



**NATIONAL
ORGANIC
COALITION**

Strengthening Organic Enforcement Rule Analysis

January 31, 2023

Strengthening Organic Enforcement Rule Analysis

Agenda overview

NOC will provide our analysis of key provisions in the rule and its impact on organic operations and certification agencies. This is a complex rule, so we will also identify questions that remain about how the rule will be implemented.

We will discuss:

- What the final rule includes and how it is different from the proposed rule.
- NOC's analysis of the rule – the good, the bad, and the ugly.
- We will discuss what questions remain regarding how the rule will be implemented.

Hang on, friends...we're in for quite a ride...



§ 205.2 Terms defined – 19 total

<i>Adverse Action</i>	<i>Certification Activity</i>	<i>Certification Office</i>
<i>Certification Review</i>	<i>Conformity Assessment System</i>	<i>Handler</i>
<i>Internal Control System</i>	<i>Organic Exporter</i>	<i>Organic Fraud</i>
<i>Organic Importer</i>	<i>Organic Integrity Database</i>	<i>Producer Group Member</i>
<i>Producer Group Operation</i>	<i>Producer Group Production Unit</i>	<i>Retail Establishment</i>
<i>Supply Chain Traceability Audit</i>	<i>Technical Requirements</i>	<i>Unannounced Inspection</i>

§ 205.2 Terms defined – *Handle*

Handle. To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, exporting for sale in the United States, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.

“The definition of *handle* is not an exhaustive list of activities that must be certified. There may be additional activities not listed in the definition that are similar to the listed activities and require certification, or different words or synonyms for the same or similar activities. The absence of a specific term in the definition of *handle* does not mean the activity is not handling or that an operation conducting this activity does not need certification.”

§ 205.100 What has to be certified

§ 205.101 Exemptions from certification

**§ 205.103 Recordkeeping by certified
operations**

§ 205.100 What has to be certified

“In response to AMS’s request for additional activities that may need to be certified, commenters suggested the following be added to the definition of *handle*: split, open, close, sort, combine, consolidate, aggregate, enclose, condition, treat, size, grade, transload, brand ownership, private label, import, export, commingle, transport, and deliver.”

“The definition of *handle* is not an exhaustive list of activities that must be certified....”

In addition, AMS included in the definition of *handle* “facilitating sale or trade on behalf of a seller or oneself” as a general category to capture activities which are integral to selling a product and may be known by various names.

§ 205.100 What has to be certified

Finally, many of these other activities are discussed throughout other sections of the rule, mainly in the explanatory text. Examples...Private Label Brands & Transloading...

Private Label Brands:

“(Response) ‘Brand owners’ or operations that sell or distribute organic products produced by another operation on their behalf may be exempt from certification if they meet the criteria of § 205.101(f). This exemption allows the buying, selling, receiving, storing, and preparing for shipment of organic products that are packaged for retail sale. The products must be sealed in tamper-evident packaging ready for retail sale, and the operation must not open or otherwise handle the retail packages. **Private labeling operations that process organic agricultural products must be certified.**” [emphasis added]

Transloading:

Read the fine print...

§ 205.101 Exemptions from certification...

the devil is in the details

(a) 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.



- Not represented as certified organic, use of organic seal, products must not be identified or represented as organic in products processed by another operation.



DESIGNATION AS A “RETAIL ESTABLISHMENT” – Applies to Exemptions (b) & (c):

- Do you sell directly to consumers, end-users, or the public?
 - YES? You might be covered as an exempt retail establishment...
- Do you only sell to other businesses (wholesale)?
 - YES? You’re not a retail establishment...
- Do you use only virtual transactions, e.g. transactions telephone, mail order, and/or online sales?
 - YES? You’re not a retail establishment.
- Do you have a physical location for consumers to purchase products?
 - YES? You might be covered as an exempt retail establishment...
 - NO? You’re not a retail establishment.




§ 205.101 Exemptions from certification...

the devil is in the details

(b) A retail establishment that does not process organically produced agricultural products.

- Does NOT process: cook, bake, heat, dry, mix, grind, churn, separate, extract, cut, ferment, eviscerate, preserve, dehydrate, freeze, or otherwise manufacture, including package, can jar, or otherwise enclose food in a container.
- MAY remove produce from shipping boxes, wash and transfer products to display cases, open bags of bulk products and transfer contents to bulk food dispensers.
- MAY use the organic seal & seal of certifier in retail labeling & display of unpackaged items; may use the “made with organic” designation in retail labeling & displays.  

