



November 20, 2018

Jenny Tucker, Ph.D.
Deputy Administrator
National Organic Program
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2646—So., Ag Stop 0268
Washington, DC 20250-0268

RE: National Organic Program's (NOP) upcoming Strengthening Organic Enforcement Rulemaking

Dear Dr. Tucker,

Thank you for this opportunity to provide feedback on the Agricultural Marketing Service (AMS) National Organic Program's (NOP) upcoming Strengthening Organic Enforcement rulemaking.

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.

The U.S. Department of Agriculture (USDA), certifiers, inspectors and organic businesses all have a shared role in protecting the integrity of the seal. 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 and ensuring a level playing field for all organic market participants – in the U.S. and abroad. The integrity of the organic certification process from farm to table is the lifeblood of the organic industry.

In addition to the ten topic areas presented on July 19, 2018, during the interactive NOP Strengthening Organic Enforcement Town Hall webinar, the Organic Trade Association's comments identify five other key areas where improvements are needed to increase the integrity of the global organic control system.

The Organic Trade Association urges timely action on all fifteen of the key areas identified in our comments. Although we have ranked each topic according to the level of impact we believe it will have in increasing organic integrity, they are all extremely important and we urge NOP to take action on each one.

In Summary:

1. **Excluded Operations:** Limit the types of operations that may be excluded from certification. Specifically, require certification of each producer, handler and handling operation in the supply chain that is producing or handling products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Exclusion from certification should be very restricted and may be granted only for transporters, storage facilities

and retail food establishments that meet the conditions and regulatory compliance requirements detailed in our comments below.

2. **Organic Integrity Database:** 1) Require Accredited Certifying Agents (ACAs) to report aggregate production area certified by crop and location at least on an annual basis to the Organic Integrity Database. Currently there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis; and 2) require ACAs to update the OID within 72 hours when an operation surrenders its certification, or its certification is suspended or revoked.
3. **Complaint & Alert System:** 1) Create a risk assessment process for prioritizing complaints; 2) improve the timing and communication around NOP's complaint system; and 3) develop a public alert system that identifies products or regions where heightened vigilance is needed.
4. **Organic Identification:** 1) Require all documentation associated with NOP certified product to include identification of organic status; and 2) require all non-retail containers and packaging to include identification of the product as organic.
5. **Testing:** 1) Update NOP's Guidance on Residue Testing (NOP 2610, 2611, 2613) to gain better consistency and bring testing methodology up to speed with industry standards and testing technology; and 2) increase required use of testing for imports and other high-risk products and/or regions.
6. **Grower Groups:** Formally respond to the National Organic Standards Board (NOSB) Recommendations on Grower Groups and conduct rulemaking to ensure consistent oversight and enforcement of group operations.
7. **Inspector and Certifier Oversight (including Satellite Offices):** 1) Increase oversight of certifiers, including satellite offices domestically as well as in foreign countries, which should be required to be audited on an annual basis; 2) Develop more robust auditing of ACAs with increased attention on whether a certifier's process and qualifications are sufficient to verify compliance and detect fraud.
8. **Equivalency and Recognition Arrangements:** 1) *Terms and conditions of equivalency arrangements:* Prioritize competency of oversight and data transparency followed by differences in regulations and materials; 2) *Communication:* Improve communications with 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; and 3) *Follow-up:* On recognition agreements, ensure that the governmental authorities, in fact, are implementing the NOP rule including associated guidance and policy.
9. **Inspectors (Qualifications, Training and Field Evaluations):** 1) Improve qualifications and training of inspectors and ACAs to monitor, detect and address fraud; and 2) Establish minimum requirements for qualifications and initial and continuing training.
10. **Import Certificates:** 1) Implement a system that collects a greater amount of data, including tracing the original product to its origin; and 2) Improve online access to electronic import

certificate system.

11. **Updates to Non-compliances and Appeals Process:** Expedite the NOP appeals process such that that appeals are reviewed and responded to in a timelier manner.
12. **Unannounced Inspections:** Require certifying agents to conduct unannounced inspections on at least 5% of certified clients. Additional unannounced inspections should be conducted as needed in response to complaints and investigations. The cost of unannounced inspections should be factored into the certifier's fee structure. Additionally, require certifiers to report to NOP annually on their programs, success rate and compliance with the minimum requirement.
13. **10-Digit HT Codes:** Prioritize increasing the number of 10-digit statistical breaks for organic products in the harmonized tariff schedule and *require* the use of the 10-digit code when it exists. Use of an organic 10-digit statistical breakout for imported organic product (if one exists) ensures accurate accounting of products entering the United States. This information is critical to understanding what products are entering the U.S. and from which countries. It is the only U.S. government produced, year-round, public data set available on the topic. Without increased number of codes and their compulsory use by industry, there is no reliable/consistent baseline for understanding volumes, prices, and origins of imported organic products. The non-use of the code should not disqualify the product as organic. However, this could prompt a mandatory test.
14. **Federated Organic Certificates:** Consider a narrower and more easily-implementable solution that will help deter fraudulent certificates. Until the Organic INTEGRITY Database is reliably providing accurate and current information for certified operations, federated organic certifications should not be mandatory.
15. **Fumigation Notifications:** Continue to increase coordination and access to available data cross border documentation systems administered across other agencies including U.S. Customs and Border Patrol (CPBs) Automated Commercial Environment (ACE), and Phytosanitary certificates. This includes notifying NOP when imported agricultural products are treated with NOP-prohibited substances at U.S. ports of entry. Notifications must include the crop/product, name of the associated company, the substance used, and information must be made available to ACAs.

We offer the following more detailed comments on select topics subject to NOP's upcoming Strengthening Enforcement Rulemaking:

EXCLUDED OPERATIONS

Operations excluded from organic certification were one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on 1) "Which types of excluded operations should be required to be certified and why?" and 2) "Should any of the current exclusions in the USDA organic regulations remain in place?"

