

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – Exemptions from Certification

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

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

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

OTA supports:

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

OTA does not support:

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

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

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

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

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

OTA further recommends:

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

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

NOP Questions

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

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

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

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

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

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

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

OTA’s Positions and Recommendations

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

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

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

Clarification of applicability

Definition of 'Handle'

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

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

Customs Brokers and Freight Forwarders

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

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

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

Definitions of ‘Handler’ and ‘Handling Operation

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

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

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

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

Clarification of exemptions from certification

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

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

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

Exemptions retained by the proposed rule

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

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

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

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

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

Exclusions removed from the proposed rule

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

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

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

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

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

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

See OTA’s requested revision in Table 1

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

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

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

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

Clarification of the retail operation exemption

Retail Operation – New Term and Definition

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

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

See OTA’s requested revision in Table 1.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Retail Operations and Distribution Centers

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

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

Retail Operations and Private-Label Arrangements

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

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

Guidance and Increased Oversight of Exempt Retail Operations

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

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

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

Exemption for storage of organic agricultural products

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

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

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

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

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

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

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

Transport of organic agricultural products

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

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

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

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

See OTA’s requested revisions in Table 1

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

Certified operations' verification and recordkeeping responsibilities

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

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

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

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

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

See OTA’s requested revisions in Table 1

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

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

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

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

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

§205.270 Organic handling requirements.

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

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

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

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

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

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

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

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

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

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

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

Respectfully submitted,



Gwendolyn Wyard
 Vice President, Regulatory and Technical Affairs



Johanna Miranda
 Farm Policy Director

cc: Laura Batcha
 Executive Director/CEO
 Organic Trade Association

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: FDA Definitions for FSMA

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

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

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

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

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