(c) A retail establishment that processes, at the point of final sale, agricultural products certified under this part as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

- MUST process organic products at the point of final sale to the consumer; products must be processed and sold in the same physical location.
- MAY include repackaging bulk containers of organic products into individual units for retail sale within an individual grocery store or a retail establishment that prepares ready-to-eat meals and sells them online to consumers from the processing location. ***
- May NOT be represented as certified organic, use of organic seal, products must not be identified or represented as organic in products processed by another operation.   

§ 205.101 Exemptions from certification...

the devil is in the details

Retail establishments NOT exempt:

- Those that sell organic products to consumers which are processed at a location separate from the point of sale. (Example: online retailers, central processing facility, processing facility that is not co-located with retail establishment.)
- Retailers that process and sell to consumers via virtual transaction – any form of transaction that does not occur in person.

All Exempt Retail Establishes must:

- Comply with the requirements of § 205.272, which describes handling requirements to prevent commingling and contact with prohibited substances.
- Follow the labeling provisions specified in § 205.310 and maintain records to (1) demonstrate that agricultural products identified as organic were organically produced and handled; and (2) verify quantities received, sold, or produced from such agricultural products.

§ 205.101 Exemptions from certification...

the devil is in the details

(d) 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. ❌ ❌ ❌

- Not represented as certified organic, use of organic seal, products must not be identified or represented as organic in products processed by another operation.

(e) An operation that only receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products that:

(1) Are enclosed in sealed, tamper-evident packages or containers prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers and are not otherwise handled while in the control of the operation.

- Intended primarily for storage and warehouse facilities.
- Comply with the requirements of § 205.272, which describes handling requirements to prevent commingling and contact with prohibited substances.
- Must have records available and must show records to a representative of the Secretary upon request.

§ 205.101 Exemptions from certification...

the devil is in the details

(f) An operation that only buys, sells, receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products already labeled for retail sale that:

(1) Are enclosed in sealed, tamper-evident packages or containers that are labeled for retail sale prior to being received or acquired by the operation; and

(2) Remain in the same sealed, tamper-evident packages or containers that are labeled for retail sale and are not otherwise handled while in the control of the operation.

- Intended primarily for distributors. May cover some distributors, brand name owners, sales brokers that purchase and/or receive products in their finished retail packaging.
- Comply with the requirements of § 205.272, which describes handling requirements to prevent commingling and contact with prohibited substances.
- Must have records available and must show records to a representative of the Secretary upon request.

§ 205.101 Exemptions from certification...

the devil is in the details

(g) A Customs broker (per 19 CFR 111.1) that only conducts customs business but does not otherwise handle organic agricultural products.

- Does not take ownership or physical possession of organic products.
- Differentiates between sales, or commodity brokers, who sell or facilitate the sale of organic products and must be certified.
- “To qualify for this exemption, Customs brokers must only conduct customs business. If a Customs broker conducts any additional activity within the definition of handle— such as selling, importing, or trading—the Customs broker must be certified.”

(h) An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.

- Referred to as a logistics broker.
- Does not take ownership or physical possession of organic products.
- Secures transport/storage to meet the needs of a third party who owns or is responsible for the agricultural product.

§ 205.101 Exemptions from certification...

the devil is in the details...gray area

Transportation Concerns: Many commenters raised transportation concerns.

What it comes down to is two-fold:

- 1) AMS stating that “OFPA and the USDA organic regulations do not provide authority to regulate the transport of organic agricultural products,” and
- 2) “AMS is defining the need for certification based on activities performed, not type of business.” Therefore, determining whether or not a rail car company or trucking company or milk truck needs to be certified is not the point; determining whether or not the activity they are performing needs certification is the real question.

Specifically, AMS had this to say about milk haulers:

“AMS is defining the need for certification based on activities performed, not type of business, because this will ensure that businesses conducting high-risk activities require certification (and conversely that businesses that conduct low-risk activities remain exempt). A milk hauler would be exempt from certification if they only transport organic milk (e.g., move milk from a dairy to a processor) but do not otherwise handle the milk (e.g., process or package loads of milk). Transport alone does not require certification.”



Deep Breath

§ 205.273 Imports to the United States

OVERVIEW: There's a lot of good in this section...and there's a lot of gray areas in this section...time will tell?