Which types of excluded operations should be required to be certified and why?

The Organic Trade Association prioritized several legislative changes for the next Farm Bill to give NOP the tools it needs to prevent fraud. One of our top priorities most relevant to the role of uncertified operations in the supply chain is the section in the Organic Farmer and Consumer Protection

Act (OFCPA) which calls for a modification to the regulations to limit the type of operations that are excluded from certification under 7 CFR §205.101. The language in the House and Senate bill reads:

MODIFICATION OF REGULATIONS ON EXCLUSIONS FROM CERTIFICATION.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Agriculture shall issue regulations to limit the type of operations that are excluded from certification under section 205.101 of title 7 Code of Federal Regulations, and any other corresponding sections.

The Organic Trade Association believes that each **producer, handler and handling operation** in the organic supply chain that is producing, handling or selling products sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified. In other words, every organic ingredient and every organic product must be handled by a certified operation from farm to retailer. The opportunity to be excluded from certification should be very limited, clearly stated and based on the scope and activity of the operation.

Uncertified entities in the supply chain that are handling organic products pose a major risk of fraud 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. Furthermore, 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. The practice of a buyer accepting an organic certificate from a supplier, with the expectation that it represents complete supply chain certification back to the farm, can only be valid if each entity in the supply chain is certified.

The following chart reflects operations that are **commonly considered “excluded”** but for which we believe certification should be required. Our comments below offer further detail.

Certification Required	**Certification may not be required
Brokers (excluding customs brokers*)	Retail Food Establishments (as described under 205.101(a) and (b))
Importers	***Transporters
Traders	****Storage Facilities that do not sell, process, package, label
Wholesalers	****Distribution Centers that do not sell, process, package, label
On-line auctions	
Agricultural Ports	

* Because of the complexity involved with importing and exporting goods, many companies use customs brokers to act as their agents. Customs brokers clear shipments of imported goods prepare required documentation for export shipments and collect duties and taxes. They act as an intermediary between importers and the government. They are paper pushers only and should not be subject to certification.

**Depending on scope and activity – see our comments below

***Operation that transports (this carve out is based on OFPA definitions) – if it does not handle (sell, process or package) and certified organic product is transported from a certified operator to another certified operator or final retailer

****Must receive certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and ship in the same wholesale or retail container without opening, reconstituting, altering, splitting, repackaging, processing or relabeling the products.

The Organic Trade Association believes that eliminating the exclusion from certification for uncertified entities that handle (sell, process, package) organic product, including agricultural ports, commodity brokers, importers, wholesalers, commodity traders and on-line auctions, regardless of whether they take physical possession of the product, is the single-most important action that can be taken to increase the integrity in the global organic control systems and create a level playing field for all organic operations.

Should any of the current exclusions in the USDA organic regulations remain in place?

Yes. However, the Organic Trade Association urges NOP to focus on “who may be excluded” rather than “who should be certified.” We urge NOP to first communicate that everyone in the supply chain producing and/or handling organic products (grow, sell, process, package, label) must be certified, and then communicate the very limited and restricted exception to the Rule.

In short, an exception to the rule may apply *only* to:

1. **Exempt operators** meeting the conditions and requirements of 205.101(a). Please note that the Organic Trade Association’s is focused on limiting the types of operations that may be **excluded**. Our legislative efforts are not aimed at **exempt** operations.
2. **Retail food establishments** and **storage facilities** that meet the conditions and requirements of § 205.101(b) as described in our comments below;
3. **Transporters**, provided: 1) they do not sell, process, or package; 2) the activity is limited to the delivery of certified organic crops or livestock from one certified entity to another; and 3) they are operating in compliance with NOP Guidance 5031 (Certification Requirements for Handling Unpackaged Organic Products).

In all cases above, the regulations need to be revised to clarify the conditions and regulatory provisions that must be met by exempt and excluded operations, particularly as it relates to commingling and contamination prevention, labeling and record keeping.

Retail Food Establishments

The Organic Trade Association strongly advocates for voluntary certification of **retail food establishments**. Retailers represent the final interface with consumers in the organic supply chain, and it is crucial that organic integrity in merchandising, handling and marketing be vigilantly maintained. While we strongly advocate for voluntary certification of retailers, we support retaining the current exclusion (and exemption) for retail food establishments, **provided** NOP:

1. Swiftly act on NOSB’s 2014 recommendation titled “Clarification and Guidance on Retail Compliance and Certification.” This recommendation (unanimously passed) requests that NOP provide clear general education and guidance on organic compliance to the retail sector and clarify specific sections of the Rule as it applies to retail food establishments.
2. Revise the regulations to clarify that all retail food establishments that are either exempt and/or excluded from certification must still comply with prevention of contact with prohibited

substances as set forth in §205.272, the labeling provisions of §205.310 and record keeping as described in §205.101(c).

3. Clarify the definition of a “retailer” as used in the NOP Town Hall Webinar. One of the retail areas NOSB requested clarification on in the 2014 recommendation is the function of on-line retailers. We understand that the early drafted regulations and the exemption and exclusions provided for retail food establishments may not have had on-line retailers in mind at the time the regulations were drafted. The regulations are out of date in this area and the Organic Trade Association views guidance in this area as a top priority.

The Organic Trade Association believes that focused education, guidance and outreach to the retail sector will help improve compliance and regulation, foster consistency across certified and non-certified operations, and promote consumer confidence in the USDA organic label.

Storage Facilities / Distribution Centers

Under conditions that need to be clearly spelled out in the organic regulations and guidance (see our suggested revisions below), **storage facilities that store and/or distribute** may be excluded from certification provided they are covered under the certified operation’s Organic System Plan that is responsible for the organic product(s). Additionally, documentation attesting to contamination/commingling prevention and record keeping practices should be maintained in the OSP *and* on-site at the storage facility location. **See Appendix A – Independent Storage Information Sheet.**

The organic regulations in combination with guidance must make it abundantly clear that an excluded storage facility or distribution center **must receive certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and ship/distribute them in the same wholesale or retail container without opening, reconstituting, altering, repackaging, splitting, processing or relabeling the products.**

Storage or distribution centers that are performing secondary packaging on organic products must be certified.

