.

Table 5: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Certificates of Organic Operation

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA positions and improve the quality, clarity and utility of the proposed rule.
Add new term	<i>INTEGRITY</i> . The National Organic Program’s electronic, web- based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors.	Revision needed: OTA does not support the proposed term and definition together. The term “integrity” is a very important term that is used commonly to describe the uncompromised quality of being authentically certified organic. We would like to reserve the use of the term to describe organic authenticity, rather than the name of a database. OTA does not have any concerns with the proposed definition for the NOP database, but we would like it to be explicitly tethered to the full phrase of ‘Organic INTEGRITY Database’ and ‘OID ‘for short.
<p>OTA Requested Revision: <u><i>Organic INTEGRITY Database (OID)</i></u>. The National Organic Program’s electronic, web- based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors.</p> <p>Also add new term to § 205.2: <u><i>Organic Integrity. The unique attributes that make a product organic, and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.</i></u></p>		
Redesignate 205.404(c) as 205.404(d); Add new 205.404(c)	In addition to the certificate of organic operation provided for in §205.404(b), a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include: (1) Name, address, and contact information for the certified operation; (2) The certified operation’s unique ID number/code that corresponds to the certified operation’s ID number/code in USDA Organic INTEGRITY; (3) A link to USDA Organic INTEGRITY or a link to the certified operation’s profile in USDA Organic INTEGRITY, along with a statement,	Revision needed: OTA supports the use of a certificate addenda. However, we do not support a requirement for the addenda to include an expiration date. <ul style="list-style-type: none"> • Certifying agents have established effective ways to indicate whether an organic certificate is current and valid. • Establishing an expiration date for a piece of paper does not serve a purpose and actually creates confusion since it would not have any effect on the operation’s certification status. • OTA believes the primary issue is and concern that needs to be addressed is the variability and lack of consistency around terms and dates used to communicate the validity of a certificate. While certifying agents have established ways to indicate whether a certificate is current and valid, the lack of

	<p>“You may verify the certification of this operation at USDA Organic INTEGRITY,” or a similar statement;</p> <p>(4) Name, address, and contact information of the certifying agent;</p> <p>(5) “Addendum issue date;” and</p> <p>(6) “Addendum expiration date,” which must not exceed the expiration date of the certificate of organic operation.</p>	<p>uniformity can be challenging to certified operations trying to assess multiple certificates from multiple certifying agents.</p> <ul style="list-style-type: none"> • The goal should be a simple and uniform way for a certifying agent or a certified operation to assess whether a certificate is current. This does not however require a certificate expiration date. <p>Recommended Guidance: To ensure organic certificates are monitored and remain current, OTA recommends that NOP include a method, in Guidance, for certifiers to follow. For example, specify the use and meaning of 1) NOP effective date; 2) certificate issue date; 3) anniversary date; and 4) certificate revision or signature date. This could be accomplished by updating NOP Guidance 2603 with a certificate/addendum template to provide further specificity on where the elements of the certificate should be located. This would help ensure further consistency.</p>
<p>OTA Requested Revision: In addition to the certificate of organic operation provided for in §205.404(b), a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include:</p> <p>(1) Name, address, and contact information for the certified operation;</p> <p>(2) The certified operation’s unique ID number/code that corresponds to the certified operation’s ID number/code in USDA Organic INTEGRITY Database;</p> <p>(3) A link to USDA Organic INTEGRITY Database or a link to the certified operation’s profile in USDA Organic INTEGRITY Database, along with a statement, “You may verify the certification of this operation at USDA Organic INTEGRITY Database,” or a similar statement;</p> <p>(4) Name, address, and contact information of the certifying agent;</p> <p>(5) “Addendum issue date;” and</p> <p>(6) “Addendum expiration date,” which must not exceed the expiration date of the certificate of organic operation.</p>		
<p>Redesignated 205.404(d)</p>	<p>Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program’s governing State official, or the Administrator.</p>	<p>No concerns</p>

Paperwork Submissions to the Administrator

Action & Section	SOE Proposed Rule Text	Revisions and/or Guidance needed to implement OTA's positions and improve the quality, clarity and utility of the proposed rule.
Remove 205.405(c)(3)	Provide notice of approval or denial to the Administrator, pursuant to §205.501(a)(14).	No Concerns.
Revise 205.501(a)(15)	<p>Maintain current and accurate data in INTEGRITY for each operation which it certifies:</p> <p>Submit to the Administrator a copy of: (i) Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance; and (ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;</p>	<p>OTA agrees that accurate and current data must be maintained in the Organic Integrity Database. Currently there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis. This hinders the ability of NOP, the State Organic Program, and certifiers to evaluate the total volume of organic product coming from any given region and accordingly detect whether fraud is occurring.</p> <p>Revision needed: OTA strongly urges NOP to issue a final rule that clearly requires data reporting by crop type, acreage and location, and number of animals by livestock type and location, on a monthly basis to the Organic Integrity Database. OTA prefers quarterly or biannual reporting including verification of no change.</p> <p>Recommendation: In addition to the data NOP makes available through the Organic INTEGRITY database, OTA recommends that NOP contract with NASS, a federal statistical agency, to analyze and turn mandatory data into a comprehensive, reliable, statistical report.</p>
<p>OTA Suggested Revision: Maintain current and accurate data in <u>organic INTEGRITY Database</u> for each operation which it certifies. Data must be reported <u>by crop type, acreage and location, and/or by number of animals, livestock type and location as determined by AMS.</u></p>		



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

Johanna Mirinda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Continuation of Certification

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter.

This comment addresses Section #6: Continuation of Certification

Summary of Organic Trade Association’s Positions and Recommendations

- OTA supports revisions to the rule that will eliminate unnecessary paperwork without compromising oversight of organic operations.
- OTA supports the clarification that operations are only required to submit sections of the Organic System Plan that have changed during the annual certification year rather than submitting a full plan every year.
- OTA supports a rule that provides certifying agents with the flexibility needed to adjust the timing of an inspection in circumstances when it is impossible to conduct an on-site inspection.
- OTA supports a requirement to conduct an on-site inspection at least once per year, but some flexibility is needed outside a strict 12-month time period. We recommend specifying that inspections must occur on an annual basis with reduced flexibility from 18 months to 15 months.
- OTA recommends a revision to the organic regulations that will provide an impossibility clause or temporary variance for conducting on-site inspections in the case of a natural disaster or natural emergency as declared by the Secretary or President. Given the unprecedented experience and the lessons learned during COVID-19, it is critical that the regulations include flexibility that allow for certifying agencies to utilize emergency remote inspections when on-site inspections are not possible.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

OTA's Positions and Recommendations

- **§ 205.406(a): OTA supports revisions to the rule that will eliminate unnecessary paperwork without compromising oversight of organic operations.** We also support consistent practices between certifying agents. The proposed change to § 205.406(a) to clarify that operations are only required to submit sections of the OSP that have changed during the annual certification process should accomplish just this. Furthermore, the proposed change is consistent with published NOP instructions (NOP 2615 and NOP 2601) and it is also largely consistent with the practice of many certifying agents. While we support this change, we also acknowledge that certifiers need the flexibility to request an OSP in its entirety as it is deemed appropriate or necessary. For example, many certifiers will request that a complete OSP be submitted every five years. The proposed change to § 205.406, however, should not create a conflict since flexibility is provided under § 205.201(a)(6) (Organic Production and Handling System Plan), and may be utilized accordingly when and if certifiers decide that submission of a complete OSP is needed. Further, as noted in the preamble and in § 205.403(c)(2), the on-site inspection must verify that the entire OSP is implemented as described.
- **§ 205.406(b): OTA does not support the proposed revisions to § 205.406(b). It is critical that certifying agents have flexibility to certify clients on an “annual basis” and to adjust the timing of an inspection in circumstances when it is impossible to conduct an on-site inspection.** The proposed rule requires certifying agents to arrange and conduct an on-site inspection of the certified operation at least once per calendar year. The intent is to remove language that could be interpreted to mean that an operation may be inspected every 18 months on an ongoing basis. However, the proposed language “once per calendar year” will be challenging since many certifying agents certify clients on an “annual” but *seasonal* basis, and the Winter season spans the calendar years. The proposal also removes critical language that *allows for flexibility* when it is *impossible* for the certifying agent to conduct the annual on-site inspection as scheduled.

OTA believes that certifying agents interpret the rule to mean that operations must be inspected every 12-months. We agree with this requirement and recognize it as a strict goal. However, certifying agents need flexibility to conduct on-site inspections on an annual basis (either seasonal or by the calendar year) and to make schedule adjustments that are sound, sensible and do not increase the fraud opportunity. The proposed revision to § 205.406(b) will unfortunately eliminate the flexibility needed for certifying agents to respond to real-life situations and make practical adjustments. OTA believes clarification that inspections are to be conducted on an annual 12-month basis (vs. once every 18 months) can be accomplished without taking away this important flexibility.

Given the unprecedented experience and the lessons learned during COVID-19, it is critical that the regulations provide scheduling flexibility as well as an impossibility clause or a temporary variance for conducting on-site inspections in the case of a natural disaster or emergency as declared by the Secretary or President. Certifying agents need the flexibility to adjust the timing of an inspection as well as to be able to conduct an emergency remote inspection (with a follow-up on-site inspection) when an on-site inspection is not possible.

➔ **Recommendation:** Revise § 205.406(b) to reference “annual basis” and retain the exception for up to 15 months, instead of 18 months. *See OTA’s requested revision in Table 6*

➔ **Recommendation:** Add § 205.403 to § 205.290(a) to allow for a temporary variance for inspections during a natural disaster or national emergency. *See OTA’s requested revisions in Table 6*

Table 6: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA Positions and improve the quality, clarity and utility of the Proposed Rule.
Revise 205.406(a)	<p>To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:</p> <p>An updated organic production or handling system plan which includes:</p> <p>1) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year; and</p> <p>Any additions or deletions to the previous year’s organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200 §205.201;</p> <p>Any additions to or deletions from the information required pursuant to §205.401(b); and</p> <p>An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and</p> <p>Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.</p>	<p>OTA supports the revision as written. No changes needed</p> <ul style="list-style-type: none"> OTA supports revisions to the rule that will eliminate unnecessary paperwork without compromising oversight of organic operations. We also support consistent practices between certifying agents. The proposed change to clarify that operations are only required to submit sections of the OSP that have changed during the annual certification process should accomplish just this.
OTA Requested Revision: None		

<p>Revise 205.406(b)</p>	<p>Following the receipt of the information specified in paragraph (a) of this section, The certifying agent shall <u>must</u> within a reasonable time arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation pursuant to §205.403 at least once per calendar year. Except, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.</p>	<p>Revision needed: Certifying agents must have the flexibility to adjust the timing of an inspection in circumstances when it is impossible to conduct an on-site inspection. OTA supports a requirement to conduct an on-site inspection at least once per year, but some flexibility is needed outside a strict 12-month time period. We recommend specifying that inspections must occur on an annual basis and we recommend retaining the existing impossibility clause, but reducing the flexibility time from 18 months to 15 months.</p> <p>Revision needed: Given the unprecedented experience and the lessons learned during COVID-19, it is critical that the regulations also include a temporary variance for conducting on-site inspections in the case of a natural disaster or natural emergency as declared by the Secretary or President. Specifically, certifying agents need to the flexibility to adjust the timing of an inspection as well as to be able to conduct an emergency remote (vs. on-site) inspection until the on-site can be rescheduled. This could be accomplished by adding §205.403 to §205.290(a) to allow for a temporary variance.</p>
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OTA Requested Revision: § 205.406(b)- The certifying agent must arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation on an annual basis, at least once per calendar year. Except, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 3 months following the certified operation's scheduled date of annual update.

OTA Requested Revision:
 §205.290 Temporary variances.
 (a) Temporary variances from the requirements in §§205.203 through 205.207, 205.236 through 205.240 and 205.270 through 205.272, and 205.403 may be established by the Administrator for the following reasons:
 (1) Natural disasters declared by the Secretary or a national emergency declared by the President;
 (2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and
 (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

Johanna Miranda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Personnel Training and Qualifications

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Sections #8: Personnel Training and Qualifications.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendation

- OTA supports strengthening certification personnel and inspector training and qualifications requirements.
- OTA recommends an expanded list of required knowledge and skills for inspectors that includes specific references to mass balance and traceability auditing skills.
- OTA supports the required one year minimum experience requirement, and recommends a revision to clarify how to define and measure the proposal for “one year of field-based experience.”
- OTA supports the requirement for qualifications and training to be specific to the scope and scale of operations assigned for certification review or inspection. We recommend that guidance be developed to define and clarify various “scopes” and “scales” for consistently evaluating whether personnel have the appropriate training and qualifications.
- OTA supports the proposed minimum 20-hour training requirement for inspectors and certification personnel.
- OTA supports the minimum requirements for on-site evaluations of inspectors once per three years. We recommend that guidance be developed to help certifiers align on scenarios when more frequent evaluations are warranted.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

NOP Questions

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

Yes. OTA supports the proposed minimum 20-hour training requirement for inspectors and certification personnel. OTA understands the 20-hours of training could include anything relevant to any skills, knowledge, or experience related to inspections (for inspectors) or certification review (for certification review personnel). See below for more details on OTA's Position and Recommendations.

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

Yes, if warranted. OTA supports requirements for onsite evaluations of inspectors and does not take objection to the once-per-3-years minimum requirement in the proposed rule. Once per 3 years is common practice by certifiers. More frequent evaluations would be ideal, but we acknowledge that the proposed rule provides for greater frequencies "if warranted." Guidance could be provided to certifiers to align on scenarios when more frequent evaluations are warranted. See below for more details on OTA's Position and Recommendations.

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

Yes. OTA recommends adding specific references to mass balance and traceability as required auditing skills for inspectors. See below for more details on OTA's Position and Recommendations.

OTA's Positions and Recommendations

- **OTA supports strengthening certification personnel and inspector training and qualifications requirements.** Improvements in qualifications and training of inspectors are key steps in improving a certifier's ability to monitor, detect and address fraud. OTA supports NOP's effort to establish minimum requirements for qualifications and initial and continuing training for certification reviewers and inspectors. It is also NOP's responsibility through its accreditation oversight to ensure that certifiers have systems in place to properly evaluate the qualifications of inspectors, and ensure that operations are being evaluated and inspected by personnel that are appropriately qualified and trained for that particular type of operation. To ensure strong and consistent implementation of these new requirements, OTA encourages that during accreditation audits, certifiers must demonstrate to NOP their procedure for how they are ensuring a sufficient number of qualified and trained personnel, that the training sources for the 20-hours of continuing education are appropriate and relevant, and that the persons conducting onsite inspector evaluations meet minimum qualification requirements.

- **OTA recommends an expanded list of required knowledge and skills for inspectors that includes specific references to mass balance and traceability auditing skills.** The proposed rule includes a comprehensive list of skills that inspectors must have in order to inspect operations assigned to them, many of them suggested by OTA in our 2018 pre-rule comments such as investigative techniques. The Strengthening Organic Enforcement Proposed Rule includes proposed requirements for inspectors to conduct mass balance audits and traceability audits during onsite inspection (See Proposed Rule Section #4: On-site Inspections). To reinforce the inspector’s capability to perform these audit exercises, OTA recommends that mass balance and traceability auditing skills are specifically listed as required inspector skills. Furthermore, the proposed rule requires that inspectors have import/export knowledge. Not all operations are engaged in import or export of organic products, so this skill is not always required. OTA recommends that the regulation be revised to require this skill only if relevant.
 - ➔ **Recommendation:** Revise §205.501(a)(4)(i)(A) to include to mass balance and traceability as required auditing skills, and to clarify that import/export requirements are only required if relevant. *See OTA’s requested revisions in Table 7 below.*
- **OTA supports the required one year minimum experience requirement, and recommends a revision to clarify how to define and measure the proposal for “one year of field-based experience.”** The proposed rule states that inspectors must have “a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect.” We support the requirement for inspectors to have at least one year of experience prior to conducting inspection. However, there is a need for clarification about how to consistently define and measure “1 year” across the many unique circumstances and types of experiences that a prospective inspector might have. For instance, when a prospective inspector is only working part-time, it is unclear how to measure whether the requirement of “1 year” of experience has been met. Although we don’t disagree with this minimum requirement, we acknowledge that there may be varying interpretations among certifiers on this point.

We also see a need for clarification about how to define and measure “field-based experience.” The term “field-based” can be interpreted in several ways. It can mean “in a relevant area of academic study” such as the field of agriculture or science. It can also mean “on-site” such as physically being in place, such as on-site on a farm or facility. NOP uses the term “field-based” in both of these ways throughout the preamble, so clarification is needed about what NOP intends with respect to inspector qualifications. To avoid confusion and to expand the types of experiences that can qualify, OTA recommends replacing “field-based” with “relevant.” We recommend that certifiers do not limit the type of experience only to inspection experience, rather any relevant experience is counted. We recommend that NOP provide guidance for determining best practices to defining and measuring “1 year of relevant experience.”