GOOD:

- Mandatory use of NOP Import Certificates “Specifically, this rulemaking requires that all imported products intended to be sold, represented, labeled, or marketed as organic in the United States must be declared as organic to U.S. Customs and Border Protection (CBP), using an NOP Import Certificate.”
- Organic Integrity Database identified must be used as the only data source for NOP Import Certificates. This eliminates confusion caused in the proposed rule language around “equivalent data source” and “NOP Form 2110-1.”
- OID to include foreign-certified operations: AMS will change access to the OID to include organic certifying agents and operations operating under organic trade arrangements or agreements, such as equivalency and recognition arrangements. “As noted by commenters, the absence of that data makes it difficult for organizations to verify the certification status of foreign-certified operations.”

EXPORTER

Persons exporting organic agricultural products to the United States must request an NOP Import Certificate from a certifying agent prior to their export.

CERTIFIER

Must review an NOP Import Certificate request and determine whether the export complies with the USDA organic regulations.

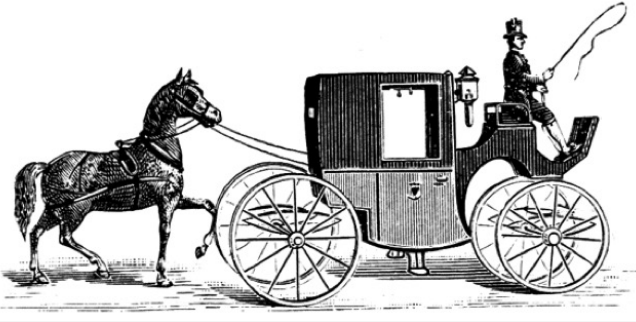
IMPORTER

Must ensure the import is accompanied by accurate NOP Import Certificate data and must verify that the shipment has had no contact with prohibited substances pursuant § 205.272 or exposure to ionizing radiation pursuant to § 205.105, since export.

CUSTOMS BROKER or IMPORTER

The customs broker (who is exempt from certification) or the importer is responsible for entering the NOP Organic Import Certificate into the Customs and Border Protection's ACE system within 10 days of the shipment touching U.S. soil.

§ 205.273 Imports to the United States...gray areas



- Timing of Import Certificates

2023



- Indefinite Coverage

§ 205.307 Labeling of Nonretail Containers

OVERVIEW: This section underwent a significant overhaul from the proposed rule to the final rule, coming out on the side of minimalism.

GOOD:

- There is <minimal> requirements for labeling of <some> nonretail containers. § 205.307(a)(1)(2)
- Revisions to § 205.307 do not limit the information that can be on a nonretail label. This gives operations the flexibility to include details they deem critical to the integrity of specific products.

§ 205.307 Labeling of Nonretail Containers...gray areas

§ 205.307(c) No required labeling on nonretail containers of retail-labeled products.

- **Concern:** Possibility of a nonretail container being fumigated or otherwise treated without anyone looking inside the container and reading the packaging of the product inside.

§ 205.307(a)

(a) Nonretail containers used to ship or store certified organic agricultural products must display:

(1) Identification of the product as organic; and

(2) The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.

- **Concern:** While this is all well and good, and while we will know how to find the “audit trail documentation for nonretail containers” based on § 205.307(a)(2), there is a lack of clarity as to where the audit trail documentation can be found.
- **Concern:** The requirement to include the product’s certifying agent on nonretail labels or in the audit trail documentation has been removed.

§ 205.400 General requirements for certification

PRODUCER GROUP OPERATIONS

OVERVIEW OF FOCUS:

Internal Control System – The rule focuses on a strong Internal Control System as the frontline mechanism for ensuring integrity of a producer group.

Certifier Oversight – Strong oversight by certifiers using clearly specified inspection methods unique to grower groups is also emphasized.

NOP Oversight – NOC would add that NOP's oversight role through the process of accrediting producer group certifiers, as is true in organic overall, is the ultimate check to ensure integrity.

PRODUCER GROUP OPERATIONS

Terms Defined

Internal control system. An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation, and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations.

Producer group member. An individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation.

Producer group operation. A producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification.

Producer group production unit. A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products.

PRODUCER GROUP OPERATIONS

- Establishes eligibility criteria for operations to qualify as producer group operations.
- Clarifies the function and responsibilities of Internal Control Systems (ICS).
- Clarifies inspection requirements for producer group operations.