Note: The term “properly labeled” refers to a NOP certified product that is labeled in accordance with the labeling requirements of the organic regulations *in addition* to identification of its organic status (see our comments below on page 13 - ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS).

For storage facilities (and any other excluded operation covered under 205.101(b)), a regulatory revision providing more specificity on the meaning of “packaged or otherwise enclosed in a container” is needed.

The Organic Trade Association recommends the following:

§ 205.101 (b)(1) Exclusions:

- (i) Are **packed and shipped by a certified operation and remain** packaged or otherwise enclosed in a **sealed, tamper-proof and properly labeled** container prior to being received or acquired by the storage operation; and

- (ii) Remain in the same package or container and are not otherwise ~~processed~~ handled while in the control of the handling operation.

The term “processed” in (ii) is replaced with “handled” to include “*sell, process and package.*”

§ 205.2 (Terms Defined) - Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

We also urge NOP to clarify that storage facilities and distribution centers that **ALWAYS MEET THESE CONDITIONS** are excluded from the requirements of this part, except:

- The requirements for prevention of commingling and contact with prohibited substances as set forth in §205.272; and
- Records sufficient to 1) prove that ingredients/products identified as organic were organically produced and handled; 2) ensure traceability; and 3) document procedures for contamination/commingling prevention.

Furthermore, records 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.

Transporters

Given the NOP definition of a “handler,” an exception to certification may be given to an **operation that “transports,”** provided they do not handle (sell, process or package) organic products and the product(s) are delivered directly from one certified operation to another certified operation or to the 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).

Accordingly, we support the guidance pasted below related to transporters/transportation in NOP Guidance 5013. However, it should apply to unpackaged *and* packaged products.

NOP Guidance 5031

4.2 An operation that transports unpackaged organic products does not need to obtain certification if it does not handle (i.e., sell, process, or package) organic products.

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.

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 organic 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.

4.3 An operation that handles unpackaged organic products (other than transporting), and is not an exempt or excluded handling operation, must be certified.

Examples of operations that handle unpackaged organic products and must be certified:

- Operations that handle certified organic hay or straw (wrapped or unwrapped) by combining or splitting loads or lots;
- Operations that handle unpackaged grain, including combining or splitting loads or lots, package, or otherwise handle the product other than for transport; and
- Fruit and vegetable wholesalers that package or label containers of certified organic produce for sale as organic.

4.4 Additional requirements

All handling operations, whether certified or not, must prevent commingling with non-organic products and contact with prohibited substances. (See § 205.272.)

Handlers that handle unpackaged organic products must maintain adequate records.

Examples of records documenting compliance with the USDA organic regulations:

- Clean truck affidavits, records of cleaning and sanitizing materials, and procedures used to clean trucks;
- Bills of lading, manifests, transaction certificates, shipping records, delivery records, invoices, lot numbers, and other audit trail documents; and
- Records documenting the audit trail, chain of custody, tanker seals, wash tags, truck and trailer numbers.

The Organic Trade Association, however, **DOES NOT** agree with the following example in section 4.1 of NOP 5031. The Organic Trade Association urges NOP to require the following operations to be certified and strike this portion from **NOP Guidance 5031**:

NOP Guidance 5031 - Section 4.1

Examples of operations that are excluded and do not need to be certified:

- Wholesale distributors, brokers, and traders that sell boxed or otherwise sealed containers of certified organic products (e.g., sealed tote bags, 55-gallon juice drums, boxed cereal, milk in cartons);
- Produce handlers who do not open, repack, trim, or relabel certified organic products (e.g., bagged salad greens, boxed produce).

Regulatory analysis; potential options for change and nuances to note

Goal:

1. Revise the regulations to require every handler and every handling operation in the organic supply chain to be certified. Every organic ingredient and every organic product must be handled (sell, process, package, label) by a certified operation, with very limited exception.
2. Revise the regulations to provide exceptions to certification for: 1) exempt operations as described in 205.101(a); 2) storage or distribution facilities (used only for wholesale or retail packaged product); 3) retail food establishments (exempt and excluded); and 4) transporters.

Analysis of NOP Handling Definitions: The regulations require each “production” or “handling operation” or specified portion of a “production” or “handling operation” to be certified. The definition of “**handling operation**” is problematic because it does not capture the activity of “**selling**” as does the definition of “**handle**.” All three definitions (handle, handler and handling operation) are in OFPA and cannot be changed.

Current NOP definition of Handle: To **sell**, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Current definition of Handling Operation: Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Excluded Operations: Recommended Change #1:

§205.100 **What has to be certified** could be revised to specify **handlers and** handling operations in order to capture the activity of “selling”:

§205.100 What has to be certified.

- (a) Except for operations exempt or excluded in §205.101, **each production or handling operation or specified portion of a production or handling operation or handler** 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.

Note: The definition of “**handle** includes” the term **process**. The definition of *processing* is as follows:

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Clarification is needed: Storage facilities commonly freeze and/or chill packaged and sealed products. There needs to be an exception made for “holding¹” for safe or effective storage (aeration, cooling, freezing) provided it does not involve prohibited inputs/materials/practices and provided it does not transform a raw agricultural commodity into a processed food. Such storage activities should not require certification provided the excluded storage facility receives certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and distributes the products in the same wholesale or retail container without opening, reconstituting, altering, repackaging, processing or relabeling the products.

Excluded Operations: Recommended Change #2:

§ 205.101(b)(1) Excluded Operations could be revised to cover the compliant activity performed by storage facilities *only* (receiving, storing and shipping) and to expand the compliance requirements as we have suggested (contamination prevention, labeling, record keeping and OSP disclosure). All other handlers and handling operations (excluding retail food establishments and transporters meeting the terms of the regulation and guidance) must be certified.

