

Making more transplants possible for low-income dialysis patients

Though its charitable premium assistance program, the American Kidney Fund (AKF) makes it possible for roughly 100 low-income dialysis patients to receive transplants each month—furthering the Administration’s *Advancing American Kidney Health* goal of increasing kidney transplants.

AKF’s financial assistance was behind nearly 1 in 20 U.S. kidney transplants in 2018:

- In 2018, just over 22,000 patients received kidney transplants in the U.S. (including 836 kidney/pancreas combination transplants).
- AKF provided grant assistance to more than 1,000 recipients who received transplants in 2018.

There are not nearly enough organs available for patients who need them:

- About 113,000 people are on the waiting list for all organs.
- Of those, 85%—more than 96,000—are waiting for a kidney or kidney/pancreas.
- Every 10 minutes another person is added to the transplant list
- 12 people die each day waiting for a lifesaving kidney transplant.

Medicare spending: Transplantation is cost-effective and AKF’s program helps patients and taxpayers

- Per patient per year Medicare spending on dialysis: \$89,367
- Per patient per year Medicare spending on kidney transplant: \$34,780
- Patients who do not have “full” insurance are not accepted onto the transplant list.ⁱ
- Medicare only (without Medigap) is not considered fully insured. Medicare recipients without a Medigap plan will be ineligible for transplant lists.ⁱⁱ
- 45% of AKF’s charitable premium assistance grants are for Medigap.
- However, Medigap policies are not mandated to be available to ESRD patients in nearly half the states.

Private insurance: The Medicare Secondary Payer Rule was implemented to control Medicare costs, and kidney patients have a legal right to stay on their private insurance for 30 months as primary payer before Medicare becomes primary. It is advantageous for ESRD patients who hope to get a kidney transplant to stay on their private insurance because patients with private insurance are more likely to get a transplant.

- **Transplant rates by insurance typeⁱⁱⁱ**
 - Commercial/private: 35% put on transplant waitlist and 22% transplanted
 - Medicare: 22% on transplant waitlist, 12% transplanted
 - Dual-eligible: 25% on transplant waitlist, 11% transplanted
 - Medicaid: 7% on transplant waitlist, 5% transplanted
- **Amount of time on dialysis before being listed^{iv}**
 - Commercial/private: 31.6% listed before initiation of dialysis and 5.4 months on dialysis before listing.
 - Medicare: 7.9% listed before initiation of dialysis and 16.9 months on dialysis before listing.
 - Medicaid: 14.2% listed before initiation of dialysis and 10.4 months on dialysis before listing.
- **Transplanted patients: time on dialysis before transplant^v**
 - Commercial/private: 1.8 years
 - Medicare: 3.8 years

Medicaid: 3.9 years

ⁱ Aleccia, JoNel, "No Cash, No Heart. Transplant Centers Require Proof Of Payment, *Kaiser Health News*, December 5, 2018. <https://khn.org/news/no-cash-no-heart-transplant-centers-require-proof-of-payment/>

ⁱⁱ Jaffe, Susan, "Buying Supplemental Insurance Can Be Hard For Younger Medicare Beneficiaries" *Kaiser Health News*, February 3, 2016. <https://khn.org/news/buying-supplemental-insurance-can-be-hard-for-younger-medicare-beneficiaries-2/>

ⁱⁱⁱ Schold, Jesse D., Jon A. Gregg, Jeffrey S. Harman, Allyson G. Hall, Pamela R. Patton, and Herwig-Ulf Meier-Kriesche. "Barriers to Evaluation and Wait Listing for Kidney Transplantation." *Clinical Journal of the American Society of Nephrology*. Vol 6. (July 2011) 1760-1767. <https://cjasn.asnjournals.org/content/clinjasn/early/2011/05/19/CJN.08620910.full.pdf>

^{iv} Keith, Douglas, Valarie B. Ashby, Friedrich K. Port, and Alan B. Leichtman, "Insurance Type and Minority Status Associated with Large Disparities in Prelisting Dialysis among Candidates for Kidney Transplantation." *Clinical Journal of the American Society of Nephrology*. Vol 3. (March 2008) 463-470. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2390941/>

^v DuBay, Derek A, Paul A MacLennan, Rhiannon D Reed, Brittany A Shelton, David T Redden, Mona Fouad, Michelle Y Martin, Stephen H Gray, Jared A White, Devin E Eckhoff, and Jayme E Locke. "Insurance Type and Solid Organ Transplant Outcomes: A Historical Perspective on How Medicaid Expansion Might Impact Transplant Outcomes." *Journal of the American College of Surgeons*. Vol 223 (4). (Oct 2016) 611-620. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5252827/>

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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 “holding”¹ 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):

- The group is established under a single legal entity.
 - Organic products produced by the group are sold only through the group's legal entity under the group's organic certification.
 - The group sells only organic products produced by the group. Spot purchasing of outside products and re-selling through the group is prohibited.
 - Individual group members must not hold independent organic certification outside of the group.
 - 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.
 - *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.
 - *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; ~~striketrough~~ = 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

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INDEPENDENT STORAGE INFORMATION SHEET

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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.

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



December 2, 2019

Paul Lewis, Ph.D.
Standards Division
National Organic Program
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-11-0009; NOP-11-04PR

RE: Origin of Livestock

Dear Dr. Lewis:

Thank you for this opportunity to provide comment to the USDA National Organic Program (NOP) proposed rule on Origin of Livestock. The USDA has reopened the comment period on the April 28, 2015 proposed rule to amend the origin of livestock requirements for dairy animals under the USDA organic regulations.