Deep Breath

§ 205.403 On-site inspections

OVERVIEW: This section codifies several inspection requirements that organic stakeholders strongly supported through comments...but leaves a few concerns.

GOOD:

- Unannounced inspections required.
- Requires that certifying agents must have the ability to conduct unannounced inspections of any operation they certify.
- Requires that the on-site inspection for all operations must verify mass-balance and trace-back audits.

§ 205.404 Certificates of organic operation

OVERVIEW: This section is improved by the revisions made, based on stakeholder recommendations, and it's all good...with one tiny disappointment.

GOOD:

- We are pleased to see the updates to the definition of Organic Integrity Database has been updated and will not be referred to as INTEGRITY going forward.
- Organic certificates for all operations will be issued through the OID, creating a universal certificate for all operations.
- Certifiers will have the option of issuing their own addenda to the certificate of organic operation, with clear requirements.
- We are extremely pleased to see the requirement for an expiration date on organic certificates has been removed.

§ 205.404 Certificates of organic operation – small disappointment

SMALL DISAPPOINTMENT:

We would have liked to have seen the definition of Organic Integrity codified in the rule. Organic integrity is one of the key tenets the SOE rule is meant to uphold. It is a term that is used often by the NOP, NOSB, organic stakeholders, and consumers, and is actually defined by AMS in the preamble text of the rule under Terminology. Including that common definition in the organic regulations would provide a clear baseline for a concept that is integral to the organic program.

Organic integrity: The unique attributes that make a product organic and define its status as organic. A product that fully complies with the USDA organic regulations has integrity, and its organic qualities have not been compromised.

§ 205.406 Continuation of certification

OVERVIEW: There were no changes made to this section from the proposed rule to the final rule, and overall, the results are positive.

GOOD:

- Reduced paperwork and efficiency of process!
- Requires a “once per calendar year” on-site inspection.

§ 205.501 General requirements for accreditation:

Mandatory reporting in Organic Integrity Database § 205.501

OVERVIEW: The rule supports the requirement for all certifying agents to maintain current data on all operations they certify in the Organic Integrity Database (OID).

GOOD:

- Update Frequency:
 - Requires an update within 72 hours for suspensions, revocations, or surrender of certification.
 - Changes support the removal of unnecessary and redundant steps from certifying agents' day-to-day operations.
- SOE gives NOP the authority to make acreage and other fields mandatory to support enforcement by certifiers and NOP.

§ 205.501 General requirements for accreditation:

Personnel Training & Qualifications § 205.501(a)(4)(5)(6)

OVERVIEW: This section of the rule lays out the requirements for accreditation regarding inspectors and certification review personnel, but more importantly, it sets a baseline for training requirements, as well as continuing education requirements, for these personnel.

Education/Qualifications:

- Inspectors & Certification Review Personnel must demonstrate:
 - <1 year experience = 50 hours training in first year prior to performing independent inspections.
 - >1 year experience = 10 hours of training for first scope, with an additional 5 hours of training for each additional scope.
- Certifiers must demonstrate:
 - Inspectors & Certification Review Personnel have a minimum of 2,000 hours of experience in each scope prior to assigning inspection responsibilities.
 - Inspectors & Certification Review Personnel maintain adequate knowledge and skills...

§ 205.501 General requirements for accreditation:

Personnel Training & Qualifications § 205.501(a)(4)(5)(6)

Evaluation:

- Inspectors:
 - <1 year experience = Annual field evaluations/witness audits.
 - >1 year experience = Field evaluations/witness audits required once every three years...
- Inspectors & Certification Review Personnel:
 - Must receive annual performance evaluations.

Of Note:

- Certifiers may share field evaluations/witness audits with each other.
- Certifiers may use qualified contractors to perform witness inspections.

Oversight of Certification Activities

§ 205.501(a)(22) General requirements for accreditation & § 205.665(a) Noncompliance procedure for certifying agents

OVERVIEW: No changes were made to the proposed regulatory text in §§ 205.2, 205.501(a)(22), and 205.665(a) with respect to oversight of certification activities from the proposed rule to the final rule.

§ 205.501(a)(22) General requirements for accreditation

(22) Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities.

§ 205.665(a) Noncompliance procedure for certifying agents



Deep Breath

Join us...

NOC Pre-NOSB Meeting
Monday, April 24, 2023

Spring 2023 NOSB Meeting
Atlanta, GA
April 25-27, 2023



Thank you!