§ 205.101 (b)(1) Exclusions: A handling operation or portion of a handling operation **that is engaged in the act or process of storing agricultural products** is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in §205.272 with respect to any organically produced products, if such operation or portion of the operation only **sells stores and distributes** organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

- (i) Are **packed and shipped by a certified operation and remain** packaged or otherwise enclosed in a **sealed, tamper-proof and properly labeled** container prior to being received or acquired by the handling operation; and
- (ii) Remain in the same package or container and are not otherwise **processed handled** while in the control of the handling operation.

This section of the rule also needs to be revised to specify that, in addition to the requirements for the prevention of contact with prohibited substances as set forth in §205.272, storage facilities are required to meet all applicable labeling requirements of the organic regulations as well as the record keeping requirements as described in §205.101(c).

¹ FDA Definition of “Holding” for Registration of Food Facilities (21CFR1.227) - *Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Additionally, storage and distribution centers must be covered under the certified operation's Organic System Plan that is responsible for the organic product(s).

NOTE: It is important to recognize the inconsistency in the existing regulations for exempt vs. excluded operations. The common practice or interpretation is that the contamination/commingling prevention, labeling and record keeping provisions apply to all exempt and excluded operations. While the Organic Trade Association strongly supports this practice, it is not reflected in the Rule. The charts below reflect the provisions that apply to each exemption or exclusion:

Exemptions – 205.101(a) (vs. Exclusions)

- (a)(1) Production or handling operation - \$5000 gross or less
 - Applicable regulations
 - Labeling (205.310)
- (a)(2) Retail establishment that handles but does not process
 - Labeling (205.310)
- (a)(3) Handling operation or portion that handles “less than 70% organic”
- (a)(4) Handling operation that only identifies organic in the ingredient statement
 - Contamination prevention
 - Labeling of 205.305 and 205.310
 - **Record keeping in 205.105(c)**

205.101 Exclusions (vs. Exemptions)

- (b)(1) Handling operation or portion of a handling operation
 - **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 and are **not otherwise processed** while in the control of the handling operation.
 - Contamination prevention
 - Labeling provisions of 205.310
- (b)(2) Retail food establishment that processes, on-site, raw and ready to eat food
 - Contamination prevention
 - Labeling provisions of 205.310

IMPORTANT: The current requirement to maintain records applies to EXEMPT operations only. As per the Organic Foods Production Act, the record keeping requirements should apply to all exempt **and** excluded operations.

7 CFR 205 - Exemptions and exclusions (205.101(c))

Records to be maintained by **exempt** operations. (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

- Prove that ingredients identified as organic were organically produced and handled; and
- (ii) Verify quantities produced from such ingredients.

(2) Records 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 or 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.

Organic Foods Production Act

§6519. Recordkeeping, investigations, and enforcement

(a) Recordkeeping

(1) In general

Except as otherwise provided in this chapter, each person who sells, labels, or represents any agricultural product as having been produced or handled using organic methods shall make available to the Secretary or the applicable governing State official, on request by the Secretary or official, all records associated with the agricultural product.

The Organic Trade Association urges NOP to revise the regulations so that all operations, exempt or excluded, from certification must still comply with:

- The requirements for the prevention of contact with prohibited substances as set forth in §205.272;
- The labeling provisions of §205.310;
- Record keeping as described in §205.101(c)

What impact will these changes have?

The Organic Trade Association 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. Furthermore, revising the regulations, as we have suggested, will help clarify and reinforce the existing requirements for organic operations and support the process for ACAs to verify compliance with the current organic standards. As a result, there will be increased consistency among ACAs in their verification process and increased scrutiny by certified businesses of their supply chains.

ORGANIC INTEGRITY DATABASE

Increased reporting to the organic INTEGRITY database was one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on “How might the rule address full supply chain traceability from farm to table?”

The Organic Trade Association believes that NOP **requiring** ACAs to report aggregate production area certified by crop and location on an at least an annual basis to the Organic INTEGRITY Database is the second-most important action 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. Although the database can accept acreage data from certifiers, not all certifiers report acreage to the database. This should be considered minimum required data. Currently, acreage data is available for less than 30% of organic operations in the U.S. and 0% in high-risk regions. As a result,

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.

The Organic Trade Association also urges NOP to require global use of the Organic INTEGRITY Database. If global use is not possible, then we recommend investment into 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 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.

Finally, the Organic Trade Association urges NOP to require ACAs to update the Organic INTEGRITY Database within 72 hours when an operation surrenders its certification, or its certification is suspended or revoked.

As we move ahead and work to improve the Organic INTEGRITY Database, the Organic Trade Association asks that members of the organic trade be included in the **OID User Groups**. Feedback from organic industry members that regularly use the Organic INTEGRITY Database - in addition to certifiers – will be incredibly valuable in enhancing a user-friendly database with increased functionality.

ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS

Although the topic of organic identification was not addressed at the NOP Town Hall on Enforcement Rulemaking, OTA sees a significant opportunity in this area for improving oversight of the organic supply chain and ensuring strong enforcement of organic regulations.

Note: Throughout these comments, we use the term “organic identification” to refer to the use of the term “organic” to identify a product as organic. We are not referring to any numbers or codes used by NOP for identifying organic operations.

Organic identification should be a baseline requirement for any and all documentation, labels, and other related items for an organic product and its supply chain. This includes all transaction documents and all product labels, including both retail and non-retail. This information is essential for connecting physical product to its organic certificate and other relevant documentation, which is critical for ensuring organic status of the product and being able to conduct traceability audits. In order to fulfill this expectation, we recommend the following new requirements:

1. **Require all documents used to document an organic transaction to include organic identification.** Any operation that is creating documentation to be used in an organic transaction (e.g., receipts, invoices, transaction certificates, bills of lading, and any other transfer documents) must include information such that it can be connected to the organic product to which the documentation pertains. The organic status of a product should be explicitly required and recorded on the title of transfer documents. The recordkeeping requirements in § 205.103 may be the appropriate place to codify this requirement.