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 Organic Trade Association continues to support the Origin of Livestock proposed rule and urges USDA to move expeditiously to a final rule to clarify and narrow the allowance to transition dairy animals into organic milk production as a one-time event. In addition to our comments submitted during the original comment period in 2015 (Attachment 1), we are submitting these additional comments to reflect new information regarding the continued need for consistent enforcement of organic dairy standards. Conditions that prompted rulemaking on origin of livestock have not changed. New information since 2015 only reaffirms the need for rulemaking to clarify and strengthen regulations on origin of livestock.

I. Inconsistent enforcement continues to cause economic harm to farmers

Milk sold or represented as organic must be from livestock that have been under continuous organic management for at least one year. This one-year transition period is allowed only when converting a conventional herd to organic. Once a distinct herd has been converted to organic production, all dairy animals must be under organic management from the last third of gestation. Although these requirements are written in the NOP regulations, certifiers are inconsistently interpreting or enforcing the regulations.

Some USDA-accredited certifiers allow dairies to routinely bring non-organic animals into an organic operation, and transition them for one year, rather than raise their own replacement animals under organic management from the last third of gestation. This practice of continuously transitioning dairy animals is a stark contrast to the letter and intent of the original regulations as described in the preamble to the original final rule. Some USDA-accredited certifiers are also allowing dairies to remove organic dairy animals from a herd, raise them using conventional feed and other prohibited management practices, and then retransition them back to organic. This practice of cycling dairy animals in and out of organic production is a violation of the organic regulations.

Because USDA has not taken action to clarify and enforce the regulations for transitioning dairy animals to organic production, the inconsistent enforcement of certifiers has created conditions where some farmers are put at an economic disadvantage. Farmers who do not raise their own organic replacement animals under organic management from the last third of gestation have lower costs of production. Our analysis indicates that organic dairy farmers who raise their calves under continuous organic management from the last third of gestation spend an average of \$600-1000 more per calf than farmers who raise calves conventionally and transition them to organic at one year of age.

Any cost-benefit analysis of the origin of livestock proposed rule should include the economic disadvantage of the status quo and the economic benefits of the final rule. The calculations presented in the 2015 comments from Select Milk show one view of the economic dynamics at play, although it does not account for the economic harm to the majority of organic farmers who are already complying with the one-time transition policy. OTA members are submitting additional information through the new public comment period that reflect more current and thorough responses to the cost-benefit analysis while taking in to account the changing market dynamics and the economic disadvantage of the status quo.

II. Organic dairy industry is experiencing stagnant growth

A level playing field for organic dairy operations is needed now more than ever. While growth in the organic industry is strong overall, the organic dairy sector is challenged by over-supply and changing consumer interests. According to the *Organic Trade Association's 2019 Organic Industry Survey*, this is the second year in a row that growth has fallen below 1% after experiencing high single-digit to low double-digit growth from 2010 to 2016. The milk and cream subcategory declined 1.3% in 2018, an only slight improvement on the 1.9% loss in 2017. With the downward pressure on dairy prices and slowdown in organic dairy consumption and sales, the importance of fair enforcement of regulatory standards is paramount.

Although the current state of over-supply in the organic milk market may reduce the incentive to expand dairy herds, organic replacement stock is available if/when a farm chooses to do so. OTA members indicate that there is sufficient supply of organic heifers, and that the availability of organic replacement stock is not expected to be a barrier to herd expansion under the final rule.

III. Federal Advisory Committee reiterates need for rulemaking

At the fall 2018 meeting of the National Organic Standards Board (NOSB), at the request of the Organic Trade Association through our public comment, NOSB unanimously passed the following resolution urging the Secretary of Agriculture to directly issue a final rule for Origin of Livestock (Attachment 2):

“It has come to the attention of the National Organic Standards Board (NOSB) that the continued state of varying interpretations and practices around the Origin of Livestock standards is creating market instability for organic producers. The 2015 USDA Origin of Livestock Proposed Rule was based on six recommendations from the NOSB between 1994 and 2006. The proposed rule responds to findings from the July 2013 USDA Office of Inspector General (OIG) audit report on organic milk operations stating that certifying agents were interpreting the origin of livestock requirements differently¹. Rulemaking is necessary to ensure consistent interpretation and enforcement of the standards for origin of livestock and provide industry with additional clarity of application of the organic dairy standards. In early 2017, the Origin of Livestock Proposed Rule was removed from the government’s Unified Agenda of Regulatory and Deregulatory Actions. Support for this rule has been expressed through public comment by the majority of organic stakeholders². Strong federal oversight is essential for creating a fair and level playing field for all certified organic operations. Therefore be it resolved by unanimous vote, the National Organic Standards Board—as USDA’s Federal Advisory Board on organic issues and representing organic farmers, ranchers, processors, retailers and consumers—urges the Secretary to directly issue a final rule for Origin of Livestock that incorporates public comments submitted in response to the Proposed Rule (Docket Number AMS-NOP-11-0009).