→ **Recommendation:** Revise 205.501(a)(4)(i)(C) to clarify how to define and measure the regulatory requirement of “1 year of field-based experience.” *See OTA’s requested revisions in Table 7 below.*

If NOP does not accept OTA’s recommended revisions, we ask NOP to please provide an explanation on the NOP’s intent for defining and measuring “one year of field-based experience” to address our concerns described above.

→ **Recommendation:** Provide guidance for determining best practices to defining and measuring “1 year of relevant experience.”

- **OTA supports the requirement for qualifications and training to be specific to the scope and scale of operations assigned for certification review or inspection. We recommend that guidance be developed to define and clarify various “scopes” and “scales” for consistently evaluating whether personnel have the appropriate training and qualifications.** Certifiers will need to have a common understanding of how to define various “scopes” and “scales” so they can consistently determine whether a person has met the qualification and training for an assigned operation. “Scale” commonly refers to scale of production (large, small, group-operations) and can also refer to scale of commercial market (direct, wholesale, export). “Scope” is clearly defined for crops, wild crops, livestock, handling, but are there many sub-scopes within each scope (crops have sub-scopes for mushrooms, field crops, produce, etc.). It will be important for certifiers to have a common methodology for evaluating whether particular combinations of scales and scopes are appropriate to meet qualification requirements for the many unique types and sizes of organic operations.

→ **Recommendation:** Provide guidance to define and clarify various “scopes” and “scales” for consistently evaluating whether personnel have the appropriate training and qualifications.

- **OTA supports the proposed minimum 20-hour training requirement for inspectors and certification personnel.** OTA understands the 20 hours of training could include anything relevant to any skills, knowledge, or experience related to inspections (for inspectors) or certification review (for certification review personnel). We support flexibility for certifiers in determining the types of training that will qualify for meeting this requirement.

- **OTA supports the minimum requirements for on-site evaluations of inspectors once per three years.** Once per 3 years is common practice by certifiers. More frequent evaluations would be ideal, but we acknowledge that the proposed rule provides for greater frequencies “if warranted.” **We recommend that guidance id developed to help certifiers align on scenarios when more frequent evaluations are warranted.**

➔ **Recommendation:** Provide guidance for certifiers to align on scenarios when more frequent onsite inspector evaluations are warranted.

- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Table 7: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.2 Add new term	<i>Certification review.</i> The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance with the USDA organic regulations. This does not include performing an inspection.	
205.501(a)(4) Revise (strikethrough removed text; underlined new text)	<u>Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the USDA organic standards certification program established under the Act and the regulations in subpart E of this part;</u>	

<p>205.501(a)(4)(i) Add</p>	<p>Inspector qualifications and training — Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the required knowledge, skills, and experience to inspect operations of the scope and scale as assigned and to evaluate compliance with the applicable regulations of this part; and</p> <p>A. Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents; and</p> <p>B. Initially and every year thereafter, inspectors must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to inspection. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and</p> <p>C. Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect before assigning inspection responsibilities;</p>	<p>Revision needed to implement OTA’s Position on <u>required knowledge and skills for inspectors</u>. The regulations need to include mass balance and traceability as required auditing skills, and also need clarification that import/export requirements are only required if relevant.</p> <ul style="list-style-type: none"> • Add specific reference to mass balance and traceability auditing skills • Add “if relevant” for import/export requirements <p>Revision needed to implement OTA’s Position on <u>one year minimum experience</u>. The regulations need to support more consistent understanding of how to measure and define the minimum requirement experience.</p> <ul style="list-style-type: none"> • Replace “field-based” with “relevant” <p>Guidance needed for determining best practices to defining and measuring “1 year of relevant experience.” See OTA’s Position on <u>one year minimum experience</u>.</p> <p>Guidance needed to define and clarify various “scopes” and “scales” for consistently evaluating whether personnel have the appropriate training and qualifications. See OTA’s Position on <u>scope and scale</u>.</p>
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OTA Requested Revision:

- 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 (if relevant), auditing practices and skills (including mass balance audits and traceability audits), ~~in~~ written and oral communications skills, sample collection, investigation techniques, and preparation of technically accurate inspection documents; and
- C. Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based relevant experience related to both the scope and scale of operations they will inspect before assigning inspection responsibilities

205.501(a)(4)(ii)
 Add

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

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

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

<p>205.501(a)(4)(iii) Add</p>	<p>Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.</p>	
<p>205.501(a)(5) Revise</p>	<p><u>Demonstrate that all persons</u> Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making <u>or certification review</u> responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned; i) Sufficient expertise must include knowledge of <u>certification to USDA organic standards and evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties.</u></p>	

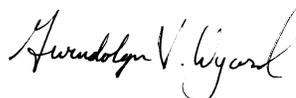
<p>205.501(a)(6) Revise</p>	<p>Conduct an annual performance evaluation of all persons who <u>conduct inspections, certification review, review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and</u> <u>or</u> implement measures to correct any deficiencies in certification services;</p> <p>(i) On-site evaluation of inspectors—Certifying agents must observe each inspector performing on-site inspections at least once every three years, or more frequently if warranted; and</p> <p>A. On-site inspector evaluations must be performed by certifying agent personnel who are qualified to evaluate inspectors;</p> <p>(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and on-site inspector evaluations.</p>	<p>Guidance needed for certifiers to align on scenarios when more frequent evaluations are warranted. See OTA’s Position on <u>on-site evaluations</u>.</p>
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Johanna Miranda
Farm Policy Director



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Oversight of Certification Activities

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter.

This comment addresses Section #9: Oversight of Certification Activities.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports the new term and definition of ‘certification activity.’
- OTA supports the new term and definition of ‘certification office,’ with clarification around the use of a home office.
- OTA supports the proposed requirement that NOP be notified of the opening of new certification offices.
- OTA recommends a notification timeframe of 45 days after certification activities begin.
- OTA does not support the revision to strike “accreditation” from the first part of § 205.640.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

OTA’s Positions and Recommendations

- **OTA supports the new term and definition of ‘certification activity.’** This new term will help clarify USDA’s oversight of the certifying agents it accredits by defining the general activities which are considered essential to the function of a certifying agent, and therefore subject to NOP oversight. We also strongly support the clarification that NOP oversight extends to the activities of any person performing work on behalf of the certifying agent, such as a subcontractor or a specific office operating in specific countries.

- **OTA supports the new term and the definition of ‘certification office,’ with clarification around the use of a home office.** The new term and definition are essential to effective NOP oversight of certification activities that occur at all certification offices and locations. It is not clear, however, if the reference to “...any site...” would include a home office. OTA views a home office where an employee works to be a remote workstation rather than a certification office.
 - ➔ **Recommendation:** OTA recommends clarification on whether a home office should be considered a ‘certification office.’ This could be provided either through a revision to the proposed definition or through Guidance.
See OTA’s requested revision in Table 8
- **OTA supports the proposed requirement that NOP be notified of the opening of new certification offices. However, we do not support the proposed notification timeframe of 90 days after certification activities begin.** This amount of time is excessive and significant certification activity could occur during that amount of time.
 - ➔ **Recommendation:** OTA recommends that certifying agents notify NOP within 45 calendar days.
See OTA’s requested revision in Table 8
- **OTA does not support the revision to strike “accreditation” from the first part of § 205.640.** There is no explanation for the change, and it is not being framed as a technical correction. It is unclear what the intent of the change is, and if it will have a substantive impact. OTA does not support a revision to the regulation that does not come with an explanation.

Table 8: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity and utility of the Proposed Rule.
Add new term 205.2	Certification activity. Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.	OTA supports this new term and definition.
Add new term 205.2	Certification office. Any site or facility where certification activities are conducted, except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.	Revision or Guidance needed: OTA supports this new term and definition. However, either a revision to the regulation or guidance is needed to clarify whether a certification office would apply to a “home office.” OTA recommends that clarification be provided in Guidance. Alternatively, the rule could be revised as shown below.
OTA Requested Revision (if not clarified in Guidance): <i>Certification office.</i> Any site or facility where certification activities are conducted, except for home offices and certification activities that occur at certified operations or applicants for certification, such as inspections and sampling.		
Add 205.501(a) (22)	Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.	Revision needed: OTA does not support the proposed timeframe of 90 days after certification activities begin. This amount of time is excessive. Instead, we recommend 45 days.
OTA Requested Revision: Notify AMS not later than 90 45 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.		

<p>Revise introductory paragraph 205.640</p>	<p>Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be reviewed, assessed, and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:</p>	<p>Do NOT revise: OTA does not support the revision to strike “accreditation” from the first part of 205.640. There is no explanation for its change, and it is not being framed as a technical correction so it’s unclear if it will have a substantive impact. It appears to connect fees and other charges generally to “services,” rather than to specifically “accreditation services,” as is intended by the regulation and the National Organic Program.</p> <p>The language omitted in the second part of the provision appears to be duplicative. Again, however, the change is not explained therefore OTA does not support a revision.</p>
<p>OTA Requested Revision: DO NOT REVISE THE REGULATION - retain the regulatory text as is: Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed, and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:</p>		
<p>Revise 205.665(a)</p>	<p>Notification. <u>(1) A written notification of noncompliance shall will be sent to the certifying agent when:</u> An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; <u>or</u> <u>The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part;</u> <u>or</u> <u>The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part.</u> <u>Such notification must shall provide:</u> A description of each noncompliance;</p>	<p>No concerns.</p>

	<p>The facts upon which the notification of noncompliance is based; and The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.</p>	
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs



Johanna Mirinda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Accepting Foreign Conformity Assessment Systems

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #10: Accepting Foreign Conformity Assessment Systems.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports the use of equivalence determinations as a tool for facilitating international organic trade, and supports the proposed rule to codify AMS’s authorities and baseline procedures in the regulations.
- OTA supports the identification and elevation of the conformity assessment system as equally important as technical requirements in an equivalency determination.
- OTA supports the authority of AMS to describe scope of equivalence determination based on outcomes of AMS’s assessment of a foreign government’s organic program. OTA also recommends that data transparency and communication be addressed as part of AMS’s assessment of a foreign government’s organic program.
- OTA does not support inclusion of specific audit timeframes as written in the proposed rule. OTA recommends regulatory revisions that will allow AMS to negotiate the terms of audit timeframes based on the findings of AMS’s assessment.
- OTA recommends regulatory revisions that will allow AMS to negotiate termination procedures as part of the equivalency determination based on the findings of AMS’s assessment.
- OTA sees increased risks with recognition agreements compared to equivalency arrangements as currently implemented across a number of issues including data transparency, communication, and enforcement.
- OTA asks NOP to clarify whether recognition agreements are intended to be covered by the equivalency determination process described in the proposed rule, and explain what will happen to current recognition agreements as a result of this rulemaking action.

- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Background

The Organic Foods Production Act part 6505(b) states (emphasis added), “Imported agricultural products may be sold or labeled as organically produced if the Secretary determines that such products have been produced and handled under an organic certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of this chapter.” This provision allows agricultural products that are certified to another country’s equivalent organic certification program to be imported and represented as organic in the United States. These international partnerships have served as an effective tool for facilitating trade of organic products without requiring certified operations to have multiple organic certifications.

Currently USDA is engaged in several international trade arrangements that facilitate trade of organic products. Each arrangement has its own unique terms and scope. **Equivalency arrangements** have been established with Canada, European Union, Japan, South Korea, Switzerland, and Taiwan (UK is pending). Equivalency arrangements are partnerships in which the United States and another country determine that each other’s organic programs are equivalent so that organic products can be sold in either country with just one organic certification. **Recognition agreements** have been established with India, Israel and New Zealand. Recognition agreements are partnerships in which the United States authorizes another country’s government to accredit certifying agents in that country to certify organic operations in that country to the USDA organic standards, and those certified products can then be sold in the United States as organic.

NOP Questions

1. ***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?***

Yes. OTA sees increased risks with recognition agreements compared to equivalency arrangements across a number of issues including data transparency, communication, and enforcement. We also asks NOP to clarify what will happen to current recognition agreements as a result of this rulemaking action. Please see below for more information about OTA’s position on recognition agreements.

OTA's Positions and Recommendations

- **OTA supports the use of equivalence determinations as a tool for facilitating international organic trade, and supports the proposed rule to codify AMS's authorities and baseline procedures in the regulations.** There are currently multiple bilateral and unilateral organic equivalency arrangements in play between the U.S. and our larger trading partners. These equivalency arrangements are key factors in facilitating trade, yet they also strengthen government to government relationships. The provisions of the proposed rule are effective to provide more transparency in the procedures used by NOP to establish these partnerships. The current regulations do not contain specific procedures used by AMS to establish equivalency arrangements. Such procedures have historically been maintained in the NOP Program Handbook. Two documents have been archived¹ (NOP 2100 and NOP 2014) and one instruction² on Recognition Agreements is effective (NOP 2200). An Audit Report³ by the USDA Office of Inspector General in 2017 OIG Report identified two findings that are relevant to the topic of foreign conformity assessments (Finding #1 - Equivalency Determination Process Not Fully Transparent; Finding #4 - Onsite Audits Not Conducted Timely).
- **OTA supports the identification and elevation of the conformity assessment system as equally important as technical requirements in an equivalency determination.** Historically, the primary method of evaluating equivalency was through overcoming barriers to differences in practice standards and allowed or prohibited inputs. As there are several major agreements up for renewal or are being revised, there is now a larger consideration of oversight and integrity at the center of these discussions. It is critical that foreign governments have sufficient oversight, accreditation, compliance and enforcement control in place to ensure that their organic technical requirements are applied and enforced. All equivalency arrangements should be based on systems of comparable rigor and standards, and this follows for continuous compliance assessment. The integrity of the conformity assessment system is pivotal to ensuring the continued success of equivalency arrangements and recognition agreements.
- **OTA supports the authority of AMS to describe the scope of equivalence determinations based on outcomes of AMS's assessment of the foreign government's organic program.** The terms and scope of any equivalence determination should be customized to the unique characteristics of the foreign government's organic program conformity assessment system and technical requirements. The assessment process is a critical step in collecting information to determine the terms and scope of any potential future equivalence determination. To ensure clarity of the items that should be included in the AMS assessment, the regulations should include specific references to conformity

¹ <https://www.ams.usda.gov/sites/default/files/media/NOP-ArchivedDocs.pdf>

² <https://www.ams.usda.gov/sites/default/files/media/2200.pdf>

³ <https://www.usda.gov/sites/default/files/01601-0001-21.pdf>

assessment system and technical requirements. Additional key elements such as data transparency and communication should also be included. AMS should negotiate terms of the equivalence determination, such as audit time-frames and termination procedures, based on the findings of AMS's assessment of a foreign government's organic program. AMS also should have the authority to amend the scope and terms of an equivalence determination as needed based on the outcomes of its assessment and any subsequent audits.

→ **Recommendation:** Revise §205.511(b) to specifically identify items that should be included in AMS's assessment of the foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA recommends that data transparency be addressed as part of AMS's assessment of a foreign government's organic program.** From the trade side, there is increasing skepticism from the private sector that we are losing data transparency. Organic producers and handlers certified to an equivalent foreign country's systems do not currently provide the same level of data transparency as USDA-certified organic operations that are listed in the NOP Organic Integrity Database. Equivalence determinations should include an assessment of the foreign country's system of data collection and reporting and work towards greater transparency of data. Ideally, information on certified operations (certificates) and certifiers (accreditation documents) should be available, comparable to the NOP Organic Integrity Database. We support global use of the NOP Organic Integrity Database, but if not possible, we recommend investing in the development of some additional system that gives organic operations and certifying agents access to the same type of information about certified operations around the world operating under equivalency arrangements or recognition agreements and selling product into the United States. The system should include operations in equivalent countries eligible to export to the U.S. as organic and operations certified to the USDA regulations by a certifier operating under a recognition agreement.

→ **Recommendation:** Revise §205.511(b) to include data transparency as an element to be addressed by AMS in its assessment of a foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA recommends that communication be addressed as part of AMS's assessment of a foreign government's organic program.** Communication is a key element of a foreign country's conformity assessment system that must be evaluated during equivalence determinations. The extent to which parties are notified of adverse actions affecting the certification of an operation or accreditation of a certifying agency should be assessed. The capacity to transfer information among certifiers and between authorities to support investigations should be taken into consideration as part of the assessment. As described throughout the proposed rule, information sharing among certifiers is a critical part of oversight and enforcement capabilities. The same benefits extend to communications between the enforcement authorities

of trading partners, certification bodies in regions and countries covered by equivalency arrangements and recognition agreements, and other institutions that protect organic integrity. The capacity to provide clear, accurate, and timely communications will help achieve the broader goal of oversight and integrity.