2. **Require all packaging of certified products to include organic identification, including non-retail containers.** Identification of organic products as organic is essential and should not be optional in any scenario. 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. The labeling requirements in § 205.303 should be revised to *require* identification of the product as organic instead of having this as an optional piece of information. (See Appendix B for suggested regulatory changes.)
3. **Organic identification is especially important on non-retail containers given the expectation that such product will be transferred and/or repackaged.** The labeling requirements in § 205.307 should be revised to *require* non-retail containers to display identification of the product as organic and the production lot number of the product in all instances. (See Appendix for suggested regulatory changes.)

Additional best practices may be provided to certifiers and certified operators through guidance or instruction in the NOP Handbook to further ensure that enough information is provided for transparency of organic status and traceability of the supply chain. For example, non-retail labels should ideally also identify the last certified organic operation that handled the product. This would allow the certificate of the last handler to be matched to the physical product identified as having been handled by that operation.

GROWER GROUPS

The certification of grower groups was one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on “What specific practices might NOP consider for Grower Groups that are not already addressed by the 2002 and 2008 NOSB recommendations?”

Under Policy Memo 11-10, NOP allows the certification of grower groups using the policies identified in the 2002 and 2008 NOSB recommendations. OTA supports NOP’s intent to formalize these policies through rulemaking because it will ensure consistent oversight and enforcement of group operations. Some aspects of group operations present inherent vulnerabilities, and therefore must be overseen by clear and enforceable regulations. Group operations, by virtue of being a collection of many production units, produce a disproportionately large amount of product compared to single operations. Products produced by group operations have historically been high-value imported products such as coffee, cocoa, tea, spices, and tropical fruits. Furthermore, compliance of group operations is primarily overseen by the group’s own Internal Control System. For all of these reasons, rulemaking related to group operations is critical for strengthening oversight of organic production.

To ensure organic integrity, NOP regulations (with accompanying guidance and/or instructions as appropriate) should address the following points about the certification of group operations:

- **Terms defined:** A definition for group operations should be included in the regulations. The definition should specify that a group operation is a single legal entity wherein multiple producers are overseen by an internal control system. OTA suggests using the term “*Group Operation*” rather than “*Grower Group*” to avoid using the term “*grower*” that is not defined or used elsewhere in the regulations.

- **Criteria for an operation to qualify for group certification:** Group certification has proven to be an essential certification tool for production of certain organic crops by smallholders in developing countries who otherwise would not have the means to obtain organic certification independently. However, the privilege of foregoing the requirement for individual certification of each group members is one that must be restricted to very specific and limited circumstances to ensure organic integrity. Operations must be required to meet very clear and distinct criteria to qualify for group certification.

The criteria for an operation to qualify for group certification shall maintain the existing scale-neutrality of the NOP regulations, and not introduce any bias towards a particular scope or scale or location of production. Rather, the criteria themselves shall regulate whether a particular operation may qualify for group certification. Therefore, it is critical that the criteria are clear and specific enough to appropriately limit operations that may qualify for group certification and not result in unintended consequences that would reduce our ability to enforce organic integrity.

Criteria for an operation to qualify for group certification should include (but are not limited to):

- o The group is established under a single legal entity.
 - o Organic products produced by the group are sold only through the group's legal entity under the group's organic certification.
 - o The group sells only organic products produced by the group. Spot purchasing of outside products and re-selling through the group is prohibited.
 - o Individual group members must not hold independent organic certification outside of the group.
 - o Individual group members must not sell any organic products outside of the group.
- **Organic System Plan for Group Operations:** NOP Handbook should be updated with templates and forms specific to group operations. These additional resources will assist certifiers in collecting appropriate and sufficient information from operations applying for group certification.
 - **Internal Control System (ICS):** A strong and effective internal control system is critical for a group operation to maintain compliance. As such, NOP should specify the required elements of an internal control system that must be developed and maintained by group operations.
 - o *Internal Surveillance of group members by the ICS:* Guidance and/or instruction are needed for ICS personnel to conduct internal surveillance of group members. Each ICS inspector should be approved by the certifier. Certifiers should provide training to ICS inspectors.
 - o *Internal Sanctions of group members by the ICS:* Guidance and/or instruction is needed for ICS personnel to issue internal sanctions to group members.
 - **Recordkeeping by group operations:** As already required by §205.103, records must be adapted to the particular business that the certifier operation is conducting. Group operations are likely to require additional unique recordkeeping systems that are adapted to the group and its internal control system and encompass all group members and production units. Records to be kept by the individual member and records to be kept by the ICS shall be specified.

As with any certified operation, the existing requirements for recordkeeping, lot tracking, and traceability shall be followed. In addition, the group operation's traceability system shall allow product to be traceable back to the individual group member.

- **Inspections by the certifier:** For group operations, the certifier is required to inspect the adequacy of the ICS as well as a meaningful sample of group members. This form of oversight and inspection is very different from a typical operation, and therefore certifiers need clear expectations and instructions for conducting inspections in a manner that ensures organic integrity and strong enforcement. In particular, instructions are needed for certifiers to verify compliance of internal control systems and to select group members to inspect.
 - o *Inspecting the ICS:* Guidance and/or instruction is needed for conducting inspections of internal control systems. Such information should include the documentation that is required from operators and how to verify the compliance of the documentation and the intended practices.
Clarification is also needed around the expectations for issuing noncompliances to group operations, and how the ICS's practice of issuing internal sanctions translates to noncompliance of the group by the certifier.
 - o *Selecting members to inspect:* Guidance and/or instruction are needed for determining the sample size and composition of members to be inspected. Such selection methodology shall include risk-based selections as well as random selections. High-risk group members shall be inspected and shall include members for which the ICS issued internal sanctions related to prohibited materials and/or audit train exercises.
Clarification is also needed around the inspection requirements for group members during an initial inspection of a new group operation, versus the inspection requirements of a new group member added to an existing certified group operation.
 - o *Inspector Qualifications:* Inspections of group operations are uniquely complex and must be conducted by an inspector qualified for such inspections. Mass balance audits are particularly critical for group operations and may be highly complex.