¹ <https://www.usda.gov/oig/webdocs/01601-0002-32.pdf>

² <https://www.regulations.gov/docket?D=AMS-NOP-11-0009>”

IV. Organic dairy industry in agreement that rulemaking is needed

The organic dairy industry is united in agreement that final rulemaking on origin of livestock is needed to clarify that dairy herd transition is one-time event. In February 2019, the Organic Trade Association’s Dairy Sector Council sent a letter to USDA urging the agency to publish a final rule (Attachment 3). The signatories on the letter represented over 90 percent of the current U.S. organic dairy market. From small family farms to some of the largest organic dairies and companies in the world, the organic dairy industry united to demand strong and consistent standards.

V. Congress directs USDA to issue a final rule

The prolonged inaction of USDA to complete final rulemaking on origin of livestock has caught the attention of Congress. Congress has demonstrated strong bi-partisan support for this important organic issue. Both the House and Senate Agriculture Appropriations bills for Fiscal Year 2020 requires USDA to issue a final rule on the Origin of Livestock within 180 days of enactment of the law (Attachment 4 & 5):

“Not later than 180 days after the date of the enactment of this Act, the Secretary of Agriculture shall issue a final rule based on the proposed rule entitled “National Organic Program; Origin of Livestock,” published in the *Federal Register* on April 28, 2015 (80 Fed. Reg. 23455): *Provided*, That the final rule shall incorporate public comments submitted in response to the proposed rule.”

The House Agriculture Subcommittee on Biotechnology, Horticulture, and Research has hosted two hearings on organic industry issues in 2019. In both hearings (Attachment 6 & 7), the need for rulemaking on origin of livestock is referenced.

- At the hearing on July 17, 2019, *Assessing the Effectiveness of the National Organic Program*, Chairwoman Stacey Plaskett inquired with USDA-AMS about the status of rulemaking on origin of livestock. Other committee members including Congresswoman Kim Schrier and Congresswoman Chellie Pingree urged USDA to move forward with origin of livestock rulemaking.
- At the hearing on October 30, 2019, *State of Organic Agriculture*, Chairwoman Stacey Plaskett inquired with witness and organic dairy farmer Steve Pierson of Organic Valley about the need for rulemaking on origin of livestock.

VI. Longstanding need for regulatory clarification is well-documented in USDA record

The need to clarify this aspect of the organic regulations has been needed for some time.

- The National Organic Standards Board began working to clarify origin of livestock standards in 1994 and has developed six recommendations between then and 2006 (Attachments 8-11).
- In the preamble to the final regulations published in 2000 that established the National Organic Program regulations, USDA-AMS explained that the intent of the regulation is that whole herd transition is a one-time event (Attachment 12).
- In 2006, AMS stated that the issue of inconsistent allowances for replacing organic dairy animals is a significant concern of the organic community, and that additional clarity is needed regarding the transition of dairy animals in to organic production (Attachment 13).
- The July 2013 Office of Inspector General audit report identified inconsistencies in the implementation of the origin of livestock requirements, and noted that such inconsistencies lead to some producers having competitive advantage over others (Attachment 14).
- As stated in the 2015 Origin of Livestock Proposed Rule, “AMS has determined that the current regulations regarding the transition of dairy animals and the management of breeder stock on organic operations need additional specificity and clarity to improve AMS’s ability to efficiently administer the NOP.”

VII. Highlights of OTA’s previously submitted comments on the proposed rule

We submitted comments on the Origin of Livestock proposed rule during the original comment period (Attachment 1). Those comments still stand, with one exception: instead of an 18-month implementation period as requested in 2015, we now support immediate implementation of a final rule on origin of livestock.

In our previously submitted comments, we expressed support for the proposed rule that clarifies that the one-year transition period for converting conventional dairy animals to organic is a one-time event. The proposed rule will be effective in eliminating much of the uneven playing field that organic dairy producers currently face under the existing regulations. Under the proposed rule, operations that are not milking cows will not be allowed to purchase conventional calves, raise them for one year organically, and then sell them to organic dairies. Additionally, organic dairy farms will not be allowed to continuously transition in replacement animals. Instead, after they have transitioned to organic production

once, all replacements will need to be raised organically from the last third of gestation. These outcomes align with the intent of the original regulations as described in the preamble to the original final rule.

In order to ensure the rule levels the playing field among organic livestock producers in a way that is easily understandable to the entire organic supply chain, we feel that the following changes must be incorporated into the final rule:

- One-time transition should be tied to each individual “certified operation” rather than “producer” because this term and approach are better understood by the entire organic supply chain and accomplish the same restrictions in how origin of livestock is regulated on organic dairy operations.
- Breeder stock used to produce organic offspring should not be allowed to rotate in and out of organic production, and the regulations should reflect the language contained in the Organic Foods Production Act (OFPA), which allows the purchase of non-organic breeding stock from any source.
- Third-year transitional crops fed to transitioning dairy animals must be produced on the certified dairy operations and described in its Organic System Plan (OSP).
- Disallowing a one-time transition for fiber-bearing animals puts U.S. livestock producers at a global disadvantage in accessing organic textile markets, and thus fiber animals should be allowed to be transitioned into organic production like dairy animals.

VIII. Widespread support during original public comment period in 2015

Public comments submitted during the original comment period (4/28/2015 - 7/27/2015) reflected widespread consensus and support for the proposed rule. A total of 1,570 comments were submitted and less than 1% of commenters opposed the rule. The other 99% of comments including form-letters were not opposed (either wholly supportive, or supportive with suggestions for the final rule).