→ **Recommendation:** Revise §205.511(b) to include communication as an element to be addressed by AMS in its assessment of a foreign government's organic program. *See OTA's requested revisions in Table 9 below.*

- **OTA does not support inclusion of specific audit timeframes as written in the proposed rule.** The regulations must avoid overly prescriptive review and reassessment schedules, and protect flexibility to accommodate unavoidable limitations of each country to participate in audits. Prescriptive timelines are ill-advised especially if they would implicate the other country to comply, as it may not be reasonable to expect other countries to comply with this prescriptive regulatory text.

Furthermore, the proposed rule text is unclear about the several aspects of the audits. The proposed rule refers to both a 2-year audit cycle and a 5-year audit cycle, but the purpose and scope of each of these types of audits are unclear. The proposed rule is unclear about whether these audits implicate the other country, or if either of the audits are required to be onsite. The proposed rule text is also unclear on the intent behind the proposed 2-year cycle. The preamble describes that the mid-term audit cycles are intended to mirror ISO standards, and are intended to provide flexibility in scheduling the mid-cycle reviews to accommodate unavoidable factors in both countries that can impact timing. However, the prescriptive 2-year time line is *not flexible* and would result in *two* mid-cycle reviews per 5-year reassessment cycle. It is also not clear whether the 2-year review is intended to be onsite and how the scope of the 2-yr review differs from the 5-year reassessment.

OTA recommends regulatory revisions that will allow AMS to negotiate the terms of audit timeframes based on the findings of AMS's assessment. The regulations should allow flexibility for AMS to negotiate the terms of the renewal timing, frequency, and procedures for reassessing the equivalency termination. AMS should negotiate these terms as part of the equivalence determination based on the findings of AMS's assessment of a foreign government's organic program. Certain countries' programs may warrant more frequent or less frequency re-reviews based on the unique characteristics of the program's conformity assessment systems. OTA recommends an audit timeframe that is agreed to by both parties during the equivalency determination process based on outcomes of AMS's assessment of the other country's systems. There should be two kinds of audits. The first type should be a mid-term audit that should only implicate NOP and not implicate the other country. The second type is a full reassessment of the arrangement that involves both countries' governments and should be conducted on a longer timeline than the mid-term audits. The audit timeframes must allow for flexibility to accommodate unavoidable limitations of each country to participate in audits.

- ➔ **Recommendation:** Revise §205.511(c) to allow flexibility for AMS to negotiate terms of renewal audit cycles as part the equivalence determination based on the findings of its assessment of the foreign government’s organic program, and revise §205.511(d) to remove prescriptive audit schedules. *OTA’s requested revisions in Table 9 below.*

If NOP does not accept OTA’s recommended revisions, we ask NOP to please provide an explanation of NOP’s intent behind the scope and timing of the proposed 2-year audit cycle to address our concerns described above.

- **OTA recommends regulatory revisions that will allow AMS to negotiate termination procedures as part of the equivalency determination based on the findings of AMS’s assessment.** Although the proposed rule identifies the conditions under which an equivalency determination may be terminated, it does not specify the procedures that should be followed by each party to carry out a termination. AMS should negotiate termination procedures as part of the equivalency determination so that termination of trade arrangements can be carried out in an orderly manner. For example, procedures should in place to provide an appropriate transition period to allow time for certifiers to get accredited under a new foreign government, and/or for certified operators to switch certifiers, and to give public notice to trade in advance of terminating an agreement.

- ➔ **Recommendation:** Revise §205.511(c) to allow flexibility for AMS to negotiate terms of termination procedures as part the equivalence determination based on the findings of its assessment of the foreign government’s organic program. *See OTA’s requested revisions in Table 9 below.*

- **OTA sees increased risks with recognition agreements compared to equivalency arrangements.** In the proposed rule, AMS asks for comments regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships: Specifically, compared with organic equivalence determinations, AMS asks if there are increased risks associated with recognition agreements where other countries’ governments oversee the implementation of NOP certification. As described above, recognition agreements are partnerships in which the U.S. authorizes another country’s government to accredit certifying agents in that country to certify operations within that country to the USDA organic standards. The U.S. has established recognition agreements with India, Israel and New Zealand.

OTA sees increased risks with recognition agreements compared to equivalency arrangements as currently implemented across a number of issues including data transparency, communication, and enforcement. The lack of data transparency is one of the top cited concerns with recognition agreements. While all other NOP-certified operations are listed in the NOP Organic Integrity Database, the operations certified

under recognition agreements are not included. Currently there is no transparency on the identities and certification status of certified operations, thus posing significant difficulties for trading partners to validate organic certificates. Also information on accreditation status and authorized scope of certification agencies is not available comparable to that available in the NOP Organic Integrity Database for USDA-accredited certification agencies. We also see concerns raised about the extent to which governmental authorities are implementing the NOP rule including associated guidance and policy. Lastly, we are concerned about the lack of alignment on decertification, revocation and reinstatement procedures of other countries operating under recognition agreements.

As currently implemented, recognition agreements are distinct from equivalency arrangements and would not appear to fit in to the equivalency determination process as described in the proposed rule. However, NOP does not explain whether recognition agreements are intended to be covered by this process of equivalence determination, and this needs clarification. Parts of the preamble in the proposed rule would suggest that recognition agreements *are covered* by this process of equivalence determination. For example, in the preamble AMS describes that the equivalence determination process has been used to establish trade arrangements for organic products with 10 other countries, 3 of which are recognition agreements. However other parts of the proposed rule would suggest that that recognition agreements *are not covered* by this rulemaking action. The text proposed in §205.511(a) in the proposed rule refers only to foreign product that is “certified under the USDA organic regulations by a USDA-accredited certifying agent” or “produced and handled under another country’s organic certification program.” It doesn’t seem that a recognition agreement would fall under either of these options because the product is not certified by a USDA-accredited certifying agent nor is certified by its own country’s equivalent organic program (recognition agreements use USDA’s organic programs, not its own). Also, the way that NOP phrases its request for comments asks about recognition agreements as “compared [to] organic equivalence determination,” implies that recognition agreements are not equivalence determinations. **OTA asks NOP to clarify whether recognition agreements are intended to be covered by the equivalency determination process described in the proposed rule, and explain what will happen to current recognition agreements as a result of this rulemaking action.**

- OTA supports the implementation of the proposals in this section (with OTA requested revisions) within one year after publication of the final rule.

Table 9: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.2 Add new term	<i>Conformity assessment system.</i> All activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product.	<p>Revision needed to clarify elements that should be included in the conformity assessment:</p> <ul style="list-style-type: none"> • Examples from preamble: accreditation and oversight of certifying agents, and compliance and enforcement activities <p>Revision needed to clarify what is meant by “product to product.”</p>
<p>OTA Requested Revision: <i>Conformity assessment system.</i> All <u>oversight, accreditation, compliance and enforcement</u> activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied <u>and enforced from product to product across all certified entities and products.</u></p>		
205.2 Add new term	<i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products.	<p>Revision needed to clarify elements included in the assessment of technical requirements:</p> <ul style="list-style-type: none"> • Add Examples from preamble: development of standards, policies and procedures • Add production practices and inputs
<p>OTA Requested Revision: <i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, <u>standards, policies,</u> and procedures <u>(and the development thereof)</u> that address the production, handling, and processing of organic agricultural products, <u>including but not limited to production practices, processing and handling practices, and allowed and prohibited inputs.</u></p>		
205.511(a) Add new section	Accepting foreign conformity assessment systems.	

<p>205.511(a) Add</p>	<p>Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country’s organic certification program may be sold, labeled, or represented as organically produced in the United States if AMS determines that such organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part (“equivalence determination”).</p>	<p>Revision needed to clarify what is an equivalency determination.</p> <ul style="list-style-type: none"> • Add definition to §205.2 using language from this section.
<p>OTA Requested Revision: Add to 205.2: <u>Equivalence determination. A determination by AMS that another county’s organic certification program provides technical requirements and a conformity assessment system governing the production and handling of products that are at least equivalent to the requirements of the Act and the regulations in this part.</u></p>		
<p>205.511(b) Add</p>	<p>Countries desiring to establish eligibility of product certified under that country’s organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will</p>	<p>Revision needed to implement OTA’s Positions described above regarding AMS’s assessment, data transparency and communication. The regulations should specifically identify items that should be included in AMS’s assessment of the foreign government’s organic program.</p> <ul style="list-style-type: none"> • Add conformity assessment system • Add technical requirements • Add data transparency • Add communication • Additional detail could be reserved for guidance as needed.

	conduct an assessment of the country's organic certification program to evaluate whether it is equivalent.	
<p>OTA Requested Revision: Countries desiring to establish eligibility of product certified under that country's organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will conduct an assessment of the country's organic certification program to evaluate whether it is equivalent. <u>AMS's assessment must include an evaluation of the country's conformity assessment system and technical requirements as defined in 205.2, as well as the country's systems for data transparency and communication.</u></p>		
205.511(c) Add	AMS will describe the scope of an equivalence determination.	<p>Revision needed to implement OTA's Positions described above regarding audit timeframes and termination procedures. The regulations should allow flexibility for AMS to negotiate terms of renewal audit cycles and termination procedures as part the equivalence determination based on the findings of its assessment of the foreign government's organic program.</p> <ul style="list-style-type: none"> • Add renewal audit timelines • Add termination procedures • Additional detail could be reserved for guidance as needed.
<p>OTA Requested Revision: AMS will describe the scope of an equivalence determination, <u>as well as terms and conditions regarding renewal audits and termination procedures of the equivalence determination, based on AMS's assessment of the foreign government's organic program as described in 205.511(b).</u></p>		
205.511(d) Add	AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government's organic certification program. AMS will reassess a country's	<p>Revision needed to implement OTA Position on audit timeframes. The regulations must avoid overly prescriptive review and reassessment schedules, and protect flexibility to accommodate unavoidable limitations of each country to participate in audits.</p>

	<p>organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government’s technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued.</p>	<ul style="list-style-type: none"> • Remove prescriptive timelines. • Add requirement to comply with renewal terms of the arrangement, which we recommend to be negotiated during the equivalency determination based on AMS’s assessment of the foreign government’s organic program (<i>see OTA Requested Revision at §205.511(c) above</i>) • Add allowance for AMS to amend scope of termination the equivalence determination based on the outcome of audits.
<p>OTA Requested Revision: AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government’s organic certification program. AMS will reassess a country’s organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government’s technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued. <u>AMS will comply with the renewal terms and conditions of the equivalence determination. Audit findings may cause AMS to amend the scope or terminate the equivalence determination.</u></p>		
<p>205.511(e) Add</p>	<p>AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country’s technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate to ensure that the country’s organic certification program is fully meeting the terms and conditions under the determination; or for other good cause.</p>	<p>Revision needed to implement OTA Position on <u>termination procedures</u>.</p> <ul style="list-style-type: none"> • Add requirement to comply with terminations terms of the arrangement, which we recommend to be negotiated during the equivalency determination based on AMS’s assessment of the foreign government’s organic program (<i>See OTA Requested Revision at §205.511(c) above</i>) <p>Revision needed clarify proposed rule text.</p> <ul style="list-style-type: none"> • Remove subjective wording (“good” is too subjective; AMS should be able to terminate for any cause)

OTA Requested Revision: AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country’s technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate to ensure that the country’s organic certification program is fully meeting the terms and conditions under the determination; or for other ~~good~~-cause. AMS will comply with the termination terms and conditions of the equivalence determination.

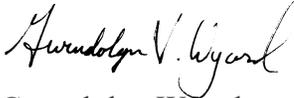
205.500(c) Remove	<p>(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:</p> <p>(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or</p> <p>(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.</p>
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Johanna Miranda
 Farm Policy Director



Gwendolyn Wyard
 Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
 Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Noncompliance, Mediation and Appeals

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Sections #11-15:

Section #11: Compliance—General

Section #12: Noncompliance Procedure for Certified Operations

Section #13: Mediation.

Section #14: Adverse Action Appeal Process—General

Section #15: Adverse Action Appeal Process—Appeals

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports the authority of NOP to investigate and enforce against violators of OFPA including uncertified operations.
- OTA supports consistent clarification that enforcement actions extend to all accountable parties per the existing definition of “responsibly connected.” OTA recommends guidance be developed to clarify procedures for certifier to report responsibly connected parties for operations that they certify, and for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1).
- OTA supports timely updates in the NOP Organic Integrity Database regarding the certification status of surrendered, suspended or revoked operations.
- OTA supports clear explanations of the mediation process and procedures as proposed in §205.663. OTA recommends guidance be developed to clarify the criteria that should be included in a certifier’s internal policies and procedures for acceptance or denial of mediation requests, and to clarify that a third-party mediator is not required per §205.663(c).

- OTA does not support the revision as proposed in §205.681 regarding administrative proceedings, and recommends revisions to clarify and maintain the appellant’s right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing.
- OTA supports the clarifications proposed for the general appeals section of the regulations at §205.680 and recommends that NOP staff itself appropriately so that it can respond to appeals in a timely manner.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Background

The Organic Foods Production Act (OFPA) part 6505(a)(1) states: (A) a person may sell or label an agricultural product as organically produced only if such product is produced and handled in accordance with this chapter; and (B) no person may affix a label to, or provide other market information concerning, an agricultural product if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with this chapter.

The NOP Regulation (§205.2) defines “Responsibly connected” as “Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.”

The NOP Handbook includes the guidance document¹ NOP 4001: AMS Office of the Administrator Adverse Action Appeal Process for the National Organic Program.

OTA’s Positions and Recommendations

- **OTA supports the authority of NOP to investigate and enforce against violators of OFPA including uncertified operations.**
- **OTA supports consistent clarification that enforcement actions extend to all accountable parties per the existing definition of “responsibly connected.”**

¹ <https://www.ams.usda.gov/sites/default/files/media/4011.pdf>

In order to ensure transparent and consistent implementation of enforcement across all responsibly connected persons to an operation, **we recommend that NOP provides guidance to certifiers on the procedures for reporting responsibly connected parties for operations that they certify.** Should responsibly connected persons be listed in the NOP Organic Integrity Database? Such information needs to be readily accessible so that certifiers can verify whether an applicant for certification is responsibly connected with an operation whose certification has been suspended.

→ **Recommendation:** Develop guidance to clarify the procedures for reporting and verifying responsibly connected parties.

Section 205.662(f)(1) includes a proposed revision that requires persons who are responsibly connected to an operation whose certification has been suspended to submit a request for eligibility to be certified. The procedures for such request are unclear. Should the person follow the same procedures as reinstatement? Such procedures should specify which entity should receive the request (NOP or the certifier), and if there are any special considerations that must be made for responsibly connected parties that are applying as a new operation. *See also OTA Comments on Certificates & Data Reporting.* **We recommend NOP that NOP provides guidance to clarify and explain the procedure for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1).**

→ **Recommendation:** Develop guidance to clarify and explain the procedure for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1).

- **OTA supports timely updates in the NOP Organic Integrity Database regarding the certification status of operations that have surrendered, suspended or revoked.** OTA supports the proposed rule that requires certifiers to update the NOP Organic Integrity Database within 3 business days when an operation surrenders its certification, or its certification is suspended or revoked. Timely communication regarding operations that have received such adverse actions is critical for effective enforcement and oversight activities by all parties. Timely updates to the NOP Organic Integrity Database are also critical for transparency about an operation's certification status. OTA's pre-rule comments² in 2018 supported this requirement (72 hours) and we maintain support for this provision.

² https://ota.com/sites/default/files/indexed_files/NOP_EnforcementRulemaking_Final.pdf

- **OTA supports clear explanation of the mediation process and procedures as proposed in §205.663.** We support the clarifications and reorganization proposed for this section of the regulations. We have no concerns with the new 30-day deadline identified in §205.663(b)(1).

We support the requirement for certifiers to have documented criteria for accepting or denying mediation. This will prevent certifiers from being able to deny mediation arbitrarily without giving a reason, and may even lead to broader use of mediation to settle enforcement cases. In order to ensure fair implementation of mediation criteria across certified operations, **we recommend that NOP provides guidance to certifiers that identifies critical aspects of mediation criteria that should be included in certifier’s internal policies and procedures.** Such guidance should reflect key excerpts from the preamble, such as not including any preconditions and explaining the types of noncompliances that can be resolved with mediation, e.g. when the corrective action(s) is clear and the noncompliance(s) is not recurrent; when the noncompliance(s) is correctable, and not willful or recurrent.

→ **Recommendation:** Develop guidance to clarify the criteria that should be included in a certifier’s internal policies and procedures for acceptance or denial of mediation requests.