INSPECTOR AND CERTIFIER OVERSIGHT (SATELLITE OFFICES)

The Organic Trade Association recognizes a strong need to increase oversight of certifiers. In general, there is a need for a more robust auditing of ACAs with increased attention on whether a certifier's process and qualifications are sufficient to verify compliance and detect fraud. There is significant attention being placed on the performance and qualifications of certifiers and inspectors. However, from an oversight perspective, we argue that even greater emphasis needs to be placed on the performance of USDA auditors and oversight effectiveness. With this in mind, we have identified three critical areas where increased attention is needed as it directly relates to organic fraud prevention: 1) satellite offices; 2) certifier-to-certifier responsiveness; and 3) risk-based accreditation.

Satellite Offices

The ability to provide direct accreditation oversight in a timely manner should be the highest priority for foreign satellite offices. As the current system stands, when a certification decision is made at an operation's headquarters, satellite offices are not required to have direct visits or to be directly accredited. This allows an easier entry of organic fraud into the supply chain, such as the recent fraudulent grain imports from Turkey.

The Organic Trade Association recognizes a potential objection that may be raised with regards to “national treatment.” Namely, the idea that if requirements are imposed on an agency in another country, then it must apply to U.S. entities as well. This creates, according to the WTO, the precedence to a non-tariff barrier to trade. Bearing in mind this concern, we propose the following ideas to improve timely oversight while not conflicting with any trade requirements: 1) eliminate the reference to “foreign” satellite offices; 2) clarify and make readily available the definition and characteristics of a satellite office, and; 3) avoid national treatment by applying the same rules to all offices regardless of location.

Certifier-to-Certifier Responsiveness

The Organic Trade Association continues to hear complaints that accredited certifiers based overseas are not sending requested information to U.S.-based accredited certifiers. Auditing paperwork prior to **export** is essential. Therefore, it is critical that ACAs are responsive to one another, and send the requested documentation needed to audit and verify shipments before they arrive at the port of entry. From a HACCP point of view, a primary critical control point is the **port-of exit**. Verifying the organic product before it leaves the country of origination is the only viable way of assuring an audit of a product back to the field. The development of an NOP pre-clearance program to validate product legitimacy prior to export, prioritizing highest risk geographies for program build-out, is another advisable step for addressing the port-of-exit critical control point. An NOP directive to overseas-accredited certifiers that they **MUST** send the information requested by U.S-based accredited certifiers is needed. Timing should be prescribed.

Risk-based accreditation

Competent and consistent application of USDA’s organic regulations by certifying agents is critical to the success of NOP as is NOP’s responsibility to ensure adequate oversight of each certifying agent. Both are principal factors to protecting organic integrity. As we know, the complexity of each organic operation and the depth of its supply chain vary significantly as do the type and number of factors that create and/or elevate the risk of fraud. It is the responsibility of NOP to assess whether a certifying agent should be authorized to certify farms and businesses to the USDA organic regulations and determine the level of oversight needed to ensure that certifiers are adequately fulfilling their responsibilities.

Given the range of risk factors that contribute to potential fraud, the Organic Trade Association fully supports the concept of risk-based accreditation oversight and the development of criteria to use to guide the process. We agree with the criteria presented in NOSB’s proposal from the fall 2018 meeting titled “**Developing Criteria for Risk-Based Accreditation Oversight**,” and offer the following suggestions/comments:

1. In general, the Organic Trade Association finds the NOSB proposal to be a good start and it addresses many of the known risk factors for fraud. We are advocating for increased levels of performance within the recommended suggestions to increase the effectiveness of the efforts and improve measures of expected outcomes. While identifying risk factors, the proposal appears to only recommend additional actions for accreditors to take when auditing or considering a first application for a certifier with elevated risk factors, rather than requiring adherence to the recommended mitigation activities. Further, the recommended risk mitigation actions are not detailed enough, nor do they provide guidance on if or when the outcomes of the mitigating measures would warrant a finding of non-compliance or prevent a certifier from achieving

accreditation. Perhaps these are meant to be next steps in the process. If so, the proposal should indicate as much.

2. As stated in the proposal, the risk factors are unranked. However, some factors appear to be of much higher risk than others, and we can assume that risk increases depending on the accumulative number of factors that may be in play. For example, a certifier that employs or contracts with inspectors or reviewers new to certification and the organic sector is common. Given appropriate oversight by senior inspectors/reviewers, this factor likely does not pose a huge area of risk. However, this factor combined with one or more of the others will have a different outcome. It may be helpful for NOSB and/or NOP to create a risk matrix defining the level of risk by considering a category of probability or likelihood against a category of consequence severity. This would be a helpful mechanism to increase visibility of risks and assist management of decision-making.
3. NOP and the Accredited Certifiers Association conduct annual certifier trainings around the United States. The NOP annual training is a key opportunity for certifying agents to receive timely information highlighting areas needing performance improvement, and helps maintain certifier consistency with respect to decision-making. The Organic Trade Association believes that attendance is critical, and the trainings should be mandatory. Therefore, moving forward, we believe missing one or more of the NOP annual trainings is a factor that could contribute to a higher risk of fraud. We recommend adding the following risk factor:
 - Certifier misses one or more of the NOP annual trainings
 - Include evaluation of whether the appropriate staff are attending the training
 - Include evaluation of whether the information received at the training is being adequately disseminated to certifier and inspector personnel

EQUIVALENCY AND RECOGNITION AGREEMENTS

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. At this point in time, there are major agreements up for renewal or that are being revised. Historically, the primary method of considering equivalency was through overcoming barriers to differences in practice standards and national list allowances. Now there is a larger consideration of oversight and integrity at the center of these discussions. From the trade side, there is increasing skepticism from the private sector that we are losing data transparency. A solution to mitigate these concerns would be to require other countries maintain a comparable certified organic database to our own. Under equivalency arrangements, there are no requirements outside of import certificates. Therefore, regarding the terms and conditions of equivalency arrangements, the current priorities should focus on compliance oversight by ensuring a competent authority and greater transparency of data.