Certifiers, advocacy groups, certified operations, consumers and hundreds of other stakeholders commented in support of regulations that would limit transition to a one-time event. Substantive comments highlighted some areas of the proposed rule that would need clarification in order to clarify the intent of the rule and ensure consistent implementation of the final rule (a selection of such comments from OTA members are provided in Attachments 15-24). USDA would need to consider these points and determine a clear path forward in the final rule.

Conclusion

The Organic Trade Association continues to support the Origin of Livestock proposed rule and urges USDA to move expeditiously to a final rule to clarify and narrow the allowance to transition dairy animals into organic milk production as a one-time event. Clarification is long overdue and is critical to leveling the playing field among organic dairy producers. Conditions that prompted rulemaking on origin of livestock have not changed. New information since 2015 only reaffirms the need for rulemaking to clarify and strengthen regulations on origin of livestock. The importance of rulemaking is acknowledged by USDA throughout the historical administrative record. The organic industry, the National Organic



Standards Board, and Congress all support the USDA in moving forward to implement final rulemaking on origin of livestock.

Respectfully submitted,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

List of Attachments (please note the PDF bookmark feature to navigate attachments)

1. Organic Trade Association's comments submitting during the original comment period in 2015
2. National Organic Standards Board resolution on Origin of Livestock from fall 2018
3. Organic Trade Association's Dairy Sector Council letter to USDA
4. Senate Agriculture Appropriations bill for Fiscal Year 2020
5. House Agriculture Appropriations bill for Fiscal Year 2020
6. Transcript from Congressional Hearing, July 17, 2019
7. Transcript from Congressional Hearing, October 30, 2019
8. NOSB Recommendation, Livestock Sources, 1994
9. NOSB Recommendation, Origin of Livestock, Fall 2002
10. NOSB Recommendation, Origin of Livestock, Spring 2003
11. NOSB Recommendation, Breeder Stock, Spring 2003
12. NOP Final Rule, December 21, 2000 (65 FR 80548)
13. NOP Final Rule, June 7, 2006 (71 FR 32804)
14. Office of Inspector General audit report, July 2013
15. Organic Valley, 2015
16. Stonyfield, 2015
17. WhiteWave, 2015
18. Harmony Organic Dairy, 2015
19. Fagundes Family Farm, 2015
20. WODPA, 2015
21. CCOF, 2015
22. OTCO, 2015
23. QAI, 2015
24. ACA, 2015

July 27, 2015

Scott Updike, Agricultural Marketing Specialist
National Organic Program, USDA-AMS-NOP
1400 Independence Ave., SW
Room 2646-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-11-0009; NOP-11-04PR

Re: Origin of Livestock Proposed Rulemaking

Dear Mr. Updike:

The Organic Trade Association (OTA)¹ would like to thank the National Organic Program (NOP) for releasing the proposed rule on Origin of Livestock. The need to clarify this aspect of the organic rule in the regulations has been needed for some time. OTA has convened an industry task force that represents the entire organic supply chain (producer, processor, and certifier) to shape our comments to NOP on the proposed rule. In 2011, OTA convened an industry task force that formed the basis for our white paper submitted to NOP on the topic. This white paper is attached to our comments as Appendix A for historical reference.

NOP's proposed rule ties the one-time transition for organic dairy cows to the NOP defined term "producer" and eliminates much of the uneven playing field that organic dairy producers currently face. Operations that are not milking cows will not be allowed to purchase conventional calves, raise them for one year organically, and then sell them to organic dairies. Additionally, organic dairy farms cannot continuously transition in replacement animals. Instead, after they have transitioned to organic production once, all replacements will need to be raised organically from the last third of gestation. We applaud NOP for this effort.

However, consistent with our position expressed in the 2011 white paper, we continue to feel that the one-time transition should be tied to the NOP defined term "certified operation"² rather than "producer³," as this better accommodates the various business structures engaged in the organic dairy industry and more clearly articulates who is eligible for a one-time transition, allowing for more effective enforcement from

¹ 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 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

² **§ 205.2 Certified operation.** A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

³ **§ 205.2 Producer.** A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products



Accredited Certifying Agents (ACAs). Below, we provide background and comments to support our position on tying transition to the “certified operation” as well as additional comments and suggestions on how to further clarify and implement the intent of the origin of livestock provisions of the USDA organic regulations.

Background

NOP proposes tying the allowance for a one-time transition for organic dairy cows to the “producer” rather than to an “entire distinct herd” as it is now in the existing regulations. This proposed rule will represent a significant shift in how organic businesses are regulated and how they will need to plan for future growth. We would like to acknowledge that the proposed rule does eliminate much of the uneven playing field that organic dairy producers have faced under the existing regulations. The proposed rule, as written, would prohibit continuous transitioning of animals on any given operation whether it be a heifer development facility, where non-organic heifers are routinely transitioned to organic dairy production over the course of 12 months and then sold or transferred to organic dairies, or an organic dairy that routinely purchases non-organic replacement heifers and transitions them to organic dairy production on an ongoing basis.

By eliminating the regulatory allowance for these two systems that continuously bringing in non-organic replacements onto an organic operation, NOP aligns the regulations with the intent of the original regulations, which are enumerated in the preamble to the final rule published in 2000:

FR 65:12-21-2000, p. 80570:

“After the dairy operation has been certified, animals brought on to the operation must be organically raised from the last third of gestation. ... Finally, the conversion provision cannot be used routinely to bring non-organically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.”

The 2015 origin of livestock proposed rule’s regulatory changes prevent producers from routinely bringing non-organically raised animals into an organic operation, and acknowledge that the one-time transition is meant to be a conversion strategy for each distinct operation. We agree with this change in approach to transition allowance.