We support the requirement for both parties to agree on the person conducting the mediation. The Preamble provides helpful information to explain that a third-party mediator isn’t required. In order to ensure fair implementation of mediation criteria across certified operations, **we recommend that NOP provides guidance to certifiers that clarifies the multiple types of “persons conducting the mediation.”** Such guidance should reflect key excerpts from the preamble, such as that a third-party mediator is not required and that mediation can be between only the two parties.

→ **Recommendation:** Develop guidance to clarify that a third-party mediator is not required per §205.663(c).

- **OTA supports the clarifications proposed for the general appeals section of the regulations at §205.680, and recommends that NOP staff itself appropriately so that NOP can respond to appeals in a timely manner.** OTA sees a need for the process to be expedited such that appeals are reviewed and responded to in a timelier manner. As currently administered, the appeals process takes too long. It can take up to a year for NOP to evaluate and respond to an appeal. When an appeal is denied and the appellant requests a hearing, it can take an additional year or more to reach a final outcome. This multi-year process is unacceptable, especially considering that the operator is still certified and able to sell products as organic throughout the entire appeals process. It is essential that NOP strike a balance between due process and efficiency to minimize the amount of time that operations are able to sell product as organic while under an adverse action. To do so, OTA recommends NOP to staff itself appropriately so that NOP can respond to appeals in a timely manner (ideally, within 6 months).

- **OTA does not support the revision as proposed in §205.681 regarding administrative proceedings.** The proposed change from “will” to “may” is implying that what should be a guaranteed right of the appellant is now at the discretion of AMS. We are concerned that the proposed text implies an erosion of due-process for certified operations. We recognize that it is likely not NOP’s intent to remove the right of the appellant, but rather to have the regulation acknowledge that the appellant may not need or want to exercise their right to an administrative hearing. As the NOP describes in the preamble, *“AMS proposes changing “will” to “may” to reflect actual practice and to recognize that AMS may pursue the resolution of appeals through expedited, alternative means, such as settlement agreements, before initiating a formal administrative proceeding. In current practice, an appellant whose appeal is denied by the Administrator has the option to request or waive a hearing. If the appellant does not request a hearing, AMS does not initiate a formal administrative proceeding and the Administrator’s appeal decision is final and takes effect. When an appellant requests a hearing, AMS and the appellant may enter into a settlement agreement prior to the hearing. This proposed revision provides flexibility to resolve appeals outside of the formal administrative process.”*

OTA recommends revisions to clarify and maintain the appellant’s right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing. The regulations must be revised to assure that the regulatory text aligns with NOP’s intent, and that the final rule language can be clearly understood. Although there are situations when an administrative proceeding may not be warranted, there are other situations when an administrative proceeding must occur to fulfill the appellant’s right to an administrative hearing. The regulation should maintain the appellant’s right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing. Furthermore, to maintain timely procedures, we also recommend that the regulations include a timeframe within which the appellant can request the hearing

➔ **Recommendation:** Revise §205.681(a)(2) and (b)(2) clarify and maintain the appellant’s right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing. *See OTA’s requested revisions in Table 10 below.*

- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Table 10: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text compared with Current Rule Text (strikethrough removed text; underlined new text)	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
205.660 (c)–(d) Redesignate	Redesignate paragraphs (c)–(d) as paragraphs (d)–(e)	
205.660(c) Add	<u>The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies, directly or indirectly, that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.</u>	Revision needed to clarify who is the Program Manager. The Program Manager is not defined in the USDA organic regulations or OFPA, and it is not a defined position at the NOP. <ul style="list-style-type: none"> • Add definition of Program Manager to §205.2.
OTA Requested Revision: Add to 205.2: <u>Program Manager. The representative to whom authority has been delegated to represent the National Organic Program.</u>		
205.661 Revise title	Investigation of certified operations.	

205.100(c)(1) Revise	<p>205.100 What has to be certified.</p> <p>(c) Any operation <u>person or responsibly connected person</u> that:</p> <p>(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1) of this title per violation.</p> <p>(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.</p>	<p>Revision needed in §205.100(c)(1) to align with the NOP's proposed edit in §205.662(g)(1).</p>
<p>OTA Requested Revision:</p> <p>(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1)(xxxvii) of this title per violation</p>		
205.662(e)(3) Add	<p><u>(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in INTEGRITY.</u></p>	
<p>OTA Requested Revision:</p> <p>(3) Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in INTEGRITY.</p>		

<p>205.662(f)(1) Revise</p>	<p>(1) A certified operation <u>or a person responsibly connected with an operation</u> whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, <u>or submit a request for eligibility to be certified</u>. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.</p> <p>(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, Except, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.</p>	<p>Guidance needed to clarify the procedures for reporting and verifying responsibly connected parties. See OTA’s Position on <u>responsibly connected</u>.</p> <p>Guidance needed to clarify and explain the procedure for responsibly connected persons to submit a request for eligibility to be certified per §205.662(f)(1). See OTA’s Position on <u>responsibly connected</u>.</p>
<p>205.662(g)(1) Revise</p>	<p>§205.662 Noncompliance procedure for certified operations.</p> <p>(g) Violations of Act. In addition to suspension or revocation, any certified operation that:</p> <p>(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1)(xxxvii) of this title per violation.</p> <p>(2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.</p>	

<p>205.663 Revise</p>	<p>§205.663 Mediation. (a) A certifying agent must submit with its administrative policies and procedures provided in §205.504(b): decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions.</p>	<p>Revision needed to clarify and consistently communicate accreditation requirements.</p> <ul style="list-style-type: none"> • Move the text at §205.663(a) to §205.504(b) so that it appears with accreditation requirements. <p>Revision needed to clarify what is Mediation.</p> <ul style="list-style-type: none"> • Add a new definition of Mediation to §205.2. <p>Guidance needed to clarify the criteria that should be included in a certifier’s internal policies and procedures for acceptance or denial of mediation requests. See OTA’s Position on <u>mediation</u>.</p>
<p>OTA Requested Revision: Add to §205.504(b): <u>Decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions</u> Add to §205.2: <u>Mediation. Mediation under the USDA organic regulations is an alternative dispute resolution mechanism, conducted between a certified operation or applicant for certification and a certifying agent or State organic program, that brings an operation into compliance with the USDA organic regulations.</u></p>		
<p>205.663 Revise</p>	<p>(b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program. (1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar</p>	<p>Guidance needed to clarify that a third-party mediator is not required per §205.663(c). See OTA’s Position on <u>mediation</u>.</p>

days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.

(2) A certifying agent or State organic program may accept or reject a request for mediation based on its own decision criteria.

(i) If a certifying agent rejects a mediation request, it must provide this rejection in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to §205.681, within 30 calendar days of the date of the written notification of rejection of the request for mediation.

(c) Both parties must agree on the person conducting the mediation.

(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.

(e) The parties to the mediation have a maximum of 30 calendar days to reach an agreement following a mediation session. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to §205.681.

(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Secretary may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any

	<p>agreement or provision not in conformance with the Act or the regulations in this part.</p> <p>(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice that it has issued.</p>	
<p>205.2 Add new term</p>	<p><u>Adverse action. A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty</u></p>	
<p>205.680 Revise</p>	<p>(a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision <u>an adverse action</u> of the National Organic Program's Program Manager may appeal such decision to the Administrator.</p> <p>(b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision <u>an adverse action</u> of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.</p> <p>(c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision <u>an adverse action</u> of a certifying agent may appeal such decision to the Administrator, Except, That, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.</p>	<p>Revision needed at §205.680(e), change “USDA organic regulations” to “regulations of this part” to be consistent with existing regulatory language.</p>

	<p>(d) Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in §205.663.</p> <p>(e) All appeals must comply with the procedural requirements in §205.681(c) and (d) of the USDA organic regulations.</p> <p>(f)(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.</p> <p>(g)(e) All appeals shall <u>must</u> be reviewed, heard, and decided by persons not involved with the decision <u>adverse action</u> being appealed.</p>	
<p>OTA Requested Revision: (e) All appeals must comply with the procedural requirements in §205.681(c) and (d) of the USDA organic regulations <u>of this part</u>.</p>		
<p>205.681(a) Revise</p>	<p>(a) Certification appeals <i>Adverse actions by certifying agents</i>. An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or <u>proposed</u> revocation of certification to the Administrator, Except, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.</p> <p>(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of</p>	<p>Revision needed to clarify and maintain the appellant's right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing. See OTA's Position on <u>administrative proceedings</u>.</p>

	<p>sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.</p> <p>(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will <u>may</u> be initiated to deny, suspend, or revoke the certification. Such proceeding shall <u>must</u> be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.</p>	
<p>OTA Requested Revision:</p> <p>(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding <u>will</u> be initiated to deny, suspend, or revoke the certification <u>if requested within 30 days of denial, unless prior to the initiation of such proceeding the Administrator and the appellant enter into a settlement agreement.</u> Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.</p>		
<p>205.681(b) Revise</p>	<p>(b) Accreditation appeals <u>Adverse actions by the NOP Program Manager.</u> An applicant for accreditation and an accredited certifying agent <u>A person affected by an adverse action, as defined by 205.2, issued by the NOP Program Manager may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.</u></p> <p>(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, <u>or an operation will continues its certification, a civil penalty will be waived and a cease-and-desist notice will be withdrawn, as applicable to the operation.</u></p> <p>(2) If the Administrator denies an appeal, a formal administrative proceeding will <u>may</u> be initiated to deny, suspend, or revoke the accreditation <u>or certification and/or levy civil penalties.</u> Such proceeding shall be conducted pursuant to</p>	<p>Revision needed to clarify and maintain the appellant's right to an administrative hearing when requested and/or when not settled through other means, and to include a timeframe within which the appellant can request the hearing. See OTA's Position on <u>administrative proceedings.</u></p>

	<p>the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H.</p>	
<p>OTA Requested Revision: If the Administrator or State organic program denies an appeal, a formal administrative proceeding <u>will</u> be initiated to deny, suspend or revoke the accreditation or certification and/or levy civil penalties <u>if requested within 30 days of denial, unless prior to the initiation of such proceeding the Administrator and the appellant enter into a settlement agreement.</u> Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H.</p>		
	<p>(c) Filing period. An appeal of a noncompliance decision must be filed <u>in writing</u> within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered “filed” on the date received by the Administrator or by the State organic program. <u>An adverse action decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless an appeal is timely filed the decision is appealed in a timely manner.</u></p>	
	<p>(d) Where and what to file. (1) Appeals to the Administrator <u>and Requests for Hearing</u> must be filed in writing and addressed to: Administrator, USDA, AMS, e/o NOP Appeals Team, 1400 Independence Avenue SW., Room 26422648-So., Stop 0268, Washington, DC 20250-0268 or <u>electronic transmission, NOPAppeals@ams.usda.gov.</u> (2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification. (3) All appeals must include a copy of the adverse decision <u>action</u> and a statement of the appellant's reasons for believing that the</p>	

	<p>decision <u>action</u> was not proper or made in accordance with applicable program regulations, policies, or procedures.</p>	

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Johanna Miranda

Johanna Miranda
Farm Policy Director

Gwendolyn V. Wyard

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Grower Group Operations

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #16: Grower Group Operations.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendation

- OTA supports certification of group operations and recommends revisions to the new terms and definitions to clarify that the grower group operation is the legal entity that is tied to the legal definition of “person” in §205.2.
- OTA recommends that group operations are identified as such in the NOP Organic Integrity Database.
- OTA recommends that grower group certification become a separate accreditation scope that certifiers must have in order to certify grower group operations.
- OTA does not support limiting group certification only to producers of crop and wild crop products. OTA recommends scope-neutrality regarding the type of products that can be produced and certified under group certification, and recommends that scope limitations are removed from the rule.
- OTA supports scale-neutrality regarding the size of groups and group members that can be certified under group certification. OTA does not support imposing limits on gross sales or field sizes of individual grower group members, nor limiting the maximum number of members allowed in a grower group operation or in a grower group production unit.
- OTA supports geographic proximity of members, and sees no need for more specific limits to further define geographic proximity.
- OTA supports the allowance for members to also have separate individual certification outside of the group should they want to sell organic products outside of the group if they are certified for such products.
- OTA does not support the current proposal that requires certifiers to inspect high-risk members based on the internal control system’s own risk criteria. OTA recommends that certifiers conduct an independent external risk assessment separate from (and in addition to) the internal

risk assessment conducted by the internal control system. OTA also recommends that NOP develop guidance to support certifiers in reaching a common understanding of the criteria that should be used to identify high risk group members and to assess risks of groups as a whole.

- OTA supports many of the specific regulatory requirements for the Internal Control System (ICS), and recommends several critical revisions to the proposed rule that will enhance and clarify the ICS's responsibilities for establishing and maintaining strong oversight and enforcement capabilities.
- OTA recommends regulatory clarifications and guidance to ensure sufficient qualifications of ICS personnel.
- OTA recommends regulatory clarifications to ensure that recordkeeping by the ICS is sufficient to demonstrate compliance.
- OTA recommends regulatory clarifications to elevate and enhance ICS requirements for member training to ensure that all group members understand and can comply with the organic regulations.
- OTA recommends regulatory clarifications and guidance to ensure internal inspections conducted by the ICS are robust, clearly understood, and consistently implemented.
- OTA recommends the development of guidance that clarifies the scenarios that would qualify as a conflict of interest in an ICS.
- OTA supports the sampling method for external inspections that requires the certifier to inspect 1.4 times the square root ($1.4\sqrt{}$) of members. We also recommend that NOP explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the $1.4\sqrt{}$ method. We also recommend that NOP provide guidance to certifiers that will help ensure that each production unit is well represented in the overall sample of external inspections.
- OTA recommends a modified requirement for external witness audits that requires the certifier to evaluate *at least 25%* of internal auditors to ensure a representative sample of ICS inspectors are evaluated.
- OTA recommends the development of guidance for certifier's external oversight and enforcement of group operations in a manner that focuses on the assessment of the internal control system.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Background

Grower groups are operations composed of multiple production sites each managed by individual farmer members who collectively market product through a single certified entity. Instead of each member having its own independent certification, the group as a whole is certified based on the group having a strong centralized internal control system that assures compliance of all members through internal inspections and sanctions. The certifier assesses compliance of the internal control system and directly inspects a sample of individual members.

According to a report¹ by the Research Institute of Organic Agriculture (FiBL), there are approximately 5,900 group operations worldwide, including 2.6 million farmers across 58 countries. Group operations are responsible for producing valuable products such as coffee and cocoa. Groups also commonly produce sugar, cotton, tropical fruits, tropical nuts, honey and other specialty crops. The number of members per group varies widely, the average size depending on the geographic region where the group is operating and the type of product produced by the operation. For example, in Latin America, the group sizes are relatively small (typically between 80-250 members; many very small groups with less than 50 members; none over 1,000 members) but individual member's landholdings are relatively large (2.5-4 hectares or greater). In contrast, group operations in Africa are very large (typically between 300-10,000 members; many very large groups over 10,000 members; largest documented group is 80,000 members) but the landholdings for each individual member are very small (< 1 hectare). Groups are also common in India and other parts of Asia.

Grower groups have been and continue to be certified organic under NOP regulations. The definition of "person" in the Organic Foods Production Act includes "groups of individuals" and cooperatives. Therefore, groups that are organized under the legal definition of "person" may apply for certification as a single legal entity. NOP-accredited certifier oversight has been guided by two recommendations from the National Organic Standards Board that were formalized by NOP in 2011 through a policy memo² currently maintained in the NOP Handbook.

Simultaneously to NOP formalizing regulatory standards for grower groups, the European Union (EU) is also embarking on formalizing group certification standards for operations certified under the EU organic program. It is common for a groups to hold dual certifications under both EU and NOP, so this is an important opportunity for NOP standards to develop in harmonization with the EU and avoid unnecessary variances that could disrupt the millions of growers worldwide that participate in group certification.

¹ <https://orgprints.org/35159/>

² <https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>

NOP Questions

1. ***Should there be limits on gross sales or field sizes of individual grower group members?***

No. Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. OTA recommends scale-neutrality in terms of eligibility for group certification, and that any concerns about larger sizes of group members or groups can and should be addressed through risk-assessment. Please see OTA's Positions and Recommendations below for more information about our position on group size limits.

2. ***Should there be a limit on the maximum number of members allowed in a grower group operation or in a grower group production unit?***

No. Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. OTA recommends scale-neutrality in terms of eligibility for group certification, and that any concerns about larger sizes of group members or groups can and should be addressed through risk-assessment. Please see OTA's Positions and Recommendations below for more information about our position on group size limits.