Separately, communications must be improved between enforcement authorities of trading partners and certification bodies in countries covered by equivalency arrangements and recognition agreements. Ensuring honest and timely communications between these bodies will help achieve the broader goal of oversight and integrity as equivalency arrangements are discussed for renewal. Lastly, regarding recognition agreements, there must be an oversight process to ensure that governmental authorities are in

fact implementing the NOP rule including associated guidance and policy. All equivalency arrangements should be based on systems of comparable rigor and standards, and this follows for continuous compliance assessment. The integrity of the compliance system is pivotal to ensuring the continued success of equivalency arrangements and recognition agreements.

IMPORT CERTIFICATES

As equivalency arrangements were signed, other countries have required export transaction-based documentation, and we have required other countries to present us with an import certificate. Recently, the E.U. has implemented a new technology for import certificates, reducing the utility burden with non-perishable items at the border. The Organic Trade Association is appreciative of NOP's new optional electronic system for imports. There is potential to have this online system account for more than just import transactions, such as greater product traceability from the point of origin to its final point of delivery. This traceability would greatly improve verification of the supply chain and further actions to generate data under equivalency arrangements. However, there are technological barriers that present difficulty when using the system. For example, industry feedback indicates that the program only works with select internet browsers. As with all new technology, testing will be critical for success of the system.

UPDATES TO NONCOMPLIANCE AND APPEALS PROCESS

The process for noncompliance and appeals was one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on "Which parts of the noncompliance and appeal process might NOP need to further clarify?"

In terms of the **noncompliance** process, OTA supports an interpretation of the current regulations that allows correction of minor or administrative noncompliances during the adverse action process to suffice for resolving the noncompliance, even if the issue has advanced to the proposed suspension stage. Examples of minor or administrative noncompliance include: late payment of invoices, late submission of documentation. The use of time, funds, and other resources by certifiers to carry out the noncompliance process for these minor issues that have already been corrected is unnecessary, when these resources could be directed towards major noncompliance and other investigations to assure organic integrity. This interpretation can be implemented through updated training from NOP staff to certifiers.

In terms of **appeals**, 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 strongly encourage NOP to staff itself appropriately so that NOP can respond to appeals in a timely manner (ideally, within 6 months).

INSPECTOR QUALIFICATIONS

Inspector qualifications were one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on "What should the minimum qualifications and training requirements be for organic inspectors?"

Improvement 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. We support the criteria and qualifications laid out in the NOSB Recommendation Inspector Qualifications², as well as the ACA's Guidance on Inspector Qualifications³.

Training of inspectors should be a top priority in ensuring that inspectors are knowledgeable and capable of conducting a rigorous on-site inspection. Critical aspects of inspector training that related to enforcement and fraud detection include: **mass balance audits**, **traceability audits**, and **investigative techniques**. NOP should work closely with the IOIA, ACA, and other qualified organizations to develop training on these skills. On-site shadowing of inspections with an expert mentor inspector should also be a mandatory part of inspector training.

Under NOP's general requirements for accreditation (§205.501), certifiers are required to "Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned." As such, it is the certifier's responsibility to ensure that inspectors are qualified to conduct the inspections for which they are assigned. It is also NOP's responsibility though its accreditation oversight to ensure that certifiers have systems in place to properly evaluate the qualifications of inspectors and ensure that operations are being inspected by an inspector that is appropriately qualified and trained to inspect that particular type of operation.

OTA supports a **licensing system** as a means for inspectors to demonstrate that an inspector is qualified and experienced with the types and scale of operations they are inspecting. A licensing system should ensure inspectors have achieved a baseline understanding of the requirements and process unique to organic certification, and must provide a mechanism for preventing inspectors from inspecting operations for which they do not have adequate expertise and experience. A licensing system can ensure that regardless of the certification body, inspector, or employment status, all inspectors meet a threshold requirement. Such licenses should be issued by organizations that have obtained an appropriate ISO accreditation.

UNANNOUNCED INSPECTIONS

Unannounced inspections were one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on "What should NOP consider about the costs of unannounced inspections?"

OTA supports a regulatory amendment that codifies the requirement for certifiers to conduct unannounced inspections of at least 5% of operations per year. Additional unannounced inspections shall be conducted as needed in response to complaints and investigations.

² <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorqualificationsApril2018.pdf>

³ <https://www.accreditedcertifiers.org/wp-content/uploads/2018/02/ACA-Guidance-on-Inspector-Qualifications-with-IOIA-Evaluation-Checklist.pdf>

OTA does not take issue with the current NOP Instruction 2609 that allow certifiers to “charge an operation for unannounced inspections as long as the fees are clearly disclosed to all certified operations.” Certifiers must clearly disclose to their clients their protocols for unannounced inspections and their fees, should they decide to charge their clients. Many certifiers have integrated the costs for unannounced into their baseline certification fee.

FEDERATED ORGANIC CERTIFICATES

Federated organic certificates were among the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on “What challenges would Certifiers face if required to use a federated organic certificate? Is there an alternative you would suggest?”