In the preamble to the proposed rule, NOP released a number of scenarios to explain how the proposed rule will affect various types of dairy operations and business structures. However, there remains a significant lack of clarity on how the proposed rule will affect the myriad of business types and structures currently engaged in the organic livestock industry. In order for OTA’s stakeholders to provide comment to NOP, we felt it was necessary to develop further analysis of the effects the proposed rule would have on the industry. The scenarios and analyses used to form the basis of OTA’s comments look at each scenario under the current regulations, the NOP proposed rule, and OTA’s 2011 white paper suggestions. This analysis is attached below in Appendix B.

We offer the following summary and more detailed comments on where we feel changes to the proposed rulemaking action are warranted.

Summary:

- One-time transition should be tied to each individual “certified operation” (that meets the definition of a proposed new term: “dairy operation”) rather than “producer” because this term and approach are better understood by the entire organic supply chain and accomplish the same restrictions in how origin of livestock is regulated on organic dairy operations.
- Breeder stock used to produce organic offspring should not be allowed to rotate in and out of organic production, and the regulations should reflect the language contained in the Organic Foods Production Act (OFPA), which allows the **purchase** of non-organic breeding stock from any source.
- Third-year transitional crops fed to transitioning dairy animals must be produced on the certified dairy operations and described in its Organic System Plan (OSP).
- Issuance of a final rule should include an 18-month implementation period to allow adequate time for businesses to adjust their practices and for education and enforcement of the rule revisions.
- Disallowing a one-time transition for fiber-bearing animals puts U.S. livestock producers at a global disadvantage in accessing organic textile markets, and fiber animals should be allowed to be transitioned into organic production like dairy animals.

Tie transition to “Certified Operation”

In OTA’s 2011 white paper on the origin of livestock issue, we suggested that one-time transition be tied to an individual certified operation. The majority of OTA’s recently assembled task force on origin of livestock continues to support tying one-time transition to each certified dairy operation. This change levels the playing field for dairy producers while also using defined terms easily understood by the entire organic supply chain. Accredited Certifying Agents (ACAs) assign responsibility, issue certificates, or administer adverse actions for each “certified operation,” and organic businesses make specific production decisions for each individual “certified operation” and its corresponding OSP. The various scenarios explored in Appendix B show that the proposed rule, and, specifically, the decision to tie one-time transition with each “producer,” will have dramatically different effects on various operations simply based on the way the owners choose to structure their businesses.

Additionally, one-time transition should only be allowed for operations currently certified, or applying for certification, to produce **organic** milk. We support including an additional definition, so that operations not actually producing organic milk cannot transition dairy animals. However, we remain concerned that NOP’s proposed definition for “dairy farm” may not fully achieve its goal. As such, we suggest NOP eliminate the term “dairy farm” and its proposed definition, and utilize the term “dairy operation” with the following definition:

Dairy operation. An operation or portion of an operation that is certified or is applying for certification of organic livestock and production of organic milk or milk products.

By utilizing this term to determine which types of operations are eligible for a one-time transition of its dairy animals, it is clear that the operation must be either currently, or working towards, producing certified organic dairy. Tying one-time transition to a distinct “certified operation” that meets the suggested definition for the new term “dairy operation” will level the playing field for organic dairy producers in the ways the sector has requested, utilize terms and definitions that are easier for operations to understand, and align with how ACAs currently enforce the organic regulations.

Breeder stock

NOP's proposed rule reiterates OFPA's ongoing allowance for non-organic breeder stock to be purchased from any source, brought onto an organic operation, and produce organic offspring, provided the breeder stock are managed organically for the last one-third of gestation. This reiteration comes despite NOSB recommendations and stakeholder feedback that recommended NOP to prevent the cycling of breeder stock in and out of organic management. OTA understands NOP's position and interpretation of OFPA. However, we feel that by amending the regulations to reflect the actual written text of OFPA, which specifies that non-organic breeder stock may be **purchased** from any source, the concern that breeder stock will regularly cycle in and out of organic management will be drastically reduced.

OFPA: §6509. Animal production practices and materials (b) Breeder stock Breeder stock may be purchased from any source if such stock is not in the last third of gestation.

Current Regulations: § 205.236(a)(3) Livestock used as breeder stock may be brought from a non-organic operation onto an organic operation at any time: **Provided**, that, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

Suggested Regulatory Change: § 205.236(a)(3) Livestock used as breeder stock may be brought purchased from a non-organic operation and brought onto an organic operation at any time: **Provided**, that, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.

While this regulatory change may not fully prevent the cycling of breeder stock in and out of organic management, it is certainly within NOP's scope of authority and will require any non-organic breeder stock brought onto an organic operation to have been **purchased** from a separate entity. This would provide a substantial disincentive to the cycling of breeder stock in and out of organic management and align better with the consensus of organic stakeholders and NOSB recommendations.

Third-year transitional feed

The current regulations clearly state that dairy operations in their last year of transition can feed transitioning dairy cows third-year transitional feed provided it originates from the farm and is described in the OSP (§ 205.236(a)(2)(i)). The proposed regulations attempt to convey the same restriction, but fall short because the requirement that third-year transitional feed originate on the farm and be described in the OSP is included in the definition of "third-year transitional crop" and is not tied, specifically, to the operation transitioning the dairy animals. OTA suggests amending the proposed regulations as follows to avoid this potential confusion:

§205.236(a)(2)(iii): During the 12-month period, dairy animals and their offspring may consume third-year transitional crops from land included in the organic system plan of the certified dairy operation;

We acknowledge that any animal born during a one-time transition where third-year transitional feed is provided, as part of the ration is, itself, considered a "transitioned" animal and not eligible for organic slaughter. However, it is important to ensure that all third-year transitional feed is sourced from the operation undergoing the transition.