3. ***Should there be a limit to the geographical distribution of members?***

No. The regulations should allow for groups to define geographic proximity based on the unique context and the geographic conditions of the region within which the group is operating. Please see OTA's Positions and Recommendations below for more information about our position on geographic distribution.

OTA's Positions and Recommendations

- **OTA supports certification of group operations.** NOP's regulatory definition of "person" provides a pathway for groups of individuals to be certified as a single legal entity. Groups legally organized as a "person" can accommodate common structures of group operations worldwide, including farmer-led groups and processor/trader-affiliated groups.
- **OTA recommends revisions to the new terms and definitions to clarify that the grower group operation is the legal entity that is tied to the legal definition of "person" in §205.2.** The eligibility requirements in the proposed rule are sufficient to require that groups are legally organized as a person. However, the terms and definitions in §205.2 would benefit from increased clarity to ensure consistent implementation. For instance, the proposed rule uses the term "person" in the definition of group *member* but not in the definition of group *operation*. This could result in confusion about which entity is tied to the legal definition of person in §205.2. "Person" is legal justification for certifying the

group operation, not individual members of a group. Furthermore, we recommend that the new terms and definitions proposed for §205.2 be improved by avoiding use of the term “single” in reference to a producer or product. “Single” would be more appropriate to describe the legal entity, or the Organic System Plan, or the certificate. Referring to “single producers” could create confusion and misrepresentation, so we recommend its removal.

- ➔ **Recommendation:** Revise the terms and definitions in §205.2 to accurately and clearly define relationships between group/member, make better use of existing term “person,” and to improve clarity and consistency. *See OTA’s requested revisions in Table 11 below.*
- **OTA recommends that grower group operations be identified as such in the NOP Organic Integrity Database.** Currently, the status of an operation as being a grower group is not visible in the Organic Integrity Database, so it is not possible to determine if an operation is a grower group or how many grower groups are certified to the NOP organic standards. This is an important point of data transparency. Ideally, the Organic Integrity Database should identify if an operation is certified as a group operation and identify how many members are in the group. The total certified acreage of the group should already be captured in requirements for operations to report certified acreage to the Administrator, because group operations would need to report data just as any other certified operation. *See also OTA’s Comments on Organic Certificates & Data Reporting.*
 - **OTA recommends that grower group certification become a separate accreditation scope that certifiers must have in order to certify grower group operations.** The ability for groups to be certified under NOP regulations while maintaining organic integrity and assuring organic compliance is dependent on the group having a strong internal control system and the certifier having a strong understanding and ability to assess compliance of group operations. The assessment and verification process for a group operation’s internal control system is significantly different from that of an individual operation. Certifiers need specific skills and training to effectively provide certification services to group operations, which requires unique additional elements of conformity assessment and auditing management systems. It is critical that certification agencies are qualified in this regard, and that NOP oversight ensure continued qualifications through accreditation audits. There doesn’t appear to be anything in OFPA that would preclude this from becoming a new accreditation scope for certifiers.
- ➔ **Recommendation:** Develop a new accreditation scope for group certification and implement a requirement that certifiers must be accredited under the new scope in order to provide certification services for group operations. *See OTA’s requested revisions in Table 11 below.*

- **OTA does not support limiting group certification only to producers of crop and wild crop products. OTA recommends scope-neutrality regarding the type of products that can be produced and certified under group certification, and recommends that scope limitations are removed from the rule.** All producers, including livestock producers, should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. The regulations should fairly and consistently apply group certification procedures across all scopes of production, just like procedures for individual certification which can be for any scope provided that the practice standards and other requirements are met. Scope-neutrality will align with the forthcoming EU organic regulations that will allow group certification for group of producers of crops, livestock, apiculture, algae, and aquaculture.

The group certification model should not discriminate against or penalize producers of livestock and livestock products. Prohibiting livestock would also exclude honey producers because apiculture is certified under the livestock scope. OTA is not able to justify (and NOP has not articulated in the preamble) a case as to why livestock should be excluded from group certification. Livestock operations do not embody an inherent incompatibility or inability to comply with organic regulations. **Concerns about increased risk of livestock operations can and should be addressed through risk-assessment.** Scope-neutrality of the regulations does not preclude certifiers from using scope as a risk factor and imposing stronger controls on high-risk groups.

→ **Recommendation:** Revise proposed rule to remove limitations to crop and wild crops and ensure fair and consistent applicability of the regulations. All producers should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. *See OTA's requested revisions in Table 11 below.*

Furthermore, the proposed terms defined and other parts of the proposed rule need better consistency in their references to production and/or handling. Both production and handling are activities that may be performed within a group or by a group member. There are several instances where production and handling are not consistently referenced, and this needs to be clarified.

→ **Recommendation:** Revise proposed rule to ensure consistent references to production and handling activities. *See OTA's requested revisions in Table 11 below.*

- **OTA supports scale-neutrality regarding the size of groups and group members that can be certified under group certification. OTA does not support imposing limits on gross sales or field sizes of individual grower group members, nor limiting the maximum number of members allowed in a grower group operation or in a grower group production unit.** Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. The regulations should fairly and consistently apply group certification procedures across all sizes and scales of production, just like procedures for individual certification which can be applied to any size or scale provided that the practice standards and other requirements are met. No other part of the regulations disqualify operations from organic certification based only on gross sales or field size or number of production sites.

Setting limits on size or scale may not necessarily lead to reduced risk or better fraud prevention. These variables in and of themselves are not an indicator of inherent incompatibility or inability to comply with organic regulations; smaller size or scale does not automatically mean less risk. **Concerns about larger sizes of group members or groups can and should be addressed through risk-assessment.** Scale-neutrality of the regulations does not preclude certifiers from using size as a risk factor and imposing stronger controls on high-risk groups. Furthermore, it would be very difficult to determine a non-arbitrary limit on size or scale that would work for a variety of production systems and geographic regions worldwide, without creating unintended negative consequence. The Indian National Programme for Organic Production (NPOP) is the only organic certification scheme that currently enforces a maximum limit (500 member per group) and appears to have resulted in data transparency challenges and no substantive evidence of strengthened organic integrity. According to the FiBL Report, these size limits have made systems less accountable and less transparent rather than improve quality. A large group that functionally operates a single group operation is split ‘on paper’ into multiple smaller groups to comply with NPOP’s size limit, but there not any change in actual practices (members in all groups are still marketing through the same centralizes system), there is less transparency in how the smaller groups are connected to each other, and it inflates the data on how many groups are operating under the scheme.

- **OTA supports geographic proximity of members and sees no need for more specific or prescriptive limits to further define geographic proximity.** The proposed rule already requires group members to be in geographical proximity, and requires the internal control system to describe its criteria for defining geographic proximity. The regulations should allow for groups to define geographic proximity based on the unique context and the geographic conditions of the region within which the group is operating.

It would be very difficult to determine a non-arbitrary limit on geographic proximity that would work for a variety of production systems and geographic regions worldwide. Setting limits on geographic proximity may not necessarily lead to reduced risk or better fraud prevention. Distance among members is not itself an indicator of inherent incompatibility or inability to comply with organic regulations; short distance

does not automatically mean less risk. **Concerns about geographic proximity of group members or groups can and should be addressed through risk-assessment.** The regulations do not preclude certifiers from using geographic proximity as a risk factor and imposing stronger controls on high-risk groups.

OTA recommends that NOP develop guidance to support certifiers in reaching a common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity. The guidance could incorporate examples from the 2008 NOSB Recommendation that defines geographic proximity as having access to the same collection or post-harvest handling facility, and/or common soils, water source, slope, topography or other physical features.

➔ **Recommendation:** Develop guidance that supports common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity.

- **OTA supports the allowance for members to also have separate individual certification outside of the group should they want to sell organic products outside of the group if they are certified for such products.** Group members are rightly prohibited from using the group's certification to individually market their own product as organic outside of the group. Group certification applies to the group operation as a single legal entity and must not be used to represent individual members. However, individual members likely produce many more types of products than are sold through the grower group. Therefore, we agree with the proposed rule that allows group members to seek separate additional individual certification should they want to sell organic products outside of the group if they are certified for such products. Since group operations often only market one type of product from its members, the option of additional individual certification would let individual members sell their other products, such as organic rotational crops, which might not be included in the group certification. It would also allow individuals to sell excess/bumper crops that might be over the group's quota for individual members. The FiBL Report cites many benefits of allowing members to have additional individual certification, such as supporting crop diversity and rotations, and supporting socioeconomic development of members.

We recognize that members that participate both in a group and also have separate individual certification may present an elevated risk. Such members would have dual certification for the same area of production and perhaps also the same type of product. We also recognize that a dual certified group member would also have more direct oversight than a typical group member because it will receive direct certification oversight and inspections from its certifier. **Increased risks that are associated with a farm being both a group member and individually certified can and should be addressed through risk assessments.** Strong systems of recordkeeping and management are essential in these operations to ensure that organic products are properly accounted for under each certification. If the member seeks individual certification

from a certificate agency other than the one certifying the group, the certification agencies should have strong communication and cooperation to ensure risks are managed appropriately.

- **OTA does not support the current proposal that requires certifiers to inspect high-risk members based on the internal control system's own risk criteria. OTA recommends that certifiers conduct an independent external risk assessment separate from (and in addition to) the internal risk assessment conducted by the internal control system.** ICS's should have their own system for describing its criteria for identifying high-risk members and managing those risks as appropriate. When it is time for the certifier to conduct its external inspections of the ICS and a sample of members, the certifier should conduct an independent risk assessment based on its own criteria for identifying high risk group members. Certifiers should not be required to use the group's risk assessment criteria, as is currently required in the proposed rule. Certifiers should continue to inspect all members that are considered high-risk according to the certifier's own risk assessment criteria. The preamble already includes a list of criteria that certifiers should consider when determining which grower group members to assess, which clearly shows that the regulations are intended to have the certifier conduct their own risk assessment based on their own criteria.

➔ **Recommendation:** Revise §205.201(c)(4) to add a requirement that the ICS have a procedure for assessing and managing risks appropriately. Revise §205.403(a)(2)(iii) to remove the reference to §205.201(c)(4), clarify that the risk assessment is conducted by the certifier, and require the certifier to have documented criteria for identifying high risk group members. *See OTA's requested revisions in Table 11 below.*

OTA recommends that NOP develop guidance to support certifiers in reaching a common understanding of the criteria that should be used to identify high risk group members and to assess risks of groups as a whole. The guidance should capture the list of risk factors identified in the preamble for individual members, such as having split or parallel production, noncompliance history, geographic proximity to other members, and whether the member also has additional individual certification. Risk assessments for group operations should also address concerns about increased risk of livestock operations, larger sizes of group members or groups, and larger geographic distribution of members. The certifier's risk assessment should also be harmonized as appropriate with other provisions for risk-assessment as proposed in the Strengthening Organic Enforcement Proposed Rule (See Section #18: Supply Chain Traceability & Fraud Prevention) that would require certifiers to have criteria to identify high-risk operations and products.

➔ **Recommendation:** Develop guidance to support common understanding and consistent implementation on the risk criteria that certifiers should use to determine which high-risk group members must be inspected.

- **OTA supports many of the specific regulatory requirements for an Internal Control System (ICS) and recommends several critical revisions to the proposed rule that will enhance and clarify the ICS's responsibilities for establishing and maintaining strong oversight and enforcement capabilities.** We also encourage NOP to develop guidance for group operation and their internal control systems to support clear understanding and consistent implementation of the new regulatory requirements. Several of the responsibilities and requirements of an Internal Control System will require enhanced explanation and examples to support a clear understanding of the regulatory text and to prepare organic operations to readily implement and comply with the regulations. OTA has identified several issues throughout this comment where regulatory revisions and additional guidance are needed to enhance and clarify the ICS's responsibility to ensure clear understanding and consistent implementation of the new regulatory requirements.

For starters, the proposed definition of Internal Control System in §205.2 should be expanded to encompass all critical elements and responsibilities of a strong well-functioning internal control system. The 2008 NOSB Recommendation included specific references to personnel, procedures, practice standards, recordkeeping, and audit trail requirements. Additionally, the proposed list of eligibility requirements in §205.400(g) is missing a basic requirement to have an Internal Control System. The ICS is which is the most fundamental eligibility requirement for groups and needs to be directly referenced.

→ **Recommendation:** Revise §205.2 to expand the definition of internal control system to encompass critical elements, and also add a reference in §205.400(g) to explicitly require group to have an ICS in order to be eligible for group certification. *See OTA's requested revisions in Table 11 below.*

- **OTA recommends regulatory clarifications and guidance to ensure sufficient qualifications of ICS personnel.** The proposed regulations require the ICS to describe the roles and responsibilities of all personnel, but are lacking an explicit requirement for such personnel to be sufficiently qualified to perform such roles and responsibilities. OTA recommends that the ICS must have a written description of the minimum qualifications of each role within the ICS. Furthermore, the ICS must ensure that it maintains a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities.

→ **Recommendation:** Revise §205.201(c)(1) to require the ICS to describe qualifications for all roles and to require that the ICS has a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities. *See OTA's requested revisions in Table 11 below.*

OTA also recommends that NOP establish guidance that will ensure a common understanding of qualifications that are expected of ICS personnel. ICS personnel are different from a certifier's review or inspector staff. Rather, the ICS is equivalent to an internal Quality Assurance department at an individually certified operation. Extending the same qualification and training requirements of certification agent personnel to the personnel of a certified operation is not appropriate. ICS personnel must be allowed to have qualifications that are adapted to the needs and availability of training within the unique context within which the group is operating. The guidance can capture the suggested qualifications and training requirements for ICS personal as written in the 2008 NOSB Recommendation. (*See also OTA position below on conflict of interest.*)

→ **Recommendation:** Provide guidance to ensure a common understanding of qualifications that are expected of ICS personnel.

- **OTA recommends regulatory clarifications to ensure that recordkeeping by the ICS is sufficient to demonstrate compliance.** Records are essential for documenting and maintaining a well-functioning internal control system and demonstrating compliance to auditors. The proposed rule is lacking an explicit requirement for the ICS to describe the records that it maintains to demonstrate compliance of the group and all group members. OTA recommends that, at minimum, the regulations specifically require the ICS to maintain the following records:
 - List of each group members, locations, products, acreage
 - Formal agreement between each group member and group's legal entity that commits the group member to complying with the internal control system's policies, the organic system plan, and the USDA organic regulations.
 - Copies of internal inspection reports
 - Copies of internal sanctions and corrections

→ **Recommendation:** Revise §205.201(c)(1) to include the specific recordkeeping requirements needed to demonstrate compliance of the group and all group members. *See OTA's requested revisions in Table 11 below.*

- **OTA recommends regulatory clarifications to elevate and enhance ICS requirements for member training to ensure that all group members understand and can comply with the organic regulations.** It is critical that individual members receive education, training, and technical assistance about how to implement and comply with the internal control system’s policies, the organic system plan, and the USDA organic regulations. The FiBL Report emphasizes that training and regular contact with farmer members are among the most if not *the most* important element of successful assurance of group compliance. The ICS should be providing information and training to all members, at least annually, to maintain their understanding, interest and commitment to compliant organic production practices.
 - ➔ **Recommendation:** Revise §205.201(c) to include a new provision that requires the ICS to describe procedures for providing training, education, and technical assistance to grower group members to ensure understanding of and compliance with ICS, OSP, and Organic Regulations. **See OTA’s requested revisions in Table 11 below.**
- **OTA recommends regulatory clarifications and guidance to ensure internal inspections conducted by the ICS are robust, clearly understood, and consistently implemented.** It is crucial that group members are present onsite during their internal inspection so that the ICS personnel can interact with and ask questions of the member to ensure a full understanding of the activities on that member’s production site. Additionally, the ICS procedures should include a description of the procedures for accepting new members and must ensure that an onsite inspection is completed by the ICS prior to accepting the new member into the group. There should also be attention paid to consistency in terminology used throughout the grower group regulations. The terms “surveillance” or “internal inspection” or some combination are used. The regulations must ensure a clear distinction between the internal inspections conducted by the ICS and the *external* inspections conducted by the certification agency.
 - ➔ **Recommendation:** Revise §205.201(c) and §205.400(g) to include provisions needed to ensure that internal inspections are robust, clearly understood, and consistently implemented. **See OTA’s requested revisions in Table 11 below.**

OTA also recommends that NOP establish guidance that will ensure a common understanding of key elements that are expected to be addressed during an ICS internal inspection of group members. Such guidance should include best practices such as ensuring that inspections are conducted at appropriate times of the year so that active production can be observed.

- ➔ **Recommendation:** Provide guidance to ensure a common understanding of internal inspection requirements expected of ICS inspectors.