OTA supports NOP’s movement towards the use of federated organic certificates (i.e., organic certificates generated within the Organic INTEGRITY database.) The use of federated organic certificates will bring many benefits to the organic sector. Primarily, the certificate will link to the specific relevant certified operation within the Organic INTEGRITY Database. Also, the use of federated organic certificates will bring consistency across certificates used by certifiers, so it is easier to identify a valid certificate and identify fraudulent designs. Additional benefits may be gained by linking aspects of the NOP federated organic certificate system to the EU Trade Control & Expert System (TRACES). It is important that federated organic certificates refrain from including any confidential or sensitive business information.

However, we see significant challenges if certifiers were to be mandated to use only federated organic certificates generated from the Organic INTEGRITY Database. At this point, certifiers are only required to update information in the database once per year, whereas the status of a certified operation’s scope, certified products, and other details may change much more often. It would be unwise to require certifiers to generate certificates from a database of outdated information. Until the Organic INTEGRITY Database is reliably providing accurate and current information for certified operations, federal organic certifications should not be mandatory. Certifiers also need time to fully adopt the taxonomy set by NOP for identifying specific certified organic products covered by the organic certificate.

Instead of moving directly to mandatory federated organic certificates, OTA suggests NOP consider a step-wise approach, with narrow and easily implementable solutions that can be achieved in the short-term to help deter fraudulent certificates. For instance, requiring a common design feature or code will help to support the end goal of increasing consistency among certificates without overburdening certifiers. At the very least, the operation’s ten-digit NOP Operation ID should be required to appear on the certificate so that the operation can easily be connected to its specific relevant entry in the Organic INTEGRITY database. These solutions can be effective in the short term while more significant updates to the Organic INTEGRITY Database are implemented by NOP, and standardization of product taxonomy are implemented by certifiers to populate the database with consistent terminology.

The Organic Trade Association thanks the National Organic Program for reaching out to the organic sector and providing this opportunity to engage early on the upcoming Strengthening Organic Enforcement rulemaking. This type of communication and collaboration build a strong and effective public-private sector relationship.

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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendices

Appendix A – OTCO Independent Storage Information Sheet

Appendix B – Organic Identification on Documents and Labels

APPENDIX B: ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS

OTA's Enforcement Rulemaking task force began to discuss specific regulatory changes that could be effective to implement our suggestions related to organic identification on retail and non-retail labels. Our current thinking is provided below (underlined = new text; ~~strikethrough~~ = deleted text):

§205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in §205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic ingredients in multiingredient products labeled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: Provided, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: Provided further, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in §205.301(a) and (b) must display:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the

product; except when the USDA seal is displayed on the principal display panel.

(21) For products labeled “organic,” identify each organic ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(32) 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.

§205.307 Labeling of non-retail 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)).”

(a) Non-retail containers of organic products used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

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

(24) The USDA seal;

(35) 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.

(b) Non-retail containers of organic products used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display

(1) identification of the product as organic;

(2) name and contact information of the handler which assembled the final product;

(3) name and contact information of the certifying agent which certified the handler which assembled the final product; and

(4) the production lot number of the product if applicable.

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



INDEPENDENT STORAGE INFORMATION SHEET

ISIS

Electronic versions available at www.tilth.org

Page 1 of 2

Operation Name: _____ **Date:** _____

- ▶ The manager of the storage facility must answer the questions below.
- ▶ Copies of the Independent Storage Information Sheet (this form) must be kept by both the OTCO certified operation and the storage facility.

The National Organic Standards section 7CFR205.101(b)(1) allows organic operations to store products at non-certified facilities as long as the products are packaged or otherwise enclosed in a container prior to being received or acquired, the organic products remain in the same package or container, and the products are not repacked or re-labeled while in the control of the storage operation.

1.1 STORAGE LOCATION

Name of Facility:

Manager or Owner:

Phone:

Fax:

Email(s):

Physical Address:

City:

State:

Zip:

Country:

1.2 STORAGE ACTIVITIES

- 1) Does the storage facility implement necessary measures to protect the organic product from contacting prohibited substances such as pesticides?
 Yes No
- 2) Does the OTCO certified operation retain ownership of the product during storage?
 Yes No
- 3) Is the organic product packaged or enclosed in a container prior to being received and does it remain in that enclosed container during storage?
 Yes No
- 4) Do the appropriate records indicate that the product is "organic"?
 Yes No
- 5) Are the records detailed enough to disclose description and amounts of organic products transferred, and to link any lot numbers assigned by the OTCO certified operation with tracking numbers or lot numbers assigned at the storage facility?
 Yes No
- 6) If pesticide fogging is performed or pesticide sprays are applied to areas where packaged or otherwise enclosed organic products are stored, are the organic products removed prior to application or covered with impermeable coverings, or otherwise protected from contacting pesticides and is this documented?
 Yes No NA

2525 SE 3rd Street, Corvallis, OR 97333, 503-378-0690 | 1-877-378-0690 | organic@tilth.org



INDEPENDENT STORAGE INFORMATION SHEET

ISIS

Electronic versions available at www.tilth.org | Page 2 of 2

- 7) Does the storage facility further process the organic product, including sorting, culling, icing or hydro cooling?
 Yes No
- 8) Does the storage facility apply any substance to the organic product or its packaging or container, including water, ethylene or controlled atmosphere treatment?
 Yes No
- 9) Does the storage facility label or re-label the organic product?
 Yes No

In order to qualify as an Independent Storage Facility and not have to undergo an inspection, the answer to questions 1-6 must be "YES" and questions 7-8 must be "NO". If you answer "YES" to question 9 please contact Oregon Tilth.

Name (Facility Manager)

Date

Signature

OTCO reserves the right to inspect any facility storing organic product owned by an OTCO certified operation as specified in 7CFR 205.400. If it is determined that the storage operation has misrepresented policies or procedures as stated on this form, or acts in a manner that might jeopardize organic integrity or tracking of the organic product, the OTCO client using the facility will be notified. They will be held responsible for correcting any noncompliance issues according to the timeline set by OTCO.