Implementation period

OTA feels that an 18-month implementation period should accompany issuance of a final rule on origin of livestock. Organic farmers cannot develop their operations based on NOSB recommendations or proposed rules, and until a final rule is issued, they will be unsure of exactly what modifications are necessary to comply with the new regulations. For this reason, an implementation period should be standard practice upon issuance of any rule change. It takes two years to bring a new dairy animal into organic production, and currently, the availability of organic replacement animals varies widely from region to region. Since the change to the origin of livestock rule will reduce the availability of replacement animals eligible to be milked organically and reduce the available genetics for herd improvement, we feel that an implementation period is warranted to allow currently certified dairy operations time to adjust their strategies for sourcing replacement animals. Similarly, ACAs will be unsure how exactly to communicate the changes to the rule to certified operations and modify their existing forms and enforcement procedures until the final rule is issued. Eighteen months ensures a full certification cycle occurs for all operations before full adherence with the final rule is enforced. Based on this realistic approach to how USDA organic regulations are adopted by certified organic operations and administered on the ground by ACAs, OTA believes that an 18-month implementation period is appropriate.

Fiber-bearing animals

OTA acknowledges NOP's conservative reading of the exception OFPA grants to transition only dairy animals to organic production as the basis for excluding fiber animals from a one-time transition to organic fiber production. However, we want to also acknowledge the parallel between dairy and fiber and the contrast these two products have to meat. Allowing organic dairy products to come from transitioned animals while requiring that organic fiber must come from animals managed organically from the last third of gestation creates its own uneven playing field and sets US organic producers at a disadvantage in the global marketplace. Currently, existing sheep producers who enter the organic lamb market are essentially locked out of the organic fiber market until their entire breeding flock has been replaced by animals managed organically from the last third of gestation, since comingling issues make shearing mixed flocks (i.e., flocks of breeding ewes that are both non-organic and organic) unrealistic. Fiber obtained from animals that are transitioned in the same manner as organic dairy cows should be allowed to be labeled as "organic" and enter the organic textile market. This will put organic producers in the U.S. on the same playing field as their international counterparts and provide access to a growing global market in organic textiles and fiber.

Conclusion

We welcome the proposed rule on origin of livestock and wish to see its swift move to final rule. However, in order to ensure the rule levels the playing field among organic livestock producers in a way that is easily understandable to the entire organic supply chain, we feel that the following changes must be incorporated into the final rule:

- ☐ One-time transition should be tied to each individual "certified operation" (that meets the definition of a proposed new term: "dairy operation") rather than "producer" because this term and approach is better understood by the entire organic supply chain and accomplishes the same restrictions in how origin of livestock is regulated on organic dairy operations.
- ☐ Breeder stock used to produce organic offspring should not be allowed to rotate in and out of organic production, and the regulations should reflect the language contained in the Organic Foods



Production Act (OFPA), which allows the **purchase** of non-organic breeding stock from any source.

- ☐ Third-year transitional crops fed to transitioning dairy animals must be produced on the certified dairy operations and described in its Organic System Plan (OSP).
- ☐ Issuance of a final rule should include an 18-month implementation period to allow adequate time for businesses to adjust their practices and for education and enforcement of the rule revisions.
- ☐ Disallowing a one-time transition for fiber-bearing animals puts U.S. livestock producers at a global disadvantage in accessing organic textile markets, and thus fiber animals should be allowed to be transitioned into organic production like dairy animals.

OTA would also like to acknowledge that the rule change may have a significant effect on the availability of diverse genetics for herd improvement. Not all offspring are suitable for certified organic production, and we may see this rule change restrict the availability of good genetics for organic dairy. Nevertheless, leveling the playing field for organic livestock producers, so the industry can continue to grow while maintaining consumer confidence in the organic label, is critical, and this proposed rule accomplishes most of these goals.

On behalf of our members across the supply chain and the country, OTA thanks NOP for this opportunity to comment on the proposed rule making on origin of livestock in organic production.

Sincerely,

Nathaniel Lewis
Senior Crops and Livestock Specialist
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

APPENDIX A: OTA White Paper on Origin of Livestock – 2011

-See attachment below

APPENDIX B: OTA Analysis of Current Regulations, Proposed Rule, and OTA 2011 White Paper Suggestions