- **OTA recommends the development of guidance that clarifies the scenarios that would qualify as a conflict of interest in an ICS.** The proposed rule at §205.201(c)(8) requires the ICS to protect against potential conflicts of interest. NOP must clarify what does and does not constitute a conflict of interest for ICS personnel. Guidance should take in to account the fact that ICS personnel are equivalent to internal staff at an individually certified operation that may give education and training to other colleagues, (*see OTA position above on ICS personnel qualifications*), so extending the same conflict of interested policies used by certifiers to individual operations is not appropriate.

OTA recommend that the guidance must protect the ability of ICS personnel to provide education, training, and technical assistance to members. If an internal inspector gives technical support and guidance about organic compliance to their members during an inspection, this should not be classified as a conflict of interest. As described above (*see OTA's position above on member training*), training and regular contact with farmer members are among the most if not *the most* important element of successful assurance of group compliance. NOP should clarify these points through guidance and ensure that group members are not deprived of ICS's technical support, information, education, and training.

→ **Recommendation:** Provide guidance to ensure a common understanding of scenarios that would qualify as a conflict of interest within an internal control system.

- **OTA recommends a modified requirement for external witness audits that requires the certifier to evaluate at least 25% of internal auditors to ensure a representative sample of ICS inspectors are evaluated.** It is important that multiple ICS inspectors are witnessed to ensure representative review of the ICS inspector activity and competency. To ensure that an appropriate sample of internal inspectors receive witness audits from the certifier, the regulations should specific a minimum number of percent of auditors that must be witnessed.

→ **Recommendation:** Revise §205.403(a)(2)(ii) to add a minimum requirement for 25% of internal auditors that must be witnessed. *See OTA's requested revisions in Table 11 below.*

- **OTA supports the sampling method for external inspections that requires the certifier to inspect 1.4 times the square root ($1.4\sqrt{}$) of the total number of grower group members.** We also recommend that NOP explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the $1.4\sqrt{}$ method. In other words, the certifier would inspect $1.4\sqrt{}$ or 2%, whichever is higher. We understand that 2% is a minimum sample size that is being considered by international group certification schemes, so it is used here as an example. Establishing a minimum percentage to kick-in once the sample exceeds $1.4\sqrt{}$ will ensure that as group size increases, the sample for external inspections increases at a rate that is more appropriate for larger size groups. The minimum percentage may also disincentivize groups from becoming very large because of the greater number of external inspections that would be required. Without the minimum percentage, very large groups may not receive a sufficient number of external inspections to properly assess compliance. (See Figure 1 below, and note that the $1.4\sqrt{}$ method increases very little, never above 400, even though the total group size is increasing by tens of thousands.) The $1.4\sqrt{}$ methodology is still important for sampling groups on the smaller size (See Figure 2 below, and note that the $1.4\sqrt{}$ results in larger sample sizes for groups under 5,000 members, approximately. Especially for very small groups, $1.4\sqrt{}$ methodology results in a larger and more appropriate sample size compared to the 2% methodology.)

→ **Recommendation:** NOP should further explore whether to establish a minimum percentage of members to be used in combination with the $1.4\sqrt{}$ method in determining the minimum sample size (e.g., $1.4\sqrt{}$ or 2%, whichever is higher).

The proposed rule currently requires certifiers to individually inspect each handling facility and at least one grower group member in each grower group production unit. As written, this does not guarantee that the total inspected members will be representative of the group across its production units. OTA initially considered whether the sampling methodology should be applied *to each production unit* to ensure representative sampling in each production unit. However we no longer see that as a viable solution, because it puts too much reliance on how the group defines its own production units and may create an incentive for groups to manipulate the number of production units to mathematically influence the number of inspections. Furthermore, if the $1.4\sqrt{}$ methodology were used for production units, it may result in *too many* inspections overall, since the square root would be taken of a smaller number (each production unit) rather than a larger number (whole group). Instead, we recommend that NOP provide guidance to certifiers that will help ensure that each production unit is well represented in the overall sample of external inspections.

→ **Recommendation:** Develop guidance regarding the procedures that certifiers can use to ensure that each production unit is well represented in the overall sample of external inspections.

Figure 1: Comparison of sample methodologies

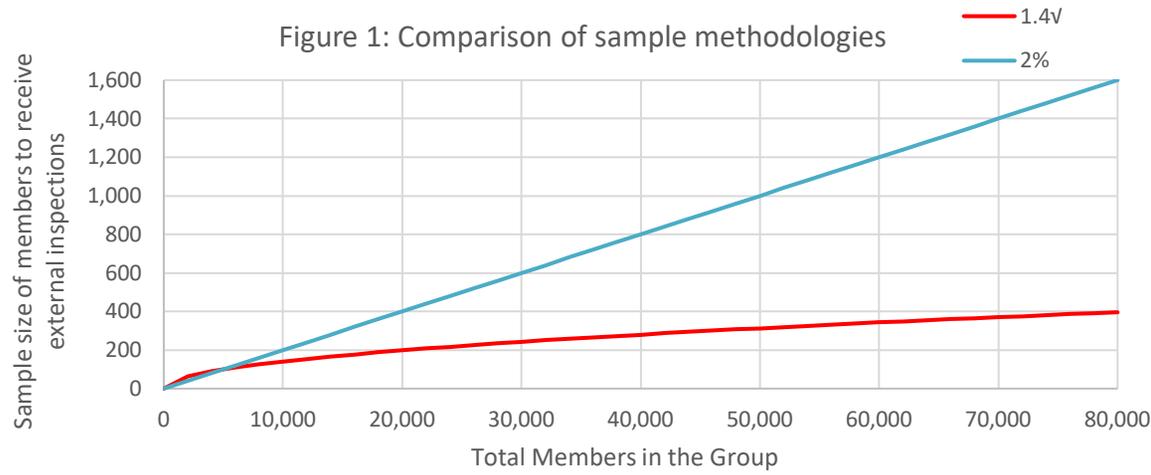
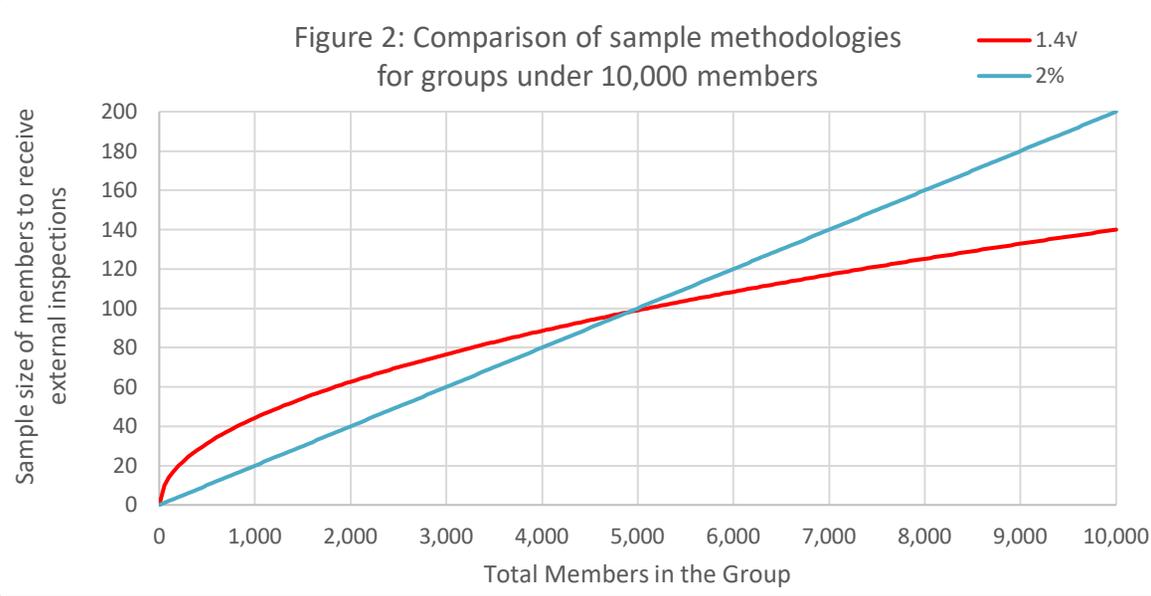


Figure 2: Comparison of sample methodologies for groups under 10,000 members



Total Members	1.4V Sample	2% Sample
50	10	1
100	14	2
500	31	10
1,000	44	20
2,000	63	40
3,000	77	60
4,000	89	80
5,000	99	100
6,000	108	120
7,000	117	140
8,000	125	160
9,000	133	180
10,000	140	200
15,000	171	300
20,000	198	400
25,000	221	500
30,000	242	600
40,000	280	800
50,000	313	1,000
60,000	343	1,200
70,000	370	1,400
80,000	396	1,600

- **OTA recommends the development of guidance for certifier’s external oversight and enforcement of group operations in a manner that focuses on the assessment of the internal control system.** Certifiers need guidance on the procedures to be used when assessing compliance of a group and issuing noncompliance or other adverse actions to a group operation. Groups require a very different approach to compliance assessments compared to individual operations. For example, if the ICS is properly issuing sanctions to members, then there is not a need for a certifier to issue an adverse action. The certifier should be issuing adverse actions to the group if the ICS is failing to assure compliance. Certifiers need guidance to ensure a common understanding of the situations that would indicate a failure of the ICS. Certifiers need guidance to evaluate when internal sanctions issued by an ICS should be elevated to a noncompliance or adverse action issued by the certifier. The increased responsibility and unique assessment skills are the very reason underlying OTA’s recommendation to establish group certification as a separate accreditation scope for certifiers (*see above for OTA’s position on accreditation scope*).

Group operations also need to have guidance to understand the expectations for when the ICS must notify the certifier of internal sanctions or noncompliant activities. For example, the ICS may issue internal sanctions and maintain documentation of subsequent corrections to have available for the certifier’s external inspection to demonstrate that the ICS is functioning properly. However, there may be circumstances when the ICS must notify the certifier immediately and not wait until their next inspection. These scenarios may include: when a group member is removed from the group, or when a member applies a prohibited substance.

➔ **Recommendation:** Provide guidance to ensure a common understanding of a certifier’s responsibilities for external oversight and enforcement of group operations in a manner that focuses on the assessment of internal control system.

We also recommend that NOP further explore whether a new subsection is needed at §205.662 (Noncompliance procedure for certified operations) to address noncompliance procedures for group operations. This new subsection could compliment the new subsection for inspections of group operations that has already been proposed for addition to §205.403(a) (On-Site inspections).

- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

Table 11: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
<p>205.2 Add new terms</p>	<p><i>Grower group operation.</i> A single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation.</p> <p><i>Grower group member.</i> A person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation.</p> <p><i>Grower group production unit.</i> A defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops.</p> <p><i>Internal control system.</i> An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer.</p>	<p>Revisions needed in the terms and definitions in §205.2 to accurately and clearly define relationships between group/member, make better use of existing term “person,” and to improve clarity and consistency. See OTA’s Position on <u>legal entity</u>.</p> <ul style="list-style-type: none"> • Remove “person” from the definition of group member and add it to the definition of group operation. The group operation is the entity that is tied to the legal definition of person in §205.2. • Avoid the terms “single” in reference to a producer or product, to avoid confusion and misrepresentation. <p>Revisions needed to implement OTA’s Position on <u>scope-neutrality</u>. The regulations should not limit group certification only to producers of crops and wild crops.</p> <ul style="list-style-type: none"> • Remove “crop and or/wild crop” and “growing or gathering” • Clarify that both production and handling are activities that may be performed within a group or by a group member <p>Revisions needed to the definition Internal Control System to include personnel, procedures, and reference to practice standards, recordkeeping, and audit trail requirements. See OTA’s Position on <u>regulatory requirements for an Internal Control System (ICS)</u>.</p> <p>Guidance needed to support common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity. See OTA’s Positions on <u>geographic proximity</u>.</p>

OTA Requested Revision:

Grower group operation. A ~~single~~ producer legally organized as a person consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan ~~certified as a single crop and/or wild crop production and handling operation implemented across multiple production sites and facilities.~~

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

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

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

205.201(c)
Add New
Section

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

- (1) Define the organizational structure, roles, and responsibilities of all personnel;
- (2) Identify grower group production units and locations;
- (3) Define geographical proximity criteria for grower group members and grower group production units;
- (4) Describe characteristics of high-risk grower group members and grower group production units;
- (5) Describe shared production practices and inputs;

Revisions needed to clarify ICS personnel qualifications in §205.201(c)(1). See OTA’s Position on qualifications of ICS personnel.

- Add requirement that ICS describes qualifications for all roles.
- Add requirement that ICS has a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities

Revisions needed to clarify ICS risk assessment procedures. See OTA’s Position on risk assessment.

- Add requirement in §205.201(c)(4) that the ICS has a procedure for assessing and managing risks appropriately

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

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

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

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

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

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

Revision needed to clarify recordkeeping requirements for ICS to demonstrate compliance of the group and all group members. See OTA's Position on **recordkeeping**.

- Include list of individual members, locations, products, acreage
- Copies of inspection reports, sanctions and corrections to be available during inspection by the certifier
- Formal agreement for each group member with the group that commits them to complying with ICS, OSP, and organic regulations

Revision needed to clarify the provision of education, training, and technical assistance to members. See OTA's Position on **member training**.

- Remove "training" from §205.201(c)(9) and add it to a new provision that requires the ICS to describe procedures for providing training, education, and technical assistance to grower group members to ensure understanding of and compliance with ICS, OSP, Organic Regulations.

Revision needed to clarify procedure for onboarding new members. See OTA's Position on **internal inspections**.

- Add requirement in §205.201(c) for ICS to describe procedures for onboarding new members into the group in a manner that assures new members are not added until an internal inspection is complete.

Revision needed in §205.201(c)(6) to add specific reference to "inspections." Otherwise it would be unclear what "surveillance" is referring to. Need to ensure that internal inspections, as described

		<p>throughout the proposed rule and preamble, are included in this regulatory section. See OTA’s Position on <u>internal inspections</u>.</p> <p>Revisions needed to clarify that both production and handling are activities that may be performed within a group or by a group member. See OTA’s Position on <u>scope-neutrality</u>.</p> <ul style="list-style-type: none"> • Add “and handling” to §205.201(c)(5) <p>Guidance needed to support a common understanding of qualifications that are expected of ICS personnel. See OTA’s Position on <u>qualifications of ICS personnel</u>.</p> <p>Guidance needed to clarify what does and does not constitute a conflict of interest for ICS personnel. See OTA’s Position on <u>conflict of interest</u>.</p> <p>Guidance needed to ensure that inspectors are conducting internal inspections at times of the season when they can observe production of certified organic products. See OTA’s Position on <u>internal inspections</u>.</p>
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OTA Requested Revisions:

(1) Define the organizational structure, roles, qualifications, and responsibilities of all personnel and the procedure to ensure that a sufficient number of qualified personnel are available to carry out all internal control system procedures and responsibilities;

(4) Describe characteristics of high-risk grower group members and grower group production units and the procedure to assess and manage risks appropriately;

(5) Describe shared production and handling practices and inputs;

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

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

(New) Describe how training, education, and technical assistance is provided to grower group members to ensure understanding of and compliance with internal control system’s policies, the organic system plan, and the organic regulations.

(New) Describe the procedure for verifying, inspecting, and accepting new members into the group that includes an onsite inspection prior to addition to the group

(New) Maintain records sufficient to demonstrate compliance of the group and all group members, including but not limited to:

- Current list of individual members, locations, products, and acreage
- Formal agreements from each group member that commits them to complying with the internal control system’s policies, the organic system plan, and the organic regulations
- Copies of internal inspection reports
- Copies of sanctions and corrections

205.400(g)
 Add New
 Section

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

- (1) Be a single producer organized as a person;
- (2) Sell, label, or represent only crops and/or wild crops as organic;
- (3) Use centralized processing, distribution, and marketing facilities and systems;
- (4) Be organized into grower group production units;
- (5) Ensure that all crops and/or wild crops sold, labeled, or represented as organic are from grower group members only;
- (6) Ensure that grower group members do not sell, label, or represent their crops and/or wild crops as

Revisions needed to implement OTA’s Position on **scope-neutrality**.
 The regulations should not limit group certification only to producers of crops and wild crops.

- Remove “crop and or/wild crop” and “growing or gathering”
- Clarify that both production and handling are activities that may be performed within a group or by a group member
- If NOP rejects our requested revision to §205.400(g)(2), we ask that NOP please clarify the text in §205.400(g)(2) to avoid unintended prohibition on split production. Language in the current proposed rule is unclear and could lead to interpretation that product can only be sold as organic, thereby prohibiting any product from being sold as conventional. However NOP preamble explains that split production is allowed and that conventional production could be a risk factor (indicating that it

<p>organic outside of the grower group operation unless they are individually certified;</p> <p>(7) Report to the certifying agent on an annual basis the name and location of all grower group members and grower group production units, and the crops, wild crops, estimated yield, and size of production and harvesting areas of each grower group member and grower group production unit;</p> <p>(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors, which must include mass-balance audits and reconciliation of each grower group member's and grower group production unit's production yield and group sales;</p> <p>(9) Document and report to the certifying agent the use of sanctions to address noncompliant grower group members, at least annually; and</p> <p>(10) Implement procedures to ensure all production and handling by the grower group operation is compliant with the USDA organic regulations and the Act, including recordkeeping requirements to ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution.</p>	<p>is intended to be allowed and managed through risk-based controls).</p> <p>Revisions needed to avoid the terms “single” and “single producer” to avoid confusion and misrepresentation. See OTA’s Position on <u>legal entity</u>.</p> <p>Revisions needed to clarify conditions under which individual certification is permitted. See OTA’s Position on <u>individual certification</u>.</p> <p>Revisions needed to specify need for member to be present during their internal inspection. See OTA’s Position on <u>internal inspections</u>.</p> <ul style="list-style-type: none"> • Add requirement in §205.400(g)(8) for the group member to be present during the internal inspection <p>Revision needed to explicitly require group to have an ICS in order to be eligible for group certification. See OTA’s Position on <u>regulatory requirements for an Internal Control System (ICS)</u>.</p> <ul style="list-style-type: none"> • Add requirement in §205.400(g) for the group to have an Internal Control System <p>Guidance needed regarding the instances when the ICS must contact the certifier. See OTA’s Position on <u>external oversight and enforcement</u>.</p>
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OTA Requested Revision:

(1) Be a **single** producer organized as a person;

~~(2) Sell, label, or represent only crops and/or wild crops as organic;~~

(6) Ensure that grower group members do not sell, label, or represent their ~~crops and/or wild crops~~ products as organic outside of the grower group operation unless they are individually certified for such products;

(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors with the member present, 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;

(New) Establish and implement an internal control system that ensures compliance of the group operation with NOP regulations

205.403(a)(2)
 Redesignate
 as
 205.403(a)(3);
 add new
 paragraph
 (a)(2)

Initial and annual on-site inspections of a grower group operation as defined in §205.2 must:
 (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.
 (ii) Conduct witness audits of internal control system inspectors performing inspections of the grower group operation.
 (iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk according to criteria in 205.201(c)(4). At least one grower group

Revision needed to clarify the requirements for witness audits. See OTA's Position on **external witness audits**.

- Add a requirement in §205.403(a)(2)(ii) to identify the minimum 25% of internal auditors that must be witnessed.

NOP should further explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the 1.4[√] method as part of the sampling method in §205.403(a)(2)(iii). See OTA's Position on **sampling method for external inspections**.

Revision needed to allow certifiers to conduct an independent risk assessment using their own risk criteria and to require certifier to have criteria for high risk group members. See OTA's Position on **risk assessment**.

	<p>member in each grower group production unit as defined in §205.2 must be inspected. (iv) Inspect each handling facility.</p>	<ul style="list-style-type: none"> Remove the reference to §205.201(c)(4) from §205.403(a)(2)(iii) and add requirement for the risk assessment to be conducted “by the certifier” Add new section to require certifiers to have criteria for identifying high risk group members. <p>Revision needed to clarify “handling facility” in §205.403(a)(2)(iv):</p> <ul style="list-style-type: none"> Avoid use of “handling facility” because it is not defined. There are already many other existing terms that we can use: handle, handling operation, and handler. Avoid creating another version. <p>Revision needed in §205.403(a)(2)(i) to correct in-text reference:</p> <ul style="list-style-type: none"> Replace §205.400(g)(8) with a more appropriate reference. Must comply with all elements of ICS, OSP, and organic regulations. <p>Guidance needed regarding the procedures that certifiers can use to ensure that each production unit is well represented in the overall sample of external inspections. See OTA’s Position on <u>sampling method for external inspections</u>.</p> <p>Guidance needed regarding the risk criteria that certifiers should use to determine which high-risk group members must be inspected. See OTA’s Position on <u>risk assessment</u>.</p> <p>Guidance needed regarding the procedure of certifiers to issue non-compliances and adverse actions to groups. See OTA’s Position on <u>external oversight and enforcement</u>.</p>
<p>OTA Requested Revision:</p>		

- (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8) this part. This must include review of the internal inspections and internal sanctions conducted by the internal control system.
- (ii) Conduct witness audits of at least 25% internal control system inspectors performing inspections of the grower group operation.
- (iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk by the certifier according to criteria in 205.201(e)(4). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.
- (iv) Inspect each handling facility operation.
- (New) A certifying agent must have documented criteria for identifying high-risk group members.

OTA Requested Revision:

§205.500 Areas and duration of accreditation. (a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, ~~or~~ handling, or grower groups, or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

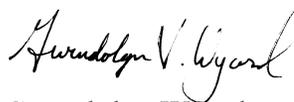
Revision needed to establish grower group operations as a separate accreditation scope. See OTA's Position on accreditation scope.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Johanna Miranda
Farm Policy Director



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Calculating Organic Percentages

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter.

This comment addresses Section #12: Calculating Organic Percentages.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports a revision to the organic regulations to clarify the division method used to calculate the organic percentage of a NOP certified product. The intent of NOP’s proposed revisions aligns with OTA’s Comments on the corresponding NOSB recommendation and NOP Draft Guidance 5037.
- OTA supports the proposed revisions with minor adjustments to further clarify that the calculation should be made “at formulation.”
- OTA requests that NOP complete its process and finalize NOP Guidance 5037. Additional clarification on when to exclude water from individual ingredients is greatly needed.
- OTA supports an implementation period of one year after the publication of the final rule.

OTA’s Positions and Recommendations

- **OTA supports revising the organic regulations to clarify the division method used to calculate the organic percentage of a NOP certified product.** There is broad consensus that the standard practice of calculating the organic percentage of a product is to divide the total net weight of combined organic ingredients **at formulation** (excluding water and salt) by the total weight of all ingredients **at formulation** (excluding water and salt). Thus, a simple change to the Regulation at § 205.302 is needed to clarify that the calculation should be made by dividing both the weight or volume of the organic ingredients, by the weight or volume of total ingredients **at the time of formulation**. Dividing the organic ingredients (at formulation) by the total ingredients (of the finished product) does not make sense because most ingredients/products lose weight during processing. Furthermore, in order to accurately calculate a percentage using division, the dividend

and the divisor must be units of the same kind. The intent of the proposed revisions aligns with OTA's Comments on the corresponding NOSB recommendation and NOP Draft Guidance 5037.

- **OTA supports the proposed revisions with minor adjustments to improve clarity around the exclusion of water and salt.** The proposal is consistent with the NOSB recommendation that informed Draft NOP 5037. However, the parenthetical placement of “(excluding water and salt)” may create confusion about whether the weight/volume of water and salt should be excluded as ingredients that are added to the product formulation (added by the certified operator making the product), or whether the weight/volume of water and salt should be excluded from each individual ingredient used in the product formulation (in addition to the water and salt added by the certified operator). The latter would be impractical in many cases and was never the intent of the NOSB recommendation. There are however some instances where water would need to be excluded from the ingredient; tea is a good example. First and foremost, OTA recommends minor revisions to improve the clarity and consistency by which certifying agents and certified operations will carry out the calculation process.

→ **Recommendation:** § 205.302(a)(1)- (3) – Add the clause “at formulation” to both the ‘dividend’ and the ‘divisor’ to further clarify that the weight/volume of the organic ingredients as well as the weight/volume of the total ingredients should be determined at formulation. It is important that the units are consistent.

→ **Recommendation:** § 205.302(a)(2) – Remove the redundant words (“the ingredients”) from the last sentence.

See OTA's s requested revisions in Table 17

- **OTA requests that NOP complete its process and finalize Draft NOP Guidance 5037.** Draft NOP Guidance 5037 was published and underwent a public comment period. However, the Guidance has not been finalized. With consideration of the public comments received, finalized Guidance is still needed to provide additional clarification that is not addressed by this proposed rule. Specifically, there is varying interpretation about the exclusion of water from individual ingredients that are used in a product formulation. There appears to be consistency around excluding water and salt when they are added to a product formulation as ingredients. Clarification is needed on when to exclude water from individual ingredients.

→ **Recommendation for Guidance:** OTA requests that NOP complete its process and Finalize Guidance 5037.

Table 17: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity and utility of the Proposed Rule.
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.	<p>Revisions needed:</p> <ul style="list-style-type: none"> • Clarification is needed to ensure that the calculation is performed “at formulation.” The weight/volume of the organic ingredients as well as the weight/volume of all ingredients should be determined “at formulation” rather than after the product is processed. OTA recommends adding “at formulation” to both the dividend and the divisor. It is important that the units are consistent. • The parenthetical placement of “(excluding water and salt)” may create confusion about whether the weight/volume of water and salt should be excluded as ingredients that are added to the product formulation (added by the certified operator making the product), or, whether the weight/volume of water and salt should be excluded from each individual ingredient used in the product formulation. <p>Guidance needed: Finalized NOP 5037 Guidance is still needed to provide additional clarification that is not addressed by this proposed rule. Specifically, there is varying interpretation about the exclusion of water from individual ingredients that are used in a product formulation. There appears to be consistency around excluding water and salt when they are added as ingredients to the product formulation.</p>
<p>OTA Requested Revision: Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation (excluding water and salt) by the total weight (excluding water and salt) of all ingredients <u>at formulation (excluding water and salt)</u>.</p>		
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) if	<p>Revision needed: The proposed revision to the last sentence is redundant and/or not clear (“ingredients and all ingredients”). OTA’s</p>

	<p>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.</p>	<p>recommended revision will simplify the sentence and make it consistent with the NOSB recommendation.</p> <p>(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of all ingredients (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of all the ingredients.</p>
<p>OTA Requested Revision: (2) Dividing the fluid volume of all organic ingredients (excluding water and salt) at formulation (excluding water and salt) by the fluid volume of all ingredients <u>at formulation (excluding water and salt)</u> 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 <u>on the basis of</u> based on single-strength concentrations of the ingredients and finished product <u>all the ingredients</u>.</p>		
<p>205.302(a) (3)</p>	<p>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.</p>	<p>Revision needed: Minor revisions are needed to further clarify the exclusion of water and salt, and that the calculation should be made “at formulation.”</p> <p>Note the NOSB recommendation): (3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of all ingredients.</p>
<p>OTA Requested Revision: (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 (excluding water and salt) by the total weight (excluding water and salt) of <u>all ingredients at formulation (excluding water and salt)</u>.</p>		

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs



Johanna Mirinda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Supply Chain Traceability and Organic Fraud Prevention

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #18: Supply Chain Traceability and Organic Fraud Prevention.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA supports adding the new term ‘*organic fraud*’ to the organic regulations to clarify the actions this proposed rule is intended to reduce and to support global communication and overall strategic direction of organic fraud prevention.
- OTA supports the proposed definition of ‘*organic fraud*’ whereas the action taking place is ‘intentional deception’ and the motivation is economic gain. However, OTA recommends that the term ‘illicit’ be removed from and the definition is revised to more clearly encompass the types of fraudulent activities that occur in the organic supply chain.
- OTA supports a requirement to include organic identification on the records maintained by a certified operation.
- OTA supports incorporating the term “audit trail” into the organic regulations at § 205.103(b)(3).
- OTA supports the proposal that certified operations must have procedures and practices to verify suppliers and prevent organic fraud. More specifically, we support a requirement that certified operations develop and implement an organic fraud prevention plan.
- OTA supports a requirement for certifying agents to share information with each other to verify supply chains and conduct investigations.
- OTA recommends adding the term ‘*supply chain traceability*’ to the organic regulations to clearly define a core concept that is integral to the purpose of this proposed rule and used throughout this proposed rule.
- OTA supports the requirement for certifiers to annually conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s). Defining ‘*supply chain traceability*’ will help the clarity of this new requirement.
- OTA supports the proposal that requires certifiers to have criteria and procedures for: (1) identifying high-risk operations and agricultural products to conduct risk-based supply chain audits; and (2) reporting credible evidence of organic fraud to the USDA.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

NOP Questions

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

No. The definition narrowly focuses on non-organic products being fraudulently labeled as organic products. The clarity of the definition would be improved with additional scenarios and examples such as making false or misleading organic claims or statements, falsifying records, fabricating fraudulent organic certificates and misrepresenting prohibited agricultural inputs as compliant with the Act and the regulations in this part. See our complete comments below.

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

No. OTA does not support establishing a specific number of trace-back audits that a certifying agent needs to conduct, because the number of high-risk operations and products will vary by certifying agent. The number of risk-based supply chain audits conducted should be relative to the number of high-risk operations or products identified by each certifying agent.

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

As explained in more detail below, it is notable that the proposed rule itself does not provide any detail on what a “robust plan for supply chain oversight and organic fraud prevention should include.” The preamble however includes a helpful explanation and lists specific components that would result in a robust plan, such as a vulnerability assessment to identify weaknesses in the operation’s practices and supply chain and mitigation measures to correct vulnerabilities and minimize risks. OTA recommends additional detail be provided in the rule itself or through guidance and/or training.

OTA’s Positions and Recommendations

- **§ 205.2: OTA supports adding the new term ‘organic fraud’ to the organic regulations to clarify the actions this proposed rule is intended to reduce.** A term and definition are needed to distinguish “intentional acts of fraud” from other actions and/or incidents that may compromise the integrity of an organic product but are not intentional acts for the purpose of economic gain. For example, intentionally labeling and selling a non-organic product as “organic” is a fraudulent act, whereas contamination of an organic product due to an inadequate buffer system is the failure of an Organic System Plan. Both circumstances result in a violation, but the contamination event should not be defined as ‘organic fraud.’ For this reason, and as explained further below, we support a definition wherein “intentional deception for economic gain” is the central action to its meaning.

‘Organic fraud’ is intentional deception for economic gain. In addition to clarifying the actions this proposed rule is intended to reduce, a definition is also needed to support global communication and overall strategic direction. Food fraud is a rapidly evolving topic and regulations and standards are evolving to keep up with these changes in the marketplace, all aimed at protecting the consumer. To assist in communication and understanding among many governments, stakeholders and trading partners globally, there is a need for

harmonization and benchmarking of key terms based on a common and well-recognized terminology framework. From this perspective, it will be most helpful if the definition of **organic fraud** is generally consistent with the most widely accepted definitions for “**food fraud**” that have been published in the past ten years and adopted by governments and private sector fraud prevention programs. Since organic fraud encompasses a wide range of agricultural products, including food and non-food, the scope extends beyond just *food*. However, while there are some unique characteristics to organic fraud, we believe the underlying concepts remain the same, whether it be food fraud, product fraud or organic fraud.

The most well-known and widely accepted definition of food fraud was published by Dr John Spink and Douglas C Moyer of the Michigan State University in 2011 and is:

- *Food fraud is a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain. ([Spink and Moyer \(2011\)](#))*

Other published definitions include:

- *Food fraud is deception, using food for economic gain ([Spink, et al 2016](#))*
- *Food Fraud: Any actions taken by businesses or individuals that deceive other businesses and/or individuals in terms of misrepresenting food, food ingredients or food packaging that brings about a financial gain. ([Elliott, 2018](#))*
- *Food fraud “is deception of consumers using food products, ingredients and packaging for economic gain and includes substitution, unapproved enhancements, misbranding, counterfeiting, stolen goods or others.” [GFSI Position on Mitigating the Public Health Risk of Food Fraud \(2014\)](#)*
- Food fraud: illegal deception for economic gain using food (all types of fraud) (CFSA, [2015a](#), [2015b](#); DEFRA, [2014](#); European Parliament, [2013](#); GFSI, 2014; ISO, 2005; ISO, [2011](#); Spink & Moyer, [2011](#)).

In reviewing these terms and definitions, two consistent qualifiers include: 1) deliberate or intentional acts of deception; and 2) economic or financial gain. For this reason, OTA strongly supports the inclusion of “intentional deception” and “economic gain” in the NOP definition of organic fraud. The term “illicit,” however, is an extra and unnecessary term that may create confusion. Organic fraud in of itself is illegal, so it seems unnecessary to qualify economic gain as being unlawful. Organic fraud is simply an intentional act, whereas the motivator is financial or economic gain. To achieve greater harmonization and reduce potential for varying interpretation, OTA suggests striking the term ‘illicit.’

In addition, OTA would like to see a definition that more clearly encompasses the types of fraudulent activities that occur in the organic supply chain. The proposed definition is very general and limits the activity to selling non-organic products as NOP certified. While all

fraudulent activity may generally fall under the umbrella of this description, it would be helpful to provide some examples, particularly ones around falsifying records and making false or misleading claims or statements on records and/or labels. OTA is also concerned that the proposed definition does not encompass agricultural input fraud, when “fertilizer fraud” holds such a prominent place in the organic sector’s history of fraud and continues to present a fraud opportunity.