Scenario	Current practices allowed under existing regulations	Allowance under proposed regulations tying transition to the “producer” and “person”	Allowance under OTA recommendation tying transition to the “operation” or certificate
Producer converting an existing conventional dairy	Allowed to transition a single	Allowed to convert a single distinct herd	Allowed to convert a single distinct herd after

farm		distinct herd after which all replacement animals must be organic from last third of gestation	after which all replacement animals must be organic from last third of gestation	which all replacement animals must be organic from last third of gestation
Producer starting a new single dairy farm		Allowed to transition conventional animals to organic on an ongoing basis if there was no single distinct herd transitioned at the onset	Only allowed to undergo a single transition period of 12 months. All animals must end transition at the same time and after transition, all replacement animals must be organic from last third of gestation	Only allowed to undergo a single transition period of 12 months. All animals must end transition at the same time and after transition, all replacement animals must be organic from last third of gestation
Producer starting more than one new dairy farm or converting more than one existing conventional dairy farms	Sole proprietor / individual who owns all farms	No distinction between operators who own a single operation or multiple operations in current rules	Since the same “producer” owns the various dairy farms, he/she is only allowed to undergo a single transition period of 12 months for all farms . All animals must end transition at the same time on all farms , and after transition, all replacement animals must be organic from last third of gestation	Each dairy farm has its own certificate and is considered its own distinct “certified operation” regardless of the farmer’s choice in business structure. Therefore, each dairy farm is allowed to undergo its own single transition period of 12 months. All animals on any given farm must end transition at the same time, and after transition, all replacement animals must be organic from last third of gestation.
	Individual who has established separate businesses entities for each dairy farm	No distinction between operators who own a single operation or multiple operations in current rules	Since each dairy farm is owned by a separate “producer” (i.e., individual business entities), each dairy farm is allowed to undergo its own single transition period of 12 months. All animals on any given farm must end transition at the same time, and	Each dairy farm has its own certificate and is considered its own distinct “certified operation” regardless of the farmer’s choice in business structure. Therefore, each dairy farm is allowed to undergo its own single transition period of 12 months. All animals on

			after transition, all replacement animals must be organic from last third of gestation.	any given farm must end transition at the same time, and after transition, all replacement animals must be organic from last third of gestation.
Producer who previously transitioned a herd, stopped farming, and is starting a new dairy farm	No restriction on farmers who had previously transitioned a herd, stopped farming (sold the cows), and would now like to transition in a new herd – he/she could transition in a new distinct herd or buy conventional animals and continuously transition them.	Since one-time transition is tied to a “producer,” and he/she used that one time with the previous herd, this dairy farmer would need to purchase only transitioned or last third organic cows to start the dairy again. However , if the dairy farmer establishes a distinct business structure or “person” (e.g., LLC), then the new distinct business structure could transition in a new conventional herd.	Starting a new dairy farm would be considered a new certified operation with a distinct OSP, and the operation would be eligible for a one-time herd transition on this “new” dairy farm, regardless of whether they transitioned a previous herd.	
Producer who purchases an existing organic dairy farm that has completed transition	Allowed to bring on additional conventional replacements and transition them provided the previous dairy farm had not transitioned a distinct herd.	The new producer would be allowed to continue to milk the existing organic herd and to undergo a one-time transition to grow or replace the herd. After such a transition, all replacement animals must be organic from the last third of gestation.	The new producer would be establishing a new “certified operation” with its own new OSP and, accordingly, would be allowed to continue to milk the existing organic herd and to undergo a one-time transition to grow or replace the herd. After such a transition, all replacement animals must be organic from the last third of gestation.	
Heifer-Rearing Operations (Proposed definition of “dairy farm”)				
Producer with a heifer-rearing operation	Allowed to continuously bring in conventional heifers and	Producers cannot transition dairy animals unless they meet the proposed		

	transition to organic dairy production	definition of a “dairy farm,” AND producers are only allowed one transition, so continuous transition of heifers would be prohibited	
Cow-Calf Operations (Proposed treatment and consideration of “Breeder Stock”)			
Producer with a cow-calf operation that only manages breeder stock organically from last third of gestation through weaning of organic young stock	Inconsistent allowances currently with beef operations who manage breeder stock organically from last third of gestation through weaning of organic young stock and then rotate breeder stock back to conventional production	Proposed regulations indicate that NOP does not have authority over management of breeder stock outside of the last third of gestation and nursing of young organic stock	OTA white paper calls for NOP to develop regulations that prevent breeder stock from rotating in and out of organic management

The Organic Trade Association (OTA)
Origin of Livestock Task Force White Paper/ Recommendation

The Organic Trade Association (OTA) is pleased to have the National Organic Program (NOP) prioritize the much needed clarification to the Origin of Livestock standards within the standards development work plans and urges swift completion of the rule making process.

We thank you for the opportunity to provide input in advance of formal rule-making regarding the Origin of Livestock provisions of the National Organic Standards (NOS). Since its founding in 1985, OTA has been the leading voice for the organic business community. OTA has 1,500 members across all parts of the supply chain, including organic farming, processing, distribution, and the retail sector. The dairy and slaughter livestock members of the OTA represent most of the organic meat, milk and dairy products produced and sold across the United States. OTA members include organic farms, suppliers, processors, certifiers, retailers and local, regional and national farmer groups.

In addition to six months of Task Force deliberation, OTA's Origin of Livestock Task Force also sought input from the broader organic community on the Origin of Livestock provisions by hosting an open round table discussion after the scheduled close of the November NOSB meeting on Wednesday November 4, 2009, in order to further industry consensus in advance of rulemaking regarding origin of livestock. The meeting was widely attended by farmers, processors, certifiers, NGOs and consumer groups.

In anticipation of rule making by the NOP on the issue of Origin of Livestock, OTA proposes several changes to the NOS § 205.236 that will clarify and simplify the regulatory language to ensure consistent interpretation.