➔ **Recommendation:** Remove the term ‘illicit’ and revise the definition to more clearly encompass the types of fraudulent activities that occur in the organic supply chain. **See OTA’s requested revision in Table 13.**

- **§ 205.103(b): OTA strongly supports the proposal to include organic identification on records maintained by a certified operation.** To ensure that a product’s status is clear throughout the audit trail, proper identification is needed on both the product label and the corresponding product records. Accordingly, OTA supports the proposed revision to § 205.103(b)(2). We also agree with AMS and support the certified operation’s flexibility to use alternative abbreviations of a products organic status on both non-retail labels and records, including but not limited to “MWO” (i.e., “made with organic”), ORG (i.e., “organic”), color designations, or other tracking systems that are used internally within a certified organic operation to denote a product’s organic status. *(See also OTA Comments on Non-retail Labeling)*
- **§ 205.103(b)(3): OTA supports incorporating the term “audit trail” into the organic regulations.** The regulations define the term ‘audit trail.’ However, it is not used in the regulations. The proposal to add this term into the record keeping requirements at § 205.103(b)(3) will help clarify that certified operations are required to maintain audit trail documentation for product handled or produced by the certified operation. This change will help clarify the type and extent of records that a certified operation needs to maintain.
- **§ 205.201(a)(3): OTA strongly supports a requirement that certified operations must describe and implement procedures to verify the organic status of suppliers and products in their supply chain and prevent organic fraud.** It is critical that certified operations implement effective practices to mitigate and prevent organic fraud, and it is necessary that such practices are described in the operation’s Organic System Plan at § 205.201(a)(3) and verified by a certifying agent. Certified operations are uniquely positioned at the front-line of organic fraud prevention and each operation has the ability to carefully assess their supply chains and identify where the gaps and weak points (‘hot spots’) may be to develop appropriate and effective fraud mitigation measures. A requirement for a certified operator to develop and implement an organic fraud prevention plan will be critical to reducing the opportunity for organic fraud. The effectiveness of the plan, however, will depend on the quality of the fraud vulnerability assessment and the corresponding process used to develop, monitor and verify organic fraud mitigation measures. From this perspective and consistent with the requirements of OTA’s organic fraud prevention program, “*Organic Fraud Prevention Solutions*,” we agree with NOP, as explained in the preamble, that a robust plan for supply chain oversight and organic fraud prevention must include the following:

- A map or inventory of the operation's supply chain which identifies suppliers;
- Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;
- A vulnerability assessment to identify weaknesses in the operation's practices and supply chain;
- Practices for verifying the organic status of any product they use;
- A process to verify suppliers and minimize supplier risk to organic integrity;
- Mitigation measures to correct vulnerabilities and minimize risks;
- Monitoring practices and verification tools to assess the effectiveness of mitigation measures; and
- A process for reporting suspected organic fraud to certifying agents and NOP.

The critical components of an organic fraud prevention plan, as listed above, are in fact requirements of OTA's fraud prevention program. It is notable, however, that the proposed rule itself does not include any of this detail and therefore NOP's expectation for what a "robust plan for supply chain oversight and organic fraud prevention would include" may not translate into practice.

OTA thanks NOP for citing OTA's *Organic Fraud Prevention Solutions* as a private sector program developed for organic operations to help detect and prevent organic fraud. Our program, in fact, was designed to train and help certified operations conduct a quality organic fraud vulnerability assessment and develop an appropriate and effective organic fraud prevention plan. We look forward to working with certified organic operations and collaborating with certifying agents to support this new requirement.

- **§§ 205.501(a)(13) and 205.504(b)(4): OTA supports the proposed requirement for certifying agents to share information with each other to verify supply chains and conduct investigations, and to have procedures for doing so.** Certifying agents must share information with one another to facilitate trace-back audits, investigations, and verification. The system simply will not work otherwise. OTA is sensitive to the need to maintain strict confidentiality with respect to certifying agents' clients and not disclose business-related information to third parties that are not involved with the regulation or certification operations. For enforcement purposes, however, we fully support a requirement that certifying agents must exchange any compliance-related information that is credibly needed to investigate an operation to determine compliance with the organic regulations.
- **§ 205.501(a)(21): OTA supports the proposed requirement for certifiers to annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s).** The proposed rule would require that certifying agents develop and maintain procedures and criteria for identifying which operations and products among those it certifies are at high risk for organic fraud, and accordingly conduct supply chain audits on a sample of operations and products which it determines to be high-risk. OTA strongly supports this new requirement. We also recognize that the process of developing and ranking risk-assessment

criteria will be a challenging, time intensive process that will evolve over time. Certifying agents will need good access to and awareness of market trends, enforcement actions and other applicable socio-economic and geo-political considerations, all relevant to fraud risk.

- **§ 205.504(b)(7): OTA supports the proposal requiring certifiers to have 1) criteria to identify high-risk operations; 2) procedures to conduct risk-based supply chain audits; and 3) procedures for reporting credible evidence of organic fraud to USDA.** We recommend that certifying agents also have procedures in place to identify high-risk operations and agricultural products for the purpose of identifying the appropriate use of unannounced inspections to meet or exceed the minimum number of unannounced inspections required by each certifying agent. OTA requests this requirement be added to the proposed requirements for unannounced inspections at § 205.403(b). See OTA’s comments on On-site Inspections, Topic #4. We have included the revision in Table 13 below as well. *See also our comments on Grower Group Operations.*

Table 13: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity and utility of the Proposed Rule
Add new term 205.2	<i>Organic Fraud:</i> Intentional deception for illicit economic gain, where non-organic products are labeled, sold, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”	<p>Revision needed: OTA supports the adding the term “Organic Fraud” to the organic regulations, however we recommend some minor revisions to:</p> <ul style="list-style-type: none"> • 1) further harmonize the definition to assist in communication and understanding among many governments, stakeholders and trading partners; and • 2) ensure that the definition includes examples to help convey the meaning and ensure that it covers all types of fraudulent activities that are witnessed in the organic supply chain.
<p>OTA Requested Revision: <i>Organic Fraud:</i> Intentional deception, for illicit economic gain <u>using the USDA organic label.</u> <u>Organic fraud includes but is not limited to labeling, selling, or representing</u> nonorganic products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” <u>deliberately making false or misleading organic claims or statements, falsifying records, fabricating fraudulent organic certificates and misrepresenting agricultural inputs as compliant with the Act and the regulations in this part.</u></p>		

Revise 205.103(b) (2)	Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, <u>including identification in records of products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable;</u>	Support: OTA supports the added requirement to include organic identification on the records maintained by a certified operation.
Add 205.103(b)(3)	Include audit trail documentation for product handled or produced by the certified operation;	Support: This change will help clarify the type and extent of records that a certified operation needs to maintain. The regulations define audit trail, but until now, it is not used within the regulations.
Revise 205.201(a) (3)	A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. <u>This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate to the certified operation’s activities.</u>	Support: OTA strongly supports the proposed requirement that certified operations must include, in the OSP, a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud.
OTA Requested Revision: None		
Revise 205.501(a) (10)	Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program’s governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except: except as provided for in §205.504(b)(5); : <u>(i) For information that must be made available to any member of the public, as provided for in §205.504(b)(5);</u> <u>(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is</u>	Support: no concerns.

	<p><u>credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and (iii) If a certified operation’s proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange.</u></p>	
<p>Revise 205.501(a) (13)</p>	<p>Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500. <u>Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;</u></p>	<p>Support: OTA strongly agrees this proposed revision is necessary in order to accomplish full supply chain traceability.</p>
<p>Redesignate as 205.501(a)(23); add new paragraph (21)</p>	<p><u>Annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s).</u></p>	<p>Revision needed: OTA supports the requirement for certifying agents to conduct risk-based supply chain audits to verify organic status of product(s) of a certified operation(s) it certifies, back to the source(s). However, the meaning of the term “source” is not clear.</p> <p>The preamble clarifies this term to mean “farm,” or the source at “any step in the supply chain.” To improve the clarity of the proposed requirement, we recommend a minor revision that will capture the explanation provided in the preamble.</p>

		<p>New term and definition needed: OTA supports adding the term ‘<i>supply chain traceability</i>’ to the organic regulations to clearly define a core concept that is integral to the purpose of this proposed rule and used throughout this proposed rule.</p>
<p>OTA Requested Revision: Annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s) <u>at any step in the supply chain</u>.</p> <p>OTA Requested Revision (NEW term – supply chain traceability): Add a new term to §205.2 - <i>Supply Chain Traceability</i>. The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards “from consumption to source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.</p>		
<p>Revise 205.504(b) (4)</p>	<p>A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10); <u>sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10);</u></p>	<p>Support: OTA agrees that sharing information with other certifying agents and maintaining confidentiality is critical and that written procedures are necessary.</p>
<p>Add 205.504(b) (7)</p>	<p><u>A copy of the criteria to identify high-risk operations and products; and procedures to conduct risk-based supply chain audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.</u></p>	<p>Support: OTA supports the proposal requiring certifiers to have criteria for (1) identifying high-risk operations and agricultural products; and procedures to conduct risk-based supply chain audits, and procedures for (2) reporting credible evidence of organic fraud to the USDA.</p> <p>Recommendation: OTA recommends that a similar requirement for apply to the assessment of unannounced inspections and grower groups. <i>See the suggestion for unannounced inspections below as well as our comments on On-site Inspections and Grower Group Operations.</i></p>

OTA Requested Revision: See suggested revision under “On-site (Unannounced) Inspections, 205.403(b).

205.403(b) - Unannounced inspections. (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. (2) A certifying agent must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum as needed and in response to complaints and investigations. ~~(2)~~ (3) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs



Johanna Mirinda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Technical Corrections

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Sections #19: Technical Corrections.

Summary of the Organic Trade Association’s (OTA) Positions and Recommendations

- OTA has no concerns with the proposed technical corrections, and recommends that these technical corrections be implemented immediately upon the effective date of the final rule.

OTA’s Positions and Recommendations

- OTA has no concerns with the proposed rule to change “produced” to “processed” in section §205.301(f)(2) and vice versa in §205.301(f)(3). These revisions are intended to better describe the application methods of ionizing radiation and sewage sludge, respectively. The current wording is the result of an erroneous error contained in a 2015 *Federal Register* publication¹. The Strengthening Organic Enforcement Proposed Rule would return the wording back to how it appeared prior to the 2015 publication.
- OTA has no concerns with the proposed rule to change “205.200” to “205.201” in section §205.400(b) and §205.401(a). Accurate citations are critical. The Strengthening Organic Enforcement Proposed Rule would update the regulatory text to refer to the accurate citation Organic System Plan requirements.
- OTA recommends that these technical corrections be implemented immediately upon the effective date of the final Strengthening Organic Enforcement Rule.

¹ <https://www.federalregister.gov/documents/2015/02/05/2015-02324/national-organic-program>



On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,

Johanna Miranda
Farm Policy Director

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha
Executive Director/CEO

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Amendments Considered but not included in the Proposed Rule

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement.

The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #20: Additional Amendments considered but not included in this Proposed Rule

Packaged Product Labeling

NOP is seeking comments on the following questions regarding private-labeled organic products and how amending the labeling requirements of §§ 205.303 – 205.304 may improve organic integrity and transparency, and facilitate the verification and traceability of organic products.

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

The choice of either handler or distributor should be determined by whichever entity is the most appropriate point of contact. In all cases, the certifying agent displayed on the label should be the certifying agent of the certified operation listed on the label. The name of the handler or distributor and its certifying agent should also match the information reported in the Organic Integrity Database. This approach provides a transparent direct route for identifying the appropriate point of contact, connecting the physical product to its organic certificate, and supporting product traceability.

2. ***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)?***

Yes. See answer above.

3. ***Should listing contract manufacturers on labels be mandatory?***

No. It should be optional. OTA does not support a mandatory listing of the manufacturer on the label. There should only need to be one certified operation and one certifying agent.

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

Private Label Organic Products.

5. *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)?*

Private Label Brand or Distributor (Retailer) / Brand name manufacturer or contract manufacturer (Handler)

Expiration of Certification

NOP considered (but did not include in proposed rule) an amendment in which an operation's certification would expire on an annual basis if the operation did not submit fees and update its certificate of organic operation. NOP is seeking comments on the following questions regarding expiration of certification:

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

OTA does not support an amendment that would cause an operation's certification status to automatically expire on an annual basis if the operation did not submit fees and update its certificate of organic operation. This system would create administrative and recordkeeping burdens without any increased protection to organic integrity.

OTA supports the current process of certification which allows organic certification to continue until certification surrendered, suspended, or revoked. The current process ensures that operations have due process. We also recognize that it is essential to strike a balance between due process and efficiency to minimize the amount of time that operations are able to sell product as organic while it exercises its right to due process. We strongly encourage NOP and certifying agents to respond to adverse actions in a timely manner.

Fees to AMS and Oversight of Certifying Agents' Fees

NOP is seeking public comments on how fees in NOP could strengthen testing and enforcement across all stakeholders to ensure that NOP keeps pace with the rapid growth and better serves the industry. This request for feedback is preceded by the following statement:

Since the final rule establishing the National Organic Program (NOP) was first published in the Federal Register in 2000, the production, marketing, and sale of organic foods has undergone tremendous growth. The proposed rule is intended to strengthen enforcement of the USDA organic regulations through many actions, including strengthened certification processes and coverage of importers, brokers, and traders of organic products. Section 2107 (a)(10) of the Act allows the NOP to include fees from producers, certifying agents and handlers. AMS periodically reviews the fees for accreditation and accreditation services to ensure that they are in compliance with Circular A-25.60 AMS also oversees the NOP fees that certifying agents and others charge for their services.

OTA does not support a user fee model. A user fee model and/or increased cost in accreditation fees would increase costs to certifying agents and these costs would be passed on to certified operations. NOP is a federal program under USDA, and Congress has consistently provided annual funds to NOP for enforcement and oversight of the organic program. NOP's budget has doubled in the last five years for this purpose, and the farm bill includes an increase in the authorization of NOP funding to keep pace with industry growth year after year. OTA maintains that funding should continue to come from congressional appropriations. NOP should make publicly available a detailed breakdown in their yearly budget outlining how federal funding is used before any further consideration or discussion of increasing user fees.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs



Johanna Mirinda
Farm Policy Director

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Implementation Timeframe

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses NOP’s request for comments on the Implementation Timeframe.

NOP 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).

Organic Trade Association’s (OTA) Positions and Recommendations

OTA supports implementation of the Strengthening Organic Enforcement Proposed Rule at the earliest feasible opportunity. In most cases, the proposed one-year implementation timeframe after publication of the final rule is suitable. However certain sections of the Proposed Rule will require significant preparation in systems and resources in order for operations and certifiers to be in compliance.

The following list is a summary of OTA’s recommended implementation timeframes for each section in the Proposed Rule (with OTA’s requested revisions and recommendations for guidance). Please refer to the OTA’s full comments on each topic for more information.

OTA’s Comment – <i>NOP Proposed Rule Section</i>	OTA’s Recommended Implementation Timeframe (from the date of publication of the final rule)
Exemptions from Certification – <i>Section #1</i>	2 Years for handling operations that must get certified as a result of this proposed rule
Imports to the United States (Import Certificates) – <i>Section #2</i>	2 Years for shipments by ground transportation from Mexico and Canada 1 year from publication of final rule for all other imports
Labeling of Nonretail Containers – <i>Section #3</i>	2 Years for all nonretail containers

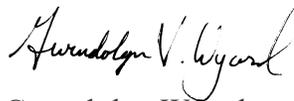
OTA's Comment – NOP Proposed Rule Section	OTA's Recommended Implementation Timeframe (from the date of publication of the final rule)
On-site and Unannounced Inspections – <i>Section #4</i>	1 Year
Organic Certificates & Data Reporting – <i>Section #5 & #7</i>	2 Years for mandatory use of Organic Integrity Database for generating certificates
Continuation of Certification – <i>Section #6</i>	1 Year
Personnel Training and Qualifications – <i>Section #8</i>	1 Year
Oversight of Certification Activities – <i>Section #9</i>	1 Year
Accepting Foreign Conformity Assessments – <i>Section #10</i>	1 Year
Noncompliance, Mediation and Appeals – <i>Section #11-15</i>	1 Year
Grower Group Operations – <i>Section #16</i>	1 Year
Calculating Percent Organic Ingredients – <i>Section #17</i>	1 Year
Supply Chain Traceability and Fraud Prevention – <i>Section #18</i>	1 Year
Technical Corrections – <i>Section #19</i>	Immediately upon final rule becoming effective

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



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