- ☐ For 205-236(a)(2)(i-iii), dairy animals, we propose language focusing on the operation rather than the herd, suggest that a transition be a one-time event, and the exception to the last third requirement.
- ☐ For 205-236(a)(3), breeding stock must be maintained organically from their arrival at the certified operation and cannot go in and out of organic production
- ☐ For 205-236(b), prohibitions, we simply note that if our proposals for 236(a)(2)(i-iii) were to be accepted, the current (b)(1) would be unnecessary.
- ☐ For 236 in general, we propose revising the section on replacement dairy stock requiring farms raising replacements to sell only stock that has been raised organically from the last third of gestation.

Situation Overview¹

There is consensus within the organic community/industry that the NOP regulations on Origin of livestock for dairy animals are in urgent need of clarification through rule making. The OTA recommendation for clarifying the Origin of Livestock practice standard is based three common goals:

- ☐ First, the standard must be understandable by all parties with consistent interpretation,
- ☐ Second, there needs to be a single standard that applies to all producers regardless of date of entry into organic production and,
- ☐ Third, the standard needs to be enforceable.

It is clear from the preamble language that the intent of the regulation is for transition to be a one-time event.

FR 65:12-21-2000, p. 80570:

“After the dairy operation has been certified, animals brought on to the operation must be organically raised from the last third of gestation. . . . Finally, the conversion provision cannot be used routinely to bring non-organically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.”

The NOP has acknowledged in the proposed rule on pasture that the current language of the rule allows for a double standard regarding replacement animals – allowing some farmers to continue to buy non organic replacement animals, depending on the method they used to initially convert their farms to organic production. Clarification of the rule is essential to eliminate this problem. The OTA task force calls for regulatory language that states clearly what the preamble expresses.

The need for resolution of these issues is urgent, as various certifiers interpret the regulation differently, farmers are held to differing standards, creating un-level playing field.

OTA's recommendations span the Origin of Livestock Practice Standard 205.236 impacting 205-236(a) (2) i-iii dairy animals, 205-236(a)(3) breeding stock and 205-236(b) prohibitions. The recommendation intentionally excludes clarification to poultry standards focusing on origin of livestock for dairy and breeder stock.

¹ The following comments represent OTA's input to NOP. While individual trade association members may have divergent views on some specific issues, overall the following recommendations represent the consensus view of OTA's membership.

In regards to clones and progeny of clones, OTA understands that the tracking and identification of progeny across multiple generations is challenging and trying to solve that problem in this rulemaking could stall the much needed resolution to questions regarding issues of livestock replacement and breeding stock. OTA recommends additional clarification in the future on the progeny issue.

Recommended Regulatory Language

OTA proposes language focusing on the operation rather than the herd, suggest that a transition be a one-time event, and propose rules for that transition.

Recommended changes

(a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: *Except, That:*

(2) Dairy animals.

- (i) A dairy operation may undergo a one time transition to organic during which time all animals that are to be part of the organic operation are under continuous organic management beginning no later than one year prior to production of milk or milk products that are to be sold, labeled, or represented as organic; and
- (ii) All animals must be converted at the same time, including young stock. Maintaining young stock as non-organic after conversion is prohibited.
- (iii) Crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and
- (iv) Once an ~~entire, distinct herd~~ operation has been converted to organic production, all dairy animals shall be under continuous organic management from the last third of gestation.

(3) Replacement dairy stock - Organic and transitioning operations must only use replacement heifers that are organic since the last third of gestation.

There was considerable discussion within the task force regarding how the regulation could be written in a way that makes clear that an operation whose Organic Systems Plan (OSP) and business model is oriented to raise replacement stock is operating under the last third requirement exclusively and that certified operations rely on last third replacement; but at the same time allows for the reasonable sale/ gifting of certified organic dairy cows (regardless of whether

they are last third or transition to organic production) between farms. Members of the task force raised the example of a young couple starting out and receiving as a gift from within their 'community' an organic dairy cow for their herd and how to allow for a transitioned animal to change ownership. Or for example a farm that is forced to sell their herd due to financial distress or illness and the operation has invested in transition and incurred increased production costs along the way. Is there a way to recoup the costs and sell the herd as certified organic when it may contained animals transitioned under the one-time transition allowance? Certainly these are not large scale examples that effect the majority of producers but the task force was concerned about maintaining an on the ground sensible regulation. OTA does not have specific recommend language to address these circumstances but rather raises the issue for NOP consideration.

(4) Breeder stock. ~~Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: Provided, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.~~ Non-organic breeder stock may be used to produce organic offspring if the breeder stock is managed organically during the last third of pregnancy. Once such breeder stock is used to produce organic offspring it:

- (i) Must be maintained under continuous organic management,
- (ii) Must not cycle in and out of organic management², and
- (iii) May nurse their organic offspring³,
- (iv) Male breeder stock may be used at any time, and are not required to be managed organically.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an organic operation ~~production~~ and subsequently managed on a non-organically operation may be not sold, labeled, or represented as organically produced or have their products sold, labeled, or represented as organic.

(2)-Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

² Consistent with the 2003 NOSB recommendation approved by the full board, OTA recommends clarification to prevent the re-transition of breeder stock in and out of organic production. Requiring breeder stock to be kept in organic management once brought onto an organic operation would simplify tracking of animals and prevent a scenario where the same animal is in and out of organic management based on where she is at in the gestation cycle.

³ In the Q&A on the NOP website, NOP has clarified that organically managed breeder stock can nurse her own calf, but cannot be milked and that milk fed to groups of calves or sold as organic. OTA recommends codifying this in the regulation.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and non-edible animal products produced